Test Report issued under the responsibility of:

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.....:	T223-0720/18
Date of issue.....:	2019-01-29
Total number of pages.....:	216 pages
CB Testing Laboratory.....:	SIQ Ljubljana *SIQ Ljubljana is accredited by Slovenian Accreditation with accreditation number.: LP-009 in the field of testing*
Address.....:	Tržaška cesta 2, SI-1000 Ljubljana, Slovenia
Applicant's name.....:	GlobTek, Inc.
Address.....:	186 Veterans Drive Northvale, NJ 07647, USA
Test specification:	
Standard.....:	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure .....:	CB Scheme
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_1K
Test Report Form Originator.....:	UL(US)
Master TRF.....:	2015-11

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Test item description ..... :	Power Supply for Medical use
Trade Mark ..... :	GlobTek
Manufacturer ..... :	GlobTek, Inc.
	186 Veterans Drive Northvale, NJ 07647, USA
Model/Type reference ..... :	GTM3T41-12-150R-3
Ratings ..... :	I/P: 230 V~; 50 Hz; 34 mA; Class II
	O/P: 12 Vdc; 150 mA

Testing procedure and testing location:		
☒ **CB Testing Laboratory:**	SIQ Ljubljana	
Testing location/ address ..... :	Tržaška cesta 2, SI-1000 Ljubljana, Slovenia	
☐ **Associated CB Testing Laboratory:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :	Gregor Cesar	
Approved by (name, function, signature) .. :	Janez Vidmar	
☐ **Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :		
Approved by (name, function, signature) .. :		
☐ **Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :		
Witnessed by (name, function, signature). :		
Approved by (name, function, signature) .. :		
☐ **Testing procedure: CTF Stage 3:**		
☐ **Testing procedure: CTF Stage 4:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :		
Witnessed by (name, function, signature). :		
Approved by (name, function, signature) .. :		
Supervised by (name, function, signature) :		

List of Attachments (including a total number of pages in each attachment):

1. Test Report: 133 pages
2. Photo documentation – Enclosure No. 1: 9 pages
3. Schematics, layouts and documentation – Enclosure No. 2: 15 pages
4. National Differences to IEC 60601-1:2015 + A1:2012 – Enclosure No. 3: 24 pages
5. European Differences – Enclosure No. 4: 35 pages

Summary of testing

Tests performed (name of test and test clause):

4.11 Power Input

5.9.2 Determination of accessible parts

7.1.2 Legibility of marking

7.1.3 Durability of marking

8.4.2 Working voltage / Power measurement

8.4.3 ME equipment intended to be connected to a power source by a plug

8.7.4.6 Touch Current

8.8.3 Dielectric Strength test of solid insulation materials with safety functions

8.8.4.1 Resistance to heat - Ball pressure test of thermoplastic parts

11.1 Excessive temperatures in ME EQUIPMENT

11.1.3d Temperature of windings by change -of-resistance method

13.2.2 relative to emission of flames, molten metal, or ignitable substances

13.2 Single Fault conditions

15.3.2 Push test

15.3.3 Impact test

15.3.6 Mould-stress relief test

15.5.1.2 : Transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION

15.5.1.3 Transformer overload test – conducted only when protective device under short-circuit test operated

15.5.2 Transformer dielectric strength after humidity preconditioning of 5.7

Testing location:

Initial testing:

SIQ Ljubljana,
Tržaška cesta 2,
SI-1000 Ljubljana, Slovenia

Revision No. 1.0:

SIQ Ljubljana
Mašera-Spasićeva ulica 10
SI-1000 Ljubljana, Slovenia

Summary of compliance with National Differences

List of countries addressed:

- **IEC 60601-1:2005 + A1:2012**

  No national differences for IEC 60601-1:2005 + A1:2012 declared.

- **IEC 60601-1:2005**

  List of countries addressed:

  - US NATIONAL DIFFERENCES to IEC 60601-1 Third edition
    National standard ANSI/AAMI ES60601-1: 2005
  - CANADA NATIONAL DIFFERENCES to IEC 60601-1 Third edition
    National standard CAN/CSA-C22.2 No. 60601-1:08
  - SWITZERLAND NATIONAL DIFFERENCES to IEC 60601-1 Third edition
    National standard SN EN 60601-1:06
  - JAPAN NATIONAL DIFFERENCES to IEC 60601-1 Third edition
    National standard: JIS T0601-1:2012
  - REPUBLIC OF KOREA Differences to IEC 60601-1 Third edition
    National standard: KS C IEC 60601-1
  -

☒ The product fulfils the requirements of EN 60601-1:2006 + A1:2013 + A12:2014

Copy of marking plate
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Direct plug-in equipment
Device type (component/sub-assembly/ equipment/ system) :	Component level power supply
Intended use (Including type of patient, application location) :	EUT is intended to provide power to medical devices with isolation grade MOOP (Means of Operator Protection)
Mode of operation ..... :	Continuous operation.
Supply connection	Direct plug-in equipment.
Accessories and detachable parts included ..... :	No accessories and detachable parts included.
Other options include ..... :	No other options included.
Testing	
Date of receipt of test item(s) ..... :	2012-03-22 **(Initial testing)**
	2018-11-05 **(Revision 1.0)**
Dates tests performed ..... :	From 2012-03-22 to 2012-04-13 **(Initial testing)**
	From 2018-11-12 to 2018-12-18 **(Revision 1.0)**
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement..... :	Pass (P)
- test object was not evaluated for the requirement..... :	N/E (collateral standards only)
- test object does not meet the requirement ..... :	Fail (F)
Abbreviations used in the report:	
- normal condition..... : N.C.	- single fault condition ..... : S.F.C.
- means of Operator protection ..... : MOOP	- means of Patient protection .... : MOPP

General remarks:

Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "K" of TRF for IEC for 60601-1 3rd edition with Amendment 1.

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☒ comma / ☐ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided .....:	☒ Yes ☐ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	1) GlobTek, Inc. 186 Veterans Drive Northvale, NJ 07647, USA 2) GlobTek (Suzhou) Co., Ltd. Building 4, No. 76, Jinling East Road, Suzhou Industrial Park, Kiangsu 215021, China 3) Shenzhen ENG Electronics Co., Ltd. Block B2, A4 first floor, A4 third-four Floor of the East, Nuclear Group Industrial District, Baishixia, Fuyun Town, Bao'an, Shenzhen, China 4) Shenzhen well into electronic Co., LTD 3 floor, Third buildings, Xinghao three industrial zone, Shajing Street, Baoan District, Shenzhen, China

General product information:
The Power Supply GTM3T41-12-150R-3 has been designed for the supplying various medical devices with integrated 2 x MOOP isolation (Means of Operator Protection) between mains and secondary accessible parts). Power supply is not intended for direct patient connection. The power supply is designed for direct plug-in use. Power is delivered to the medical device via secondary SELV wire with the DC plug at the end. The power supply unit is provided with plastic enclosure without openings. Power supply unit is provided without operating LED indicator. EUT is direct plug-in power supply unit and therefore not treated as end medical product. Indicator lights shall be checked during end medical product approval. The power supply in maintenance free. The power supply is intended for operating at ambient temperature up to 40°C. The unit shall not be used for use in an oxygen rich environment. The unit it is not intended to be use with flammable anaesthetics and not intended for use in conjunction with flammable agents.

Summary of testing
The risk management requirements of the standard according to ISO 14971:2007 were addressed. Essential performance shall be determined within the end medical equipment. The unit is direct plug-in equipment. The unit provides internally two fuses in both supply leads. In addition, thermal cut-out is provided on the primary side of the transformer windings. Power supply unit was evaluated only for Means of Operator Protection: - 2 x MOOP between primary and secondary circuit - 2 x MOOP between primary and external plastic enclosure surface Secondary output circuit is separated from mains by reinforced insulation and rated SELV. The output does not provide hazard energy level. Power supply is provided with user instruction related to the user and technical specification related to the service personnel. The power supply is rated as class II (provided in fully plastic enclosure) construction. Mains transformer provides reinforced insulation between primary and secondary circuit. This transformer is built up to fulfil the requirement of insulation class A. See also list of safety critical components. The equipment has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 2000 m. Power supply unit is provided with plastic enclosure made by non-flammable material V-0 See also list of safety critical components. Cleaning shall be considered within end product investigation.

History Sheet

Date	Report Number	Change	Revision No.
2012-04-26	T223-0123/12	Initial Test Report issued.	—
2019-01-29	T223-0720/18	Test report updated from IEC 60601-1:2005 (3rd Edition) to IEC 60601-1:2005 (3rd Edition) + A1:2012. No changes on the product since last approval. After review, the following tests were considered required: - Clause 8.7: Leakage current measurements - Clause 8.8.3: Dielectric strength test - Clause 8.9: Creepage distances and air clearances due to evaluation for up to 5.000 meters altitude. Update list of critical components. Review of the risk management file (RMF) performed.	1.0

INSULATION DIAGRAM

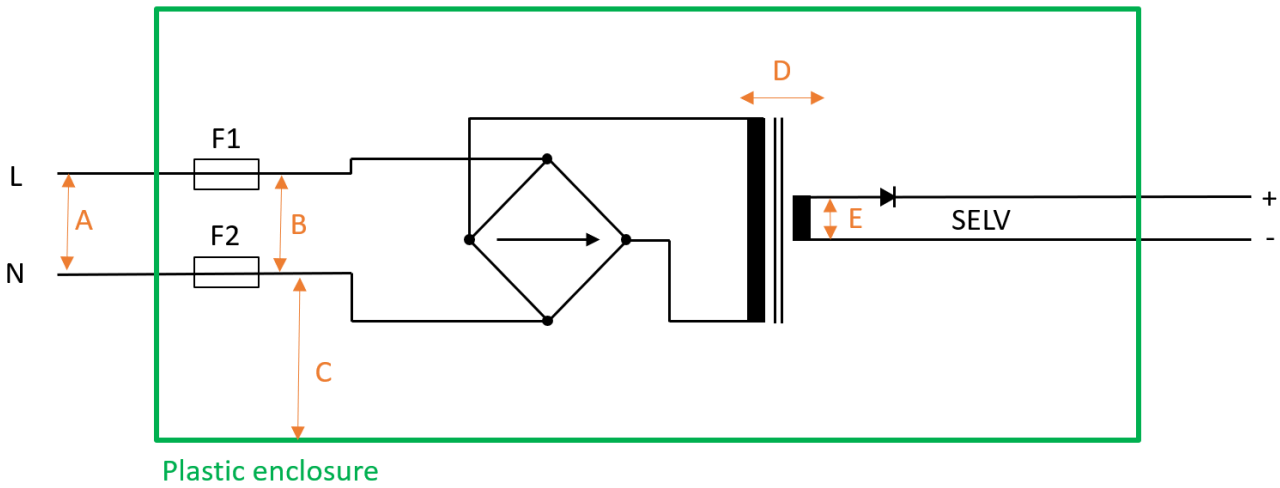

TABLE: INSULATION DIAGRAM		P
Pollution degree..... :	PD 2	—
Overvoltage category..... :	OVC II	—
Altitude..... :	Up to 2.000 meters **Revision 1.0:** Up to 5.000 meters	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
A	1 x MOOP	IIIb	250	354	2,5	2,0	11,1	11,1	Measured between L and N before mains fuses.
B	1 x MOOP	IIIb	250	354	Verified via short-circuiting.				
C	2 x MOOP	IIIb	250	354	5,0	4,0	10,2 See a)	10,2 See a)	To accessible outer side of the enclosure.
D	2 x MOOP	IIIb	250	354	5,0	4,0	6,2	6,2	Measured between primary and secondary windings via core
Revision 1.0:									
A	1 x MOOP	IIIb	250	354	3,0	3,0	11,1	11,1	Measured between L and N before mains fuses.
B	1 x MOOP	IIIb	250	354	Verified via short-circuiting.				
C	2 x MOOP	IIIb	250	354	6,0	6,0	10,2 See a)	10,2 See a)	To accessible outer side of the enclosure.
D	2 x MOOP	IIIb	250	354	6,0	6,0	6,2	6,2	Measured between primary and secondary windings via core

Supplementary Information:

a) Distance between transformer core and outer accessible enclosure: 2,3 mm+1,6+1,3 mm= 5,2 mm

b) Distance between primary windings and transformer core: 5,0 mm

c) Distance between secondary windings and transformer core: 1,2 mm

d) Distance between transformer core and secondary PCB: 2,0 mm

e) Both primary wires are fixed together by strep.

Revision 1.0: Evaluation for up to 5.000 meters altitude (Multiplication factor 1,48 used for clearances according to Table 8.).

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer
  windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		**P**
4.1	**Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse**	--	**P**
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		**P**
4.2.2	**General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007)..... :**	See Appended RM Results Table 4.2.2.	**P**
4.2.3	**Evaluating RISK**		**P**
4.2.3.1	**a) Compliance with the standard reduces residual risk to an acceptable level**	All residual risk reduced to an acceptable level by the manufacturer.	**P**
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN..... :	RISK MANAGEMENT PLAN Document: GT-RMPLAN2018-003	**P**
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.	--	**P**
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.	According to risk management process as established by the manufacturer.	**P**
4.2.3.2	**MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.**	--	**P**
4.3	**Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.**	No essential performance defined by the manufacturer. End product consideration.	**N/A**
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.	--	**N/A**
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated	--	**N/A**
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE..... :	See Appended Table 4.3	**N/A**
	- RISK CONTROL measures implemented	--	**N/A**
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented	--	**N/A**
4.4	**EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE ..... :**	Expected operating life time specified within technical specifications: 5 years minimum.	**P**
4.5	**Alternative RISK CONTROL methods utilized:**	No alternative risk control methods utilized.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific risks: (ISO 14971 Cl. __)	**N/A**
	Alternative means based scientific data or clinical opinion or comparative studies .....:	--	**N/A**
4.6	**RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 .....:**	See Appended Insulation Diagram Table No parts that can come with the patient. EUT is medical power supply.	**N/A**
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient ....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**
	Assessment identified the APPLIED PART TYPE requirements .....:	Type B/BF/CF	**N/A**
4.7	**ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 .....:**	All applicable single fault conditions performed according to the standard. No safety hazard occurs during single fault testing.	**P**
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....: **(ISO 14971 Cl. 4.2-4.4)**	RISK ANALYSIS reference: (ISO 14971 Cl. __)	**N/A**
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically .....:	See appended Table 13.2 for simulated physical test.	**P**
4.8	**All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified....:**	All components used according to their applicable ratings. See Table 8.10: List of critical components.	**N/A**
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	--	**N/A**
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__) All components used according to their applicable ratings.	**N/A**
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION....:	See Table 8.10 b. No components bridging reinforced insulation.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Components determined to be acceptable where used as a MEANS OF PROTECTION ..... :	RMF Reference to specific RISKS:	**N/A**
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following	--	**P**
	a) Applicable safety requirements of a relevant IEC or ISO standard	Approved critical components used. See Table 8.10: List of critical components.	**P**
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	--	**P**
4.9	**A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately..... :**	See appended Table 8.10 b No such components incorporated within the power supply unit.	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:	See Table 8.10 b	**N/A**
4.10	**Power supply**		**P**
4.10.1	**ME EQUIPMENT is suitable for connection to indicated power source** (select applicable)**..... :**	Power supply unit is suitable for connection to supply mains. EUT is direct plug-in equipment provided with EU plug. See enclosed pictures of the unit for details.	**P**
4.10.2	**Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:**	Not hand-held equipment.	**N/A**
	– 250 V for HAND-HELD ME EQUIPMENT (V) ..... :	Not hand-held equipment.	**N/A**
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)..... :	Rated input voltage: 230 Vac	**P**
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	--	**N/A**
4.11	**Power input**		**P**
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%..... :	See appended Table 4.11	**P**
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.1	**Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:**	Type test performed according to all applicable clauses of standard IEC 60601-1:2005 (3rd Ed.) + A1:2012.	**N/A**
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. **(ISO 14971 Cl. 4.2-4.4)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
5.3	**Tests conducted within the environmental conditions specified in technical description**	--	**P**
	Temperature (ºC), Relative Humidity (%) .....:	0-40°C 0 to 90% RH.	**—**
	Atmospheric Pressure (kPa).....:	540-1060 hPa	**—**
5.5	**a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) .....:**	230 Vac (+/-10% tolerance considered during type testing)	**P**
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) .....:	Supply frequency: 50 Hz	**P**
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current .....:	Supply voltage: 230 Vac Only AC supply voltage used for supplying power supply unit.	**P**
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered.....:	--	**N/A**
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions .....:	No such components. EUT is medical direct plug-in equipment.	**N/A**
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Mains operated equipment.	**N/A**
5.7	**ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3 ..... :**	Complete power supply unit was subject to humidity preconditioning treatment.	**P**
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	Standard humidity treatment performed: T = 27,7°C Relative humidity: 94%RH Time: 48 hours	**—**
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.9.1	**APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... :**	See clause 4.6 Remark No applied parts provided.	**N/A**
5.9.2	**ACCESSIBLE PARTS**		**P**
5.9.2.1	**Accessibility determined using standard test finger of Fig. 6**	See Appended Table 5.9.2 Power supply unit is provided with plastic enclosure without openings.	**P**
5.9.2.2	**Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s**	No openings provided.	**N/A**
5.9.2.3	**Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS ..... :**	No actuating mechanisms provided.	**N/A**
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL ..... :	--	**N/A**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	**CLASS I ME EQUIPMENT, externally powered**	Medical direct plug-in power supply is not Class I equipment. EUT is Class II equipment.	**N/A**
	CLASS II ME EQUIPMENT, externally powered	Medical direct plug-in power supply is Class II equipment.	**P**
	INTERNALLY POWERED ME EQUIPMENT	EUT is not internally powered equipment.	**N/A**
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements	--	**N/A**
	TYPE B APPLIED PART	No applied parts provided.	**N/A**
	TYPE BF APPLIED PART	--	**N/A**
	TYPE CF APPLIED PART	--	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS	--	**N/A**
6.3	**ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529..... :**	IP20 (not marked). EUT is not protected against ingress of water (ordinary equipment).	**P**
6.4	**ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :**	No such parts.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.5	**ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2**	EUT was not evaluated for use in an oxygen rich environments.	**N/A**
6.6	**CONTINUOUS or Non-CONTINUOUS OPERATION.....:**	Power supply unit is designed for continuous operation. No markings provided on the outer side of the enclosure.	**P**
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		**P**
7.1.2	**Legibility of Markings Test for Markings specified in Clause 7.2-7.6.....:**	See Appended Table 7.1.2	**P**
7.1.3	**Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE**	See appended Tables 7.1.3 and 8.10	**P**
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.2.1	**At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :**	All required markings are provided on the marking plate.	**P**
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ..... :	See above.	**N/A**
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	Packaging not part of the investigation.	**N/A**
	Single use item marked ..... :	No such material, component, accessory or equipment parts intended for single use.	**N/A**
7.2.2	**ME EQUIPMENT marked with:**	See below.	**P**
	– the name or trademark and contact information of the MANUFACTURER	Trademark and web address provided on the marking plate. See attached copy of marking plate for details. Due the fact, that power supply is not end medical product, web address as a contact information is sufficient. End product shall be marked with complete contact information as required by the standard.	**P**
	– a MODEL OR TYPE REFERENCE	Model provided on the marking plate. See attached copy of marking plate for details.	**P**
	– a serial number or lot or batch identifier; and	Serial number provided on the marking plate. See attached copy of marking plate for details.	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	– the date of manufacture or use by date	The date of manufacture provided on the marking plate. See attached copy of marking plate for details. WWVV, WW=week VV=year, example 3611	**P**
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	No detachable components provided.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.4)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	--	**N/A**
	– a MODEL OR TYPE REFERENCE	--	**N/A**
	Software forming part of a PEMS identified with a unique identifier ..... :	No software incorporated. EUT is medical direct plug-in power supply.	**N/A**
7.2.3	**Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS**	Symbol not required. EUT is medical direct plug-in equipment.	**N/A**
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	--	**N/A**
7.2.4	**ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and..... :**	No accessories provided.	**N/A**
	– with a MODEL or TYPE REFERENCE	--	**N/A**
	– a serial number or lot or batch identifier	--	**N/A**
	– the date of manufacture or use by date	--	**N/A**
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	--	**N/A**
7.2.5	**ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following**	Mains operated equipment.	**N/A**
	– the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or	--	**N/A**
	– Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.	--	**N/A**
7.2.6	**Connection to the Supply Mains**		**P**
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	Marking plate is visible when power supply unit is inserted into mains socket outlet.	**P**
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	EUT is not permanently installed equipment.	**N/A**
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) .....:	230 Vac Markings provided on the marking plate.	**P**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) .....:	--	**N/A**
	– Nature of supply and type of current.....:	Symbol '' ~ '' provided near rated supply voltage.	**P**
	Symbols 1-5, Table D.1 (used for same parameters.....:	Symbol No. 1 from table D.1 used for input voltage. Symbol No. 4 from table D.1 used for output voltage.	**P**
	– RATED supply frequency or RATED frequency range in hertz .....:	50 Hz	**P**
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT .....:	Provided on the marking plate of power supply unit.	**P**
7.2.7	**RATED input in amps or volt-amps, (A, VA) .....:**	Rated input expressed in Amperes: 34 mA	**P**
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:	Rated input expressed in Amperes: 34 mA	**P**
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W).....:	Rated input expressed in Amperes: 34 mA	**P**
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) .....:	--	**N/A**
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:	--	**N/A**
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W).....:	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.8	**Output connectors**		**P**
7.2.8.2	**Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment**	Rating of the output connector provided on the marking plate. See copy of marking plate for details.	**P**
	Rated Voltage (V), Rated Current (A) ..... :	See copy of marking plate for details.	**—**
	Rated Power (W), Output Frequency (Hz)..... :	DC output voltage.	**—**
7.2.9	**ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0… :**	IP20 equipment; therefore IP protection not marked on the enclosure.	**P**
7.2.10	**Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ..... :**	No applied parts provided.	**N/A**
	TYPE B APPLIED PARTS with symbol 19 of Table D.1	--	**N/A**
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 ..... :	--	**N/A**
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 ..... :	--	**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1..... :	--	**N/A**
	Proper symbol marked adjacent to or on connector for APPLIED PART..... :	--	**N/A**
	Safety sign 2 of Table D.2 placed near relevant outlet ..... :	--	**N/A**
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use ..... :	--	**N/A**
7.2.11	**ME EQUIPMENT suitable for CONTINUOUS OPERATION**	No markings provided; therefore EUT is intended for continuous operation.	**P**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time ..... :	EUT is designed for continuous operation.	**N/A**
7.2.12	**Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder**	Fuses are not accessible by the operator.	**N/A**
	Fuse type..... :	--	**—**
	Voltage (V) and Current (A) rating ..... :	--	**—**
	Operating speed (s) and Breaking capacity .... :	--	**—**
7.2.13	**Physiological effects – safety sign and warning statements ..... :**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**
7.2.14	**HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1**	No such terminals provided.	**N/A**
7.2.15	**Requirements for cooling provisions marked...:**	Not provided.	**N/A**
7.2.17	**Packaging marked with special handling instructions for transport and/or storage.....:**	EUT is not special handling equipment.	**N/A**
	Permissible environmental conditions marked on outside of packaging .....:	Component, to be determined as part of end product. Storage conditions specified within the technical specifications.	**N/A**
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK .....:	See Appended RM Results Table 7.2.17	**N/A**
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK. .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	No sterile parts.	**N/A**
7.2.18	**RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:**	--	**N/A**
	- the RATED flow rate also marked	--	**N/A**
7.2.19	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL .....:**	No functional earth terminal provided. EUT is Class II equipment.	**N/A**
7.2.20	**Removable protective means marked to indicate the necessity for replacement when the function is no longer needed .....:**	--	**N/A**
7.2.21	**MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms ....:**	Not mobile equipment.	**N/A**
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.3.1	**Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W) .....:**	No heating elements provided.	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL	--	**N/A**
7.3.2	**Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts ..... :**	No such parts within the equipment.	**N/A**
7.3.3	**Type of battery and mode of insertion marked:**	--	**N/A**
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL ..... :	No batteries provided. Mains operated equipment.	**N/A**
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK .....:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD..... :	--	**N/A**
7.3.4	**Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ..... :**	Type and rating of internal non-accessible primary fuses provided within technical specifications: FUSE 2/3: T0,3A / 250 V (50 A breaking capacity) Primary fuses are not intended to be replaced by the operator.	**P**
	Voltage (V) and Current (A) rating ..... :	Characteristics provided within technical specification.	**—**
	Operating speed(s), size & breaking capacity. :	Characteristics provided within technical specification.	**—**
7.3.5	**PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1**	No protective earth terminal provided. Class II equipment.	**N/A**
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	--	**N/A**
7.3.6	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS**	No functional earth terminal provided.	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.7	**Terminals for supply conductors marked adjacent to terminals.....:**	EUT is direct plug-in equipment. No such terminals provided.	**N/A**
	Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections.....: (ISO 14971 Cl. 4.3)	RMF Reference to specific RISKS: (ISO14971 Cl. __)	**N/A**
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	--	**N/A**
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	--	**N/A**
	Marking for connection to a 3-phase supply, complies with IEC 60445	--	**N/A**
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made	--	**N/A**
7.3.8	**"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections**	--	**N/A**
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	--	**N/A**
7.4	**Marking of controls and instruments**		**N/A**
7.4.1	**The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 or**	No main switch provided.	**N/A**
	– indicated by an adjacent indicator light, or	--	**N/A**
	– indicated by other unambiguous means	--	**N/A**
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and	--	**N/A**
	– status indicated by adjacent indicator light	--	**N/A**
	– status indicated by other unambiguous means	--	**N/A**
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or	--	**N/A**
	– status indicated by adjacent indicator light	--	**N/A**
	– status indicated by other unambiguous means	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
7.4.2	**Different positions of control devices/switches indicated by figures, letters, or other visual means**	No control devices provided.	**N/A**
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)**	RMF Reference to specific RISKS: (ISO14971 Cl.__)	**N/A**
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE..... :	--	**N/A**
	– or an indication of direction in which magnitude of the function changes	--	**N/A**
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009	--	**N/A**
7.4.3	**Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units**	--	**N/A**
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units	--	**N/A**
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3..... :	See Appended Tables 7.1.2 and 7.1.3.	**N/A**
7.5	**Safety signs**		**N/A**
	Safety sign with established meaning used	No safety signs used.	**N/A**
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	RMF Reference to specific RISK & Marking: (ISO 14971 Cl.__)	**N/A**
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT	--	**N/A**
	Specified colours in ISO 3864-1 used for safety signs ..... :	--	**N/A**
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	--	**N/A**
	Safety signs including any supplementary text or symbols described in instructions for use	--	**N/A**
	- and in a language acceptable to the intended OPERATOR	--	**N/A**
7.6	**Symbols**		**P**
7.6.1	**Meanings of symbols used for marking described in instructions for use ..... :**	Provided within user instruction.	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
7.6.3	**Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable**	According to Annex D.	**P**
7.7	**Colours of the insulation of conductors**		**N/A**
7.7.1	**PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation**	EUT is not Class I equipment; therefore no protective earth conductor provided.	**N/A**
7.7.2	**Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations**	--	**N/A**
7.7.3	**Green and yellow insulation identify only following conductors:**	Not used.	**N/A**
	– PROTECTIVE EARTH CONDUCTORS	--	**N/A**
	– conductors specified in 7.7.2	--	**N/A**
	– POTENTIAL EQUALIZATION CONDUCTORS	--	**N/A**
	– FUNCTIONAL EARTH CONDUCTORS	--	**N/A**
7.7.4	**Neutral conductors of POWER SUPPLY CORDS are "light blue"**	EUT is direct plug-in equipment; therefore no power supply cord provided.	**N/A**
7.7.5	**Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1**	--	**N/A**
7.8	**Indicator lights and controls**		**N/A**
7.8.1	**Red indicator lights used only for Warning**	No indicator lights provided. EUT is direct plug-in power supply unit and not treated as end medical product. End product consideration.	**N/A**
	Yellow indicator lights used only for Caution	No indicator lights provided.	**N/A**
	Green indicator lights used only for Ready for use	No indicator lights provided.	**N/A**
	Other colours: Meaning other than red, yellow, or green (colour, meaning) .....:	No indicator lights provided.	**N/A**
7.8.2	**Red used only for emergency control**	--	**N/A**
7.9	**ACCOMPANYING DOCUMENTS**		**Š**
7.9.1	**ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description**	Technical specifications provided by the manufacturer.	**P**
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:	--	**P**
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to.....:	GlobTek with address provided within technical specifications.	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	– MODEL OR TYPE REFERENCE.....:	Model name provided within technical specifications.	**P**
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT	No electronic documents provided. Only paper version provided by the manufacturer and evaluated.	**N/A**
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	--	**P**
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	--	**P**
7.9.2	**Instructions for use include the required information**		**P**
7.9.2.1	**– use of ME EQUIPMENT as intended by the MANUFACTURER:**	EUT is medical direct plug-in power supply intended for supplying end medical product by its output voltage (polarized output cable provided).	**P**
	– frequently used functions,	EUT is medical direct plug-in power supply intended for supplying end medical product by its output voltage (polarized output cable provided).	**P**
	– known contraindication(s) to use of ME EQUIPMENT	EUT is medical direct plug-in power supply; therefore no contraindications to use of the equipment.	**N/A**
	– parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	No such parts identified by the manufacturer.	**N/A**
	– name or trademark and address of the MANUFACTURER	Provided within technical specifications.	**P**
	– MODEL OR TYPE REFERENCE	Provided within technical specifications.	**P**
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	--	**N/A**
	– the PATIENT is an intended OPERATOR	--	**N/A**
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	--	**N/A**
	– functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	--	**N/A**
	– maintenance the PATIENT can perform	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	--	**N/A**
	Instructions for use are in a language acceptable to the intended operator	English version evaluated.	**P**
7.9.2.2	**Instructions for use include all warning and safety notices**	Provided within technical specifications.	**P**
	Warning statement for CLASS I ME EQUIPMENT included	Class II equipment.	**N/A**
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	--	**N/A**
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	Not specified. EUT is medical direct plug-in power supply. Shall be evaluated during end medical product approval.	**N/A**
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	--	**N/A**
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	--	**N/A**
7.9.2.3	**Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions**	Mains operated equipment.	**N/A**
7.9.2.4	**Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source**	No additional power source provided. Mains operated equipment.	**N/A**
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**	Specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time..... :	--	**N/A**
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ..... :	--	**N/A**
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK ..... :	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.5	**Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE**	--	**P**
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	--	**N/A**
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	--	**N/A**
	APPLIED PARTS specified	No applied parts provided.	**N/A**
7.9.2.6	**Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation**	--	**N/A**
7.9.2.7	**Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device**	Shall be provided within user manual of the end medical product. EUT is direct plug-ion power supply unit.	**N/A**
7.9.2.8	**Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation**	--	**N/A**
7.9.2.9	**Information provided to operate ME EQUIPMENT**	EUT is medical direct plug-in power supply.	**N/A**
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	--	**N/A**
7.9.2.10	**A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message**	Not messages provided.	**N/A**
7.9.2.11	**Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT**	End product consideration. Power supply unit is provided without operating indicator.	**N/A**
7.9.2.12	**Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified**	No applied parts provided.	**N/A**
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	No such parts.	**N/A**
7.9.2.13	**Instructions provided on preventive inspection, calibration, maintenance and its frequency**	EUT is maintence free. No preventive inspection, calibration and maintenance necessary.	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	--	**N/A**
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	No such parts specified by the manufacturer.	**N/A**
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	No rechargeable batteries incorporated.	**N/A**
7.9.2.14	**A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided**	--	**N/A**
	Other equipment providing power to ME SYSTEM sufficiently described	Mains operated equipment.	**N/A**
7.9.2.15	**Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use .....:**	Provided within technical specifications: The power supply has to be disposed appropriately. Please refer to local regulations (Waste Electrical and Electronic Equipment).	**P**
7.9.2.16	**Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)**	--	**N/A**
7.9.2.17	**Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation**	--	**N/A**
7.9.2.18	**The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization**	--	**N/A**
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization	--	**N/A**
7.9.2.19	**The instructions for use contain a unique version identifier .....:**	Technical specifications, version: A	**P**
7.9.3	**Technical description**		**P**
7.9.3.1	**All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use**	--	**P**
	Technical description separable from instructions for use contains required information, as follows		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	--	**N/A**
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	--	**N/A**
	a unique version identifier..... :	--	**N/A**
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	--	**N/A**
7.9.3.2	**The technical description contains the following required information**		**N/A**
	– type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT ..... :	EUT is not permanently installed equipment.	**N/A**
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	--	**N/A**
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	No such parts within the equipment.	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	There is a note within the technical specification related to the service personnel: Please use only components approved by the manufacturer.	**N/A**
7.9.3.3	**Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair**	--	**N/A**
7.9.3.4	**Means used to comply with requirements of 8.11.1 clearly identified in technical description**	Mains plug is considered as disconnecting device (Direct plug-in equipment).	**P**

8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**P**
8.1	**Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS**	--	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION ..... : (ISO 14971 Cl. 4.3)	RMF Reference to specific RISKS: Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003) (Risk No.: 3) (ISO 14971 Cl. 4.3)	**P**
8.2	**Requirements related to power sources**		**N/A**
8.2.1	**Connection to a separate power source**		**N/A**
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	EUT is intended for connection to the mains.	**N/A**
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	--	**N/A**
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	--	**N/A**
8.2.2	**Connection to an external d.c. power source**		**N/A**
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	EUT is intended for connection to the mains.	**N/A**
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE	--	**N/A**
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset	--	**N/A**
8.3	**Classification of APPLIED PARTS**		**N/A**
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No applied parts provided.	**N/A**
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART	--	**N/A**
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	--	**N/A**
8.4	**Limitation of voltage, current or energy**		**P**
8.4.2	**ACCESSIBLE PARTS and APPLIED PARTS**		**P**
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :	See appended Table 8.7	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT .....:	See appended Table 8.7 Measured on the outer plastic enclosure (metal foil used) and on the output of the power supply unit.	**P**
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed	--	**N/A**
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.).....:	See appended Table 8.4.2	**P**
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J).....:	See appended Table 8.4.2	**P**
	d) Voltage and energy limits specified in c) above also applied to the following:	--	**N/A**
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	--	**N/A**
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	No such parts	**N/A**
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	No openings provided.	**P**
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N	--	**P**
	Test repeated with a TOOL specified in instructions for use	--	**N/A**
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	--	**N/A**
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	--	**N/A**
	A TOOL is required when it is possible to prevent the devices from operating	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.4.3	**Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V)..... :**	See appended Table 8.4.3 No capacitor provided between line and neutral.	**P**
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC ...:	See appended Table 8.4.3	**N/A**
8.4.4	**Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC ...:**	See appended Table 8.4.4	**N/A**
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL	--	**N/A**
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description ..... :	--	**N/A**
8.5	**Separation of parts**		**P**
8.5.1	**MEANS OF PROTECTION (MOP)**		**P**
8.5.1.1	**Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4**	2 x MOOP provided between primary and accessible parts and between primary and secondary circuit within the equipment.	**P**
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION	--	**N/A**
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10	--	**P**
8.5.1.2	**MEANS OF PATIENT PROTECTION (MOPP)**	Protection categorized as operator protection.	**N/A**
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test ..... :	See appended Table 8.8.3	**N/A**
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	--	**N/A**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	--	**N/A**
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ..... :	See appended Tables 8.8.3 and 8.10	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c.....:	See appended Tables 8.8.3 and 8.10	**N/A**
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	--	**N/A**
	Voltage $_{Total\ Working}$ (V) and C $_{Nominal}$ (µF).....:	--	**—**
8.5.1.3	**MEANS OF OPERATOR PROTECTION (MOOP)**	Protection categorized as operator protection.	**P**
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	--	**N/A**
	– dielectric strength test .....:	See appended Table 8.8.3	**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	--	**N/A**
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	--	**P**
	– limits of Tables 13 to 16 (inclusive); or	--	**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	--	**N/A**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	Class II equipment.	**N/A**
	– or with requirements and tests of IEC 60950-1 for protective earthing.....:	--	**N/A**
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION.....:	See Appended Tables 8.8.3 and 8.10 No bridging components.	**N/A**
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION.....:	See Appended Tables 8.8.3 and 8.10 No bridging components.	**N/A**
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	--	**N/A**
	Voltage $_{Total\ Working}$ (V) and C $_{Nominal}$ (µF).....:	--	**—**
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION	--	**N/A**
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION .....:	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION .... :	Considered.	**P**
8.5.2	**Separation of PATIENT CONNECTIONS**		**N/A**
8.5.2.1	**PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE ..... :**	No patient connections provided.	**N/A**
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	--	**N/A**
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function	--	**N/A**
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS .....:	--	**N/A**
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	--	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4.... :	See appended Table 8.7	**N/A**
	Dielectric strength test conducted per 8.8.3.... :	See appended Table 8.8.3	**N/A**
	CREEPAGE and CLEARANCES measured ..... :	Refer to Insulation Diagram	**N/A**
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s	--	**N/A**
8.5.2.2	**PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED .... :**	--	**N/A**
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	--	**N/A**
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low	--	**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4.... :	See appended Table 8.7	**N/A**
	Dielectric strength test conducted per 8.8.3.... :	See appended Table 8.8.3	**N/A**
	Relevant CREEPAGE and CLEARANCES measured	Refer to Insulation Diagram	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits.....: (ISO 14971 Cl. 4.2-4.4, 5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.5.2.3	**A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE**		**N/A**
	– cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT.....:	No patient leads provided.	**N/A**
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter	--	**N/A**
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	--	**N/A**
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1	--	**N/A**
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,	--	**N/A**
	Test finger test (10 N) .....:	See appended Table 5.9.2	**N/A**
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces .....: **(ISO 14971 Cl. 4.2-4.4, 5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
8.5.4	**WORKING VOLTAGE**	--	**P**
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V).....:	Supply voltage: 230 Vac	**P**
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V) .....:	--	**N/A**
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) .....:	See Insulation Diagram and Insulation Table	**P**
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)..... :	No applied parts provided.	**N/A**
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No applied parts provided.	**N/A**
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :	No motors provided.	**N/A**
8.5.5	**DEFIBRILLATION-PROOF APPLIED PARTS**	No applied parts provided.	**N/A**
8.5.5.1	**Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety**	--	**N/A**
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	--	**N/A**
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :	See appended Table 8.5.5.1a	**N/A**
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS..... :	See appended Table 8.5.5.1b	**N/A**
8.5.5.2	**Means provided to limit energy delivered to a 100 Ω load ..... :**	See appended Table 8.5.5.2	**N/A**
8.6	**Protective and functional earthing and potential equalization of ME EQUIPMENT**		**N/A**
8.6.1	**Requirements of 8.6.2 to 8.6.8 applied**	EUT is Class II equipment.	**N/A**
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8	--	**N/A**
8.6.2	**PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR..... :**	--	**N/A**
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL	--	**N/A**
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside .... :	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	--	**N/A**
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	--	**N/A**
8.6.3	**PROTECTIVE EARTH CONNECTION not used for a moving part,**	No moving parts.	**N/A**
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to proof of reliability: (ISO 14971 Cl.__)	**N/A**
8.6.4	**a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop ..... :**	See appended Table 8.6.4	**N/A**
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits .....:	See appended Table 8.6.4 & Clause 8.7	**N/A**
8.6.5	**Surface coatings**		**N/A**
	Poorly conducting surface coatings on conductive elements removed at the point of contact	--	**N/A**
	Coating not removed when requirements for impedance and current-carrying capacity met	--	**N/A**
8.6.6	**Plugs and sockets**		**N/A**
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections	--	**N/A**
	– applied also where interchangeable parts are PROTECTIVELY EARTHED	--	**N/A**
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		**N/A**
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	No potential equalization conductor provided.	**N/A**
	–accidental disconnection avoided in NORMAL USE	--	**N/A**
	– Terminal allows conductor to be detached without a TOOL	--	**N/A**
	– Terminal not used for a PROTECTIVE EARTH CONNECTION	--	**N/A**
	– Terminal marked with symbol 8 of Table D.1	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard	--	**N/A**
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR	--	**N/A**
8.6.8	**FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION**	--	**N/A**
8.6.9	**Class II ME EQUIPMENT**		**N/A**
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow	--	**N/A**
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.	--	**N/A**
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS	--	**N/A**
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		**P**
8.7.1	**a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3..... :**	See appended Tables 8.7	**P**
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 ..... :	See appended Tables 8.7	**P**
8.7.2	**Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except**	--	**P**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	--	**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	Class II equipment.	**N/A**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	--	**N/A**
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE	No applied parts provided.	**N/A**
8.7.3	**Allowable Values**		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b .:	See appended Table 8.7 Leakage current meter with frequency characteristics as specified on Fig. 12 b) used.	**P**
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz.....:	See appended Table 8.7 No applied parts provided.	**N/A**
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC}) .....:	See appended Table 8.7	**P**
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}).....:	See appended Table 8.7 Class II equipment.	**N/A**
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 .....:	See appended Table 8.7 EUT not permanently installed equipment.	**N/A**
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device.....:	See appended Table 8.7	**N/A**
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION.....:	See appended Table 8.7	**N/A**
8.7.4	**LEAKAGE and PATIENT AUXILIARY CURRENTS measurements.....:**	See appended Table 8.7	**P**
8.8	**Insulation**		**P**
8.8.1	**Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing**	--	**P**
	Insulation exempted from test (complies with clause 4.8)	No components bridging insulation.	**N/A**
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	--	**N/A**
8.8.2	**Distance through solid insulation or use of thin sheet material**		**P**
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	--	**P**
	a) 0.4 mm, min, distance through insulation, or	Thickness of the bobbin: 0,60 mm (measured between primary and secondary windings).	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	--	**P**
	– at least two layers of material, each passed the appropriate dielectric strength test..... :	See appended Table 8.8.3	**N/A**
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test..... :	See appended Table 8.8.3 Separate primary and secondary windings.	**N/A**
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION	--	**N/A**
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION	--	**N/A**
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when	--	**P**
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	--	**N/A**
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	--	**N/A**
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	--	**N/A**
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer	--	**N/A**
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded	--	**N/A**
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded	--	**N/A**
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values	--	**N/A**
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension..... :	--	**N/A**
	Finished component complied with routine dielectric strength tests of 8.8.3 ..... :	See appended Table 8.8.3	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Tests of Annex L not repeated since material data sheets confirm compliance .....:	See Table 8.10 and Material Information Attachment	**N/A**
8.8.3	**Dielectric Strength**		**P**
	Solid insulating materials with a safety function withstood dielectric strength test voltages .....:	See appended Table 8.8.3	**P**
8.8.4	**Insulation other than wire insulation**		**P**
8.8.4.1	**Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT**	--	**P**
	ME EQUIPMENT and design documentation examined.....:	--	**P**
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003) (Risk No.: 5, 6) (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat .....:	Manufacturer is using approved materials with adequate temperature characteristics. See Table 8.10: List of critical components for details.	**P**
	Tests conducted in absence of satisfactory evidence for resistance to heat .....:	--	**N/A**
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus ...:	See Table 8.8.4.1	**P**
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C).....:	See Table 8.8.4.1 Transformer bobbin material.	**P**
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION	--	**N/A**
8.8.4.2	**Resistance to environmental stress**		**P**
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9	EUT is provided with plastic enclosure to cover all internal insulation parts.	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such materials used for insulation.	**N/A**
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	--	**N/A**
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	Rubber not used for insulation.	**N/A**
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h	--	**N/A**
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		**P**
8.9.1.1	**CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)..... :**	Refer to Insulation Diagram.	**P**
8.9.1.15	**CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1**	No applied parts provided.	**N/A**
8.9.2	**a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied..... :**	See appended Table 8.9.2 Sufficient creepage and clearance distances provided between parts of opposite polarity before mains fuses. Short circuit performed after primary fuses. No hazardous situation.	**N/A**
8.9.3	**Spaces filled by insulating compound**		**N/A**
8.9.3.1	**Only solid insulation requirements applied where distances between conductive parts filled with insulating compound**	No parts filled with insulation compounds.	**N/A**
	Thermal cycling, humidity preconditioning, and dielectric strength tests	--	**N/A**
8.9.3.2	**For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage)..... :**	See appended Table 8.9.3.2	**N/A**
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	--	**N/A**
8.9.3.3	**Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:	--	**N/A**
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage .....:	See appended Table 8.9.3.4	**N/A**
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage	--	**N/A**
8.9.4	**Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree ……**	Pollution degree:2	**P**
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	Refer to Insulation Diagram supplemental information for location and force used	**P**
8.10	**Components and wiring**		**P**
8.10.1	**Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely .....:**	All components mounted securely. Secondary circuit is fixed to transformer core with insulation tape.	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components.....: **(ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003) (Risk No.: 3) (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
8.10.2	**Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment .....:**	Accidental detachment prevented. Primary wires are soldered to the primary pins (through the hole method used in addition). Output cable is provided with cord anchorage to prevent displacement of the secondary wires in case of accidental displacement.	**P**
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.10.3	**Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken ..... :**	See Appended Table 5.9.2 No such flexible cords provided.	**N/A**
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		**N/A**
8.10.4.1	**Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION**	EUT is not cord-connected hand-held parts and cord-connected foot-operated control devices.	**N/A**
8.10.4.2	**Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3**	--	**N/A**
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3	--	**N/A**
8.10.5	**Mechanical protection of wiring**		**N/A**
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges ..... :	No moving parts provided.	**N/A**
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	--	**N/A**
8.10.6	**Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead**	--	**N/A**
8.10.7	**a) Insulating sleeve adequately secured..... :**	See appended Table 8.10 No insulation sleeve used.	**N/A**
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	--	**N/A**
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C ..... :	See appended Table 8.10 No such high temperature rises obtained during normal use of the equipment.	**N/A**
8.11	**MAINS PARTS, components and layout**		**P**
8.11.1	**a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles ..... :**	See appended Table 8.10 EUT is medical direct plug-in power supply; therefore mains plug is considered as disconnecting device.	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	EUT is not permanently installed equipment.	**N/A**
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position	--	**N/A**
	- the isolation device specified in the ACCOMPANYING DOCUMENTS	--	**N/A**
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description .....:	See appended Table 8.10	**N/A**
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV .....:	See appended Table 8.10	**N/A**
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	--	**N/A**
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	--	**N/A**
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH .....:	See appended Table 8.10 EUT is medical direct plug-in power supply; therefore mains plug is considered as disconnecting device.	**P**
	g) A fuse or a semiconductor device not used as an isolating means	--	**N/A**
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device	EUT is medical direct plug-in power supply; therefore mains plug is considered as disconnecting device.	**P**
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such parts.	**N/A**
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage	--	**N/A**
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause	--	**N/A**
	Standard test finger applied	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.2	**MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2**	No multiple-socket outlet provided.	**N/A**
8.11.3	**POWER SUPPLY CORDS**		**N/A**
8.11.3.1	**MAINS PLUG not fitted with more than one POWER SUPPLY CORD**	No power supply cord provided. EUT is medical direct plug-in power supply.	**N/A**
8.11.3.2	**POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53)... :**	See appended Table 8.10	**N/A**
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ..... :	See appended Table 8.10	**N/A**
8.11.3.3	**NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 ..... :**	--	**N/A**
8.11.3.4	**APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6..... :**	See appended Table 8.10	**N/A**
8.11.3.5	**Cord anchorage**		**N/A**
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	EUT is medical direct plug-in power supply. No power supply cord provided.	**N/A**
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or	--	**N/A**
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	--	**N/A**
	– metal provided with an insulating lining affixed to cord anchorage	--	**N/A**
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	--	**N/A**
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components	--	**N/A**
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	--	**N/A**
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18.....:	See appended Table 8.11.3.5	**N/A**
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests	--	**N/A**
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position	--	**N/A**
	CREEPAGE and CLEARANCES not reduced below limits in 8.9	--	**N/A**
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged	--	**N/A**
8.11.3.6	**POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment**	No power supply cord provided.	**N/A**
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	--	**N/A**
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g).....:	See appended Table 8.11.3.6	**N/A**
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance	--	**N/A**
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D .....:	See appended Table 8.11.3.6	**N/A**
8.11.4	**MAINS TERMINAL DEVICES**		**N/A**
8.11.4.1	**PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection**	EUT is medical direct plug-in power supply.	**N/A**
	Terminals alone are not used to keep conductors in position	--	**N/A**
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors	--	**N/A**
	Screws and nuts clamping external conductors do not serve to secure any other component	--	**N/A**
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	--	**N/A**
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	--	**N/A**
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction	--	**N/A**
8.11.4.3	**Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times**	Through the hole method in additional to soldering used for primary wires.	**P**
8.11.4.4	**Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened**	EUT is medical direct plug-in power supply.	**N/A**
8.11.4.5	**Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors**	--	**N/A**
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test	--	**N/A**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		**P**
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection . :	See appended Table 8.10. Two primary fuses provided (in both supply leads). EUT is Class II equipment. .	**P**
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ..... :	Two primary fuses provided (in both supply leads). EUT is Class II equipment. .	**P**
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed equipment.	**N/A**
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART	--	**N/A**
	Protective devices have adequate breaking capacity to interrupt the max. fault current ..... :	See appended Table 8.10	**P**
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	Class II equipment.	**N/A**
	Justification for omission of fuses or OVER-CURRENT RELEASES documented ..... :	--	**N/A**
8.11.6	**Internal wiring of the MAINS PART**		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable .....:	Min. 0,75 mm^2	**P**
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient.....:	See appended Table 8.10 for details.	**P**
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		**P**
9.2	**HAZARDS associated with moving parts**		**N/A**
9.2.1	**When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level..... :**	No moving parts provided.	**N/A**
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)	--	**N/A**
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and	--	**N/A**
	RISK CONTROLS implemented .....:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	All RISKS associated with moving parts have been reduced to an acceptable level	--	**N/A**
9.2.2	**TRAPPING ZONE**		**N/A**
9.2.2.1	**ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:**	--	**N/A**
	– Gaps in Clause 9.2.2.2, or	--	**N/A**
	– Safe distances in Clause 9.2.2.3, or	--	**N/A**
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or	--	**N/A**
	– Continuous activation in Clause 9.2.2.5	--	**N/A**
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.2	**A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20.....:**	See appended Table 9.2.2.2	**N/A**
9.2.2.3	**A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 ..... :**	See appended Table 9.2.2.2	**N/A**
9.2.2.4	**GUARDS and other RISK CONTROL measures**		**N/A**
9.2.2.4.1	**A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK.....:**	See appended Table 15.3	**N/A**
9.2.2.4.2	**FIXED GUARDS held in place by systems that can only be dismantled with a TOOL**	--	**N/A**
9.2.2.4.3	**Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open**	--	**N/A**
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,	--	**N/A**
	– absence or failure of one of their components prevents starting, and stops moving parts	--	**N/A**
	Movable GUARDS complied with any applicable tests	--	**N/A**
9.2.2.4.4	**Other RISK CONTROL designed and incorporated into to the control system stops movement and**	--	**N/A**
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or	--	**N/A**
	ME EQUIPMENT is SINGLE FAULT SAFE	--	**N/A**
9.2.2.5	**Continuous activation**		**N/A**
	Continuous activation used as a RISK CONTROL, complies with the following	--	**N/A**
	a) movement was in OPERATOR'S field of view	--	**N/A**
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR	--	**N/A**
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or	--	**N/A**
	- the continuous activation system is SINGLE FAULT SAFE	--	**N/A**
9.2.2.6	**Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK	--	**N/A**
9.2.3	**Other MECHANICAL HAZARDS associated with moving parts**		**N/A**
9.2.3.1	**Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated**	No moving parts.	**N/A**
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or	--	**N/A**
	- activation does not result in an unacceptable RISK	--	**N/A**
9.2.3.2	**Over travel past range limits of the ME EQUIPMENT prevented ..... :**	--	**N/A**
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse ... :	See appended Table 9.2.3.2	**N/A**
9.2.4	**Emergency stopping devices**		**N/A**
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power..... :	No emergency stopping device provided.	**N/A**
	a) Emergency stopping device reduced RISK to an acceptable level	--	**N/A**
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)**	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM	--	**N/A**
	c) Emergency stopping device actuator was readily accessible to OPERATOR	--	**N/A**
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	--	**N/A**
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD	--	**N/A**
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	--	**N/A**
	g) Means for stopping of movements operate as a result of one single action	--	**N/A**

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	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	--	**N/A**
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"	--	**N/A**
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed	--	**N/A**
	k) Emergency stopping device is suitable for its application	--	**N/A**
9.2.5	**Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping ..... :**	EUT is medical direct plug-in power supply.	**N/A**
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	--	**N/A**
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented	--	**N/A**
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
9.3	**Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered .....:**	No rough surfaces, no sharp corners and no sharp edges.	**P**
9.4	**Instability HAZARDS**		**N/A**
9.4.1	**ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE**	Equipment not intended to be placed on the surface.	**N/A**
9.4.2	**Instability – overbalance**		**N/A**
9.4.2.1	**ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested.....:**	See appended Table 9.4.2.1	**N/A**
9.4.2.2	**Instability excluding transport**		**N/A**
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ... :	See appended Table 9.4.2.2	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	A warning provided when overbalance occurred during 10° inclined plane test	--	**N/A**
9.4.2.3	**Instability from horizontal and vertical forces**		**N/A**
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it	Mass of equipment less than 25 kg.	**N/A**
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK	--	**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)	See appended Table 9.4.2.3	**N/A**
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	--	**N/A**
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning.... :	--	**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b) ..... :	See appended Table 9.4.2.3	**N/A**
9.4.2.4	**Castors and wheels**		**N/A**
9.4.2.4.1	**Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE**	--	**N/A**
9.4.2.4.2	**Force required to move MOBILE ME EQUIPMENT did not exceed 200 N..... :**	See appended Table 9.4.2.4.2	**N/A**
9.4.2.4.3	**MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold ..... :**	See appended Table 9.4.2.4.3	**N/A**
9.4.3	**Instability from unwanted lateral movement (including sliding)**		**N/A**
9.4.3.1	**a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control**	EUT is medical direct plug-in power supply.	**N/A**
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements	--	**N/A**
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See appended Table 9.4.3.1	**N/A**
9.4.3.2	**Instability excluding transport**		**N/A**
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test ..... :	See appended Table 9.4.3.2	**N/A**
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See appended Table 9.4.3.2	**N/A**

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9.4.4	**Grips and other handling devices**		**N/A**
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method	No grips and other handling devices provided.	**N/A**
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS	--	**N/A**
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying	--	**N/A**
	c) Carrying handles and grips and their means of attachment withstood loading test .....:	See appended Table 9.4.4	**N/A**
9.5	**Expelled parts HAZARD**		**N/A**
9.5.1	**Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE.....:** **(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	All identified RISKS associated with expelled parts mitigated to an acceptable level	No expelled parts can occur.	**N/A**
9.5.2	**Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....:**	See appended Table 8.10	**N/A**
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		**N/A**
9.6.1	**Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and**	EUT not produces acoustic energy or vibration.	**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity.....:	--	**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and **(ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	All identified RISKS mitigated to an acceptable level	--	**N/A**
9.6.2	**Acoustic energy**		**N/A**
9.6.2.1	**PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE**	EUT not produces acoustic energy. EUT is medical direct plug-in power supply.	**N/A**
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) .....:	--	**—**

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	- 83 dBA (when halving the cumulative exposure time) (dBA) ..... :	--	**—**
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB) ..... :	--	**—**
9.6.2.2	**RISK MANAGEMENT FILE examined ..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
9.6.3	**Hand-transmitted vibration**		**N/A**
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values	--	**N/A**
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2)..... :	--	**N/A**
	– Accelerations for different times, inversely proportional to square root of time (m/s^2) ..... :	--	**N/A**
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		**N/A**
9.7.2	**Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE ..... :** **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	--	**N/A**
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure	--	**N/A**
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	--	**N/A**
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply	--	**N/A**
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	--	**N/A**
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
9.7.3	**Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:**	--	**N/A**
	a) RATED maximum supply pressure from an external source	--	**N/A**
	b) Pressure setting of a pressure-relief device provided as part of assembly	--	**N/A**
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device	--	**N/A**
9.7.4	**Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests.....:**	--	**N/A**
9.7.5	**A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPal .....:**	See appended Table 9.7.5	**N/A**
9.7.6	**Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE .:**	No such devices incorporated.	**N/A**
9.7.7	**Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests.....:**	No pressure-relief devices provided. EUT is medical direct plug-in power supply.	**N/A**
	a) Connected as close as possible to pressure vessel or parts of system it is to protect	--	**N/A**
	b) Installed to be readily accessible for inspection, maintenance, and repair	--	**N/A**
	c) Could be adjusted or rendered inoperative without a TOOL	--	**N/A**
	d) With discharge opening located and directed as to not to release material towards any person	--	**N/A**
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure	--	**N/A**
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	--	**N/A**
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device..... : **(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
9.8	**HAZARDS associated with support systems**		**N/A**
9.8.1	**ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .. :**	See appended Table 8.10 EUT is not intended to support loads. EUT is medical direct plug-in power supply.	**N/A**
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	--	**N/A**
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK	--	**N/A**
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES	--	**N/A**
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials	--	**N/A**
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
9.8.2	**Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest**	--	**N/A**
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing ..:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system ..: **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	All identified RISKS are mitigated to an acceptable level	--	**N/A**
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK.....:	See appended Table 8.10	**N/A**
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results .....: **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISK: (ISO 14971 Cl.__)	**N/A**
9.8.3	**Strength of PATIENT or OPERATOR support or suspension systems**		**N/A**
9.8.3.1	**ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints.....:**	--	**N/A**
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts	--	**N/A**
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER	--	**N/A**
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	--	**N/A**
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS	--	**N/A**
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ..... :	See copy of Marking Label	**N/A**
9.8.3.2	**a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR ..... :**	--	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests..... :	See appended Tables 8.10 and 9.8.3.2	**N/A**
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK	--	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test ..... :	See appended Tables 8.10 and 9.8.3.2	**N/A**
9.8.3.3	**Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test**	See appended Table 9.8.3.3	**N/A**
9.8.4	**Systems with MECHANICAL PROTECTIVE DEVICES**		**N/A**
9.8.4.1	**a) A MECHANICAL PROTECTIVE DEVICE provided for the support system**	EUT is medical direct plug-in power supply unit.	**N/A**
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:	--	**N/A**
	– Designed based on TOTAL LOAD	--	**N/A**
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	--	**N/A**
	– Activated before travel produced an unacceptable RISK	--	**N/A**
	– Takes into account Clauses 9.2.5 and 9.8.4.3	--	**N/A**
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests ..... :	See appended Table 8.10	**N/A**
9.8.4.2	**Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	--	**N/A**
9.8.4.3	**MECHANICAL PROTECTIVE DEVICE intended to function once**		**N/A**
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE :	EUT is medical direct plug-in power supply.	**N/A**
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal	--	**N/A**
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.	--	**N/A**
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE	--	**N/A**
	– Compliance confirmed by examination and following test .....:	See appended Table 8.10	**N/A**
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT	--	**N/A**
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR	--	**N/A**
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	--	**N/A**
9.8.5	**Systems without MECHANICAL PROTECTIVE DEVICES**		**N/A**
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES .....:	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system .....: **(ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		**N/A**
10.1	**X-Radiation**		**N/A**
10.1.1	**The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT ..... :**	See Table 10.1.1 EUT not produces X-radiation.	**N/A**
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
10.1.2	**RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or.....:**	--	**N/A**
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
10.2	**RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE.....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__) EUT not produces alpha, beta, gamma, neutron and other radiation.	**N/A**
10.3	**The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2**	EUT not produces microwave radiation.	**N/A**
	Microwave radiation is propagated intentionally	--	**N/A**
10.4	**Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.**	No such components incorporated within the equipment.	**N/A**
10.5	**RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
10.6	**RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
10.7	**RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**

11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**	**P**
11.1	**Excessive temperatures in ME EQUIPMENT**	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
11.1.1	**Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and ..... :**	See appended Table 11.1.1 Duration of the contact of the external enclosure is assumed to be between 1 and 10 seconds (normal time needed for disconnecting direct plug-in adapter from the mains) for external parts of the enclosure.	**P**
	Surfaces of test corner did not exceed 90 °C	Temperature of test corner not exceeds 90°C in normal conditions.	**P**
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	Not operated.	**P**
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISK: Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003) (Risk No.: 8) (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
11.1.2	**Temperature of APPLIED PARTS**		**N/A**
11.1.2.1	**APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply ..... :**	See appended Table 11.1.2.1 and appended. No applied parts.	**N/A**
	Clinical effects determined and documented in the RISK MANAGEMENT FILE **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use	--	**N/A**
11.1.2.2	**APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION :**	See appended Table 11.1.2.2	**N/A**
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:	--	**N/A**
	Maximum Temperature ..... :	--	**—**
	Conditions for safe contact, e.g. duration or condition of the PATIENT ..... :	--	**—**
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	APPLIED PARTS surface temperature of equal to or less than 41°C	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted.....:	RMF Reference to specific RISKS:	**N/A**
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
11.1.3	**Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	See appended Table 11.1.3d and RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE .....:	RMF Reference to specific RISKS:	**N/A**
11.1.4	**GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL**	--	**N/A**
11.2	**Fire prevention**		**P**
11.2.1	**ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3**	See clause 15.3.	**P**
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**		**N/A**
11.2.2.1	**RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of .....:**	See appended Table 8.10 EUT is not intended for use in conjunction with oxygen rich environment.	**N/A**
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions	--	**N/A**
	1) when temperature of material raised to its ignition temperature	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature	--	**N/A**
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	--	**N/A**
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	--	**N/A**
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton	--	**N/A**
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :	See appended Table 11.2.2.1	**N/A**
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :	--	**N/A**
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3 ..... :	See appended Tables 4.11, 11.1.1, 11.2.2.1 and 13.2	**N/A**
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)..... :	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes	--	**N/A**
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE .....:	--	**N/A**
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases .....:	--	**N/A**
11.2.2.2	**RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT**	--	**N/A**
11.2.2.3	**Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks**	--	**N/A**
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques	--	**N/A**
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means	--	**N/A**
11.2.3	**SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered**		**N/A**
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) .....:	--	**N/A**
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) .....:	--	**N/A**
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a).....:	--	**N/A**
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a).....:	--	**N/A**
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas .....:	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		**P**
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 ..... :	EUT complies with the construction requirements for fire enclosure. In addition, single faults performed.	**P**
	Constructional requirements were met, or	Direct plug-in power supply is provided with plastic enclosure without openings (Flammability V-0). All internal components are mounted on the PCB rated V-0. Output cable is classified as VW-1. Short circuit on the cable output performed. No deformation of the cable, no hazard.	**P**
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Justification, when requirement not met ..... :	--	**N/A**
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials ..... :	See appended Table 8.10 Output cable is classified as VW-1. Short circuit on the cable performed. No deformation of the cable, no fire, no emission of flames, no hazard.	**P**
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data ..... :	See appended Table 8.10 PCB is rated V-0.	**P**
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings	--	**N/A**
	b) Fire ENCLOSURE met following:	--	**P**
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	EUT is provided with plastic enclosure without openings.	**P**
	2) No openings on the sides within the area included within the inclined line C in Fig 39	EUT is provided with plastic enclosure without openings.	**P**
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials ..... :	See appended Table 8.10 Plastic enclosure is classified V-0	**P**
11.4	**ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics**		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	EUT is not intended for use with flammable anaesthetics.	**N/A**
11.5	**ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents**		**N/A**
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**		**N/A**
11.6.1	**Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT ..... :**	See Appended Table 11.6.1 End product consideration.	**N/A**
11.6.2	**Overflow in ME EQUIPMENT**	No liquid reservoir provided.	**N/A**
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.....:	See Appended Table 11.6.1	**N/A**
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.	--	**N/A**
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.	--	**N/A**
11.6.3	**Spillage on ME EQUIPMENT and ME SYSTEM**	No liquid use. End product consideration.	**N/A**
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See appended Tables 11.6.1; 8.7, 8.8.3 and RMF Reference to specific RISK: (ISO 14971 Cl. __)	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill ..... :	--	**N/A**
11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		**N/A**
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	See Appended Table 11.6.1 No protection against ingress of water provided. EUT is direct plug-in equipment.	**N/A**
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION...:	See appended Tables 8.7 8.8.3	**N/A**
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		**N/A**
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use ..... :	See Appended Tables 11.6.1, 8.7, and 8.8.3	**N/A**
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER ..... :	EUT is medical direct plug-in power supply. Cleaning or disinfection process not specified by the manufacturer. End product consideration.	**N/A**
11.6.7	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		**N/A**
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests..... :	See appended Tables 8.7 8.8.3, and 11.6.1	**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
11.6.8	**RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
11.7	**ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented**	No such parts.	**N/A**
11.8	**Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**	Shall be evaluated during end medical product approval. EUT is medical direct plug-in power supply.	**N/A**
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

12.1	**RISKS associated with accuracy of controls and instruments stated .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
12.2	**RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING .....:**	See Report based on IEC 60601-1-6	**N/A**
12.3	**MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. .....:**	See Report based on IEC 60601-1-8	**N/A**
12.4	**Protection against hazardous output**		**N/A**
12.4.1	**RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
12.4.2	**- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
12.4.3	**RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
12.4.4	**RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
12.4.5	**Diagnostic or therapeutic radiation**		**N/A**
12.4.5.1	**Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation**	--	**N/A**
	Radiation safety ensured by compliance with requirements of appropriate standards	--	**N/A**
12.4.5.2	**ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3 .....:**	See IEC 60601-1-3 Report	**N/A**
12.4.5.3	**RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as.....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
12.4.5.4	**RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as.....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
12.4.6	**RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		**P**
13.1	**Specific HAZARDOUS SITUATIONS**		**P**
13.1.2	**Emissions, deformation of ENCLOSURE or exceeding maximum temperature**		**P**
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur	Not occur during single fault testing.	**P**
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	No deformation of the enclosure occurs.	**P**
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 ..... :	See appended Table 11.1.1	**N/A**
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23..... :	See appended Table 11.1.1	**P**
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded	Considered.	**P**
	Limits for windings in Tables 26, 27, and 31 not exceeded	Temperature of transformer windings not exceeded.	**P**
	Table 22 not exceeded in all other cases	--	**P**
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	See appended Table 13.1.2	**N/A**
13.1.3	**– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed ..... :**	See appended Table 8.7	**P**
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed ..... :	See appended Table 8.7 Output voltage of the medical direct plug-in power supply.	**P**
13. 2	**SINGLE FAULT CONDITIONS**		**P**
13.2.1	**During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination**	See appended Table 13.2	**P**
	ME EQUIPMENT complied with 13.2.2 -13.2.12..... :	See appended Table 13.2	**P**
	RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:	--	**N/A**
13.2.13	**ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature**	No heating elements or motors provided. EUT is intended for continuous operation.	**N/A**
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted	--	**N/A**
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).	--	**N/A**
13.2.13.2	**ME EQUIPMENT with heating elements**		**N/A**
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements provided.	**N/A**
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	--	**N/A**
	a 3) other ME EQUIPMENT with heating elements met test	--	**N/A**
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	--	**N/A**
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration	--	**N/A**
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part	--	**N/A**
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself	--	**N/A**
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V).....:	--	**N/A**
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted	--	**N/A**
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION	--	**N/A**
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and	--	**N/A**
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	--	**N/A**
	2) When more than one control provided, they were disabled in turn	--	**N/A**
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	--	**N/A**
13.2.13.3	**ME EQUIPMENT with motors**		**N/A**
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	No motors provided.	**N/A**
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test	--	**N/A**
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition	--	**N/A**
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	--	**N/A**
	b) Motor met running overload protection test of this clause when:	--	**N/A**
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	--	**N/A**
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	--	**N/A**
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) ..... :	--	**N/A**
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload	--	**N/A**
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	--	**N/A**
	Test not conducted based on other justifications (justification) .....:	--	**N/A**
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10	--	**N/A**
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		**N/A**
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	EUT is designed for continuous operation.	**N/A**
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	--	**N/A**
	Motor winding temperatures did not exceed values in 13.2.10.....:	--	**N/A**
	Insulation Class.....:	--	**—**
	Maximum temperature measured (°C) .....:	--	**—**

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**N/A**
14.1	**Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or**	EUT is not programmable electrical medical system.	**N/A**
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK .....:	--	**N/A**
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)	RMF Reference to specific RISKS: ISO 14971 Cl. __)	**N/A**
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	--	**N/A**
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 6204:2006 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 ..... :	--	**N/A**
	Software development process applied according to Clause 5 of IEC 62304..... :	--	**N/A**
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 ..... :	--	**N/A**
	Software development process Configuration Management applied according to Clause 8 of IEC 62304..... :	--	**N/A**
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304 ..... :	--	**N/A**
14.2	**Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process ..... :**	--	**N/A**
14.3	**RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan**	--	**N/A**
14.4	**A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented**	--	**N/A**
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	--	**N/A**
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	--	**N/A**
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	--	**N/A**
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	--	**N/A**
14.5	**A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained**	--	**N/A**
14.6	**RISK MANAGEMENT PROCESS**		**N/A**
14.6.1	**MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS.....:**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems .....: (ISO 14971 Cl. 4.3)	RMF Reference to specific HAZARDS: (ISO 14971 Cl. __)	**N/A**
14.6.2	**Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2.:**	--	**N/A**
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure .....: (ISO 14971 Cl. 6.1)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	**N/A**
14.7	**A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem.....: (ISO 14971 Cl. 6.3)**	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	**N/A**
14.8	**An architecture satisfying the requirement is specified for PEMS and each of subsystems.....: (ISO 14971 Cl. 6.3)**	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	**N/A**
14.9	**Design is broken up into sub systems and descriptive data on design environment documented.....:**	--	**N/A**
14.10	**A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures .....: (ISO 14971 Cl. 6.3)**	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	**N/A**
	– milestone(s) when VERIFICATION is to be performed for each function	--	**N/A**
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	--	**N/A**
	– selection and utilization of VERIFICATION tools	--	**N/A**
	– coverage criteria for VERIFICATION	--	**N/A**
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented	--	**N/A**
14.11	**A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE .....:**	--	**N/A**
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	The person with overall responsibility for PEMS VALIDATION is independent	--	**N/A**
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	**N/A**
14.12	**Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE**	--	**N/A**
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304..... :	--	**N/A**
	Software Process for Software changes applied according to Clause 5 of IEC 62304..... :	--	**N/A**
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304..... :	--	**N/A**
	Configuration management of software changes applied per Clause 8 of IEC 62304 .... :	--	**N/A**
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 .... :	--	**N/A**
14.13	**For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following ..... :**	--	**N/A**
	a) Purpose of the PEMS connection to an IT-NETWORK	--	**N/A**
	b) required characteristics of the IT-NETWORK	--	**N/A**
	c) required configuration of the IT-NETWORK	--	**N/A**
	d) technical specifications of the network connection, including security specifications	--	**N/A**
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK	--	**N/A**
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)	RMF Reference to specific hazardous situations: (ISO 14971 Cl. __)	**N/A**
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		**N/A**
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS	--	**N/A**
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis	--	**N/A**
	- Changes to the IT-NETWORK include: **- changes in network configuration** **- connection of additional items** **- disconnection of items** **- update of equipment** **- upgrade of equipment**	--	**N/A**
15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
15.1	**RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS .....:**	See Attached IEC 60601-1-6	**N/A**
15.2	**Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance**	No such parts provided.	**N/A**
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	--	**N/A**
15.3	**Mechanical strength**		**P**
15.3.1	**Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**	See below.	**P**
15.3.2	**Push test conducted.....:**	See Appended Table 15.3.	**P**
	No damage resulting in an unacceptable RISK sustained	No damage of the enclosure, no cracks. EUT is provided with enclosure with adequate strength and rigidity.	**P**
15.3.3	**Impact test conducted.....:**	See Appended Table 15.3.	**P**
	No damage resulting in an unacceptable RISK sustained	No damage of the enclosure, no cracks. EUT is provided with enclosure with adequate strength and rigidity.	**P**
15.3.4	**Drop test**		**P**
15.3.4.1	**Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested.....:**	See Appended Table 15.3 Drop test performed only for reference. EUT is medical direct plug-in power supply unit.	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	No unacceptable RISK resulted	No damage of the enclosure, no cracks. EUT is provided with enclosure with adequate strength and rigidity.	**P**
15.3.4.2	**Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test .....:**	See Appended Table 15.3. EUT is medical direct plug-in power supply; therefore test not applicable.	**N/A**
	No damage resulting in an unacceptable RISK sustained	--	**N/A**
15.3.5	**MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests..... :**	See Appended Table 15.3 EUT is not mobile equipment.	**N/A**
	No damage resulting in an unacceptable RISK sustained	--	**N/A**
15.3.6	**Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK**	EUT is provided with plastic enclosure with adequate rigidity and strength.	**P**
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C..... :	Test was performed at 71°C ambient temperature. Maximum temperature rise measured on the enclosure top during normal operation: 60,1°C at 40°C ambient temperature. No damage of the enclosure.	**P**
	No damage resulting in an unacceptable RISK	No damage of the enclosure.	**P**
15.3.7	**INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT**	--	**N/A**
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK	--	**N/A**
15.4	**ME EQUIPMENT components and general assembly**		**P**

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, ...: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__) Output cable is soldered to the PCB through the hole within the equipment by the manufacturer. In additional, cord anchorage for output cable provided. It cannot be connected or disconnected without the use of tool.	**N/A**
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions, ...:	--	**N/A**
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection.....:	--	**N/A**
15.4.2	**Temperature and overload control devices**		**P**
15.4.2.1	**a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION .....: (ISO 14971 Cl. 4.2-4.4, 5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No such components incorporated within the power supply unit. Only non-resettable thermal cut-out provided.	**N/A**
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No such component used.	**N/A**
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided.....: (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003) (Risk No.: 15) (ISO 14971 Cl. 4.2-4.4)	**N/A**
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE ....: (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__) End product consideration.	**N/A**
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	--	**N/A**
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests	--	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17	--	**N/A**
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 ..... :	See appended Table 13.2	**P**
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards.....	--	**N/A**
	- In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times	--	**N/A**
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	No such components incorporated within the equipment. Non-resettable thermal cut-out and primary fuses provided.	**N/A**
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times	--	**N/A**
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	Approved thermal cut-out provided.	**N/A**
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating	--	**N/A**
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating : (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
15.4.2.2	**Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS**	No thermostats incorporated.	**N/A**
15.4.3	**Batteries**		**N/A**
15.4.3.1	**Battery housings provided with ventilation.... :** **(ISO 14971 Cl. 4.2-4.4)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__) No batteries inside power supply unit provided. Mains operated equipment.	**N/A**
	Battery compartments designed to prevent accidental short circuiting	--	**N/A**
15.4.3.2	**Means provided to prevent incorrect connection of polarity ..... :**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries.....: (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
15.4.3.3	**Overcharging of battery prevented by virtue of design.....:**	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries .....: (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
15.4.3.4	**Primary lithium batteries comply with IEC 80086-4**	--	**N/A**
	Secondary lithium batteries comply with IEC 62133	--	**N/A**
15.4.3.5	**A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire.....:**	--	**N/A**
	Protective device has adequate breaking capacity	--	**N/A**
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented	--	**N/A**
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or	--	**N/A**
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION	--	**N/A**
15.4.4	**Indicator lights provided to indicate ME EQUIPMENT is ready for.....:**	EUT is not end medical product. End product consideration.	**N/A**
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	--	**N/A**
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No heaters provided.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters .....: (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Requirement not applied to heated stylus-pens for recording purposes	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Indicator lights provided on ME EQUIPMENT to indicate an output exists	No indicator lights provided. EUT is medical direct plug-in power supply unit and therefore not treated as end medical product. Shall be evaluated during end medical product approval.	**N/A**
	Colours of indicator lights complied with 7.8.1	--	**N/A**
	Charging mode visibly indicated	No charging mode provided.	**N/A**
15.4.5	**RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		**N/A**
15.4.6.1	**a) Actuating parts cannot be pulled off or loosened during NORMAL USE**	No actuating parts of controls provided.	**N/A**
	b) Controls secured so that the indication of any scale always corresponds to the position of the control	--	**N/A**
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	--	**N/A**
	When torque values per Table 30 applied knobs did not rotate ..... :	See appended Table 15.4.6	**N/A**
	Tests conducted with no unacceptable RISK . :	See appended Table 15.4.6	**N/A**
15.4.6.2	**Stops on rotating/ movable parts of controls are of adequate mechanical strength ..... :**	See appended Table 15.4.6	**N/A**
	Torque values in Table 30 applied..... :	See appended Table 15.4.6	**N/A**
	No unexpected change of the controlled parameter when tested ..... :	See appended Table 15.4.6	**N/A**
15.4.7	**Cord-connected HAND-HELD and foot-operated control devices**		**N/A**
15.4.7.1	**a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1**	EUT is not cord-connected hand-held or foot-operated control device.	**N/A**
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage ..... :	--	**N/A**
15.4.7.2	**Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :**	--	**N/A**
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	--	**N/A**
15.4.7.3	**a) Foot-operated control device is at least rated IPX1**.....:	See appended Table 11.6.1	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 ....:	See appended Table 11.6.1	**N/A**
15.4.8	**Aluminium wires less than 16 mm² in cross-sectional area are not used**	Aluminium wires not used.	**P**
15.4.9	**a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed**	--	**N/A**
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	--	**N/A**
	A pressure-release device operating during NORMAL USE is provided	--	**N/A**
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	--	**N/A**
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	--	**N/A**
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		**P**
15.5.1	**Overheating**		**P**
15.5.1.1	**Transformers of ME EQUIPMENT are protected against overheating .....:**	See appended Tables 15.5.1.2 and 15.5.1.3	**P**
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31	--	**P**
	Dielectric strength test conducted after short circuit and overload tests .....:	See appended Table 15.5.2 No break-down of the insulation.	**P**
15.5.1.2	**Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved .....:**	See appended Table 15.5.1.2	**P**
	Short circuit applied directly across output windings	Short circuit performed on transformer secondary windings.	**P**
15.5.1.3	**Multiple overload tests conducted on windings .....:**	See appended Table 15.5.1.3 Only one secondary winding.	**N/A**
15.5.2	**Transformers operating at a frequency above 1kHz tested according to clause 8.8.3 .....:**	--	**P**
	Transformer windings provided with adequate insulation	--	**P**
	Dielectric strength tests were conducted .....:	See appended Table 15.5.2	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
15.5.3	**Transformers forming MEANS OF PROTECTION as required by 8.5 comply with ..... :**	See appended Table 8.10 Transformer tested within the equipment.	**P**
	- Means provided to prevent displacement of end turns	Prevented by design.	**P**
	- protective earth screens with a single turn have insulated overlap	--	**N/A**
	- Exit of wires form internal windings of toroid transformers protected with double sleeving	Not toroidal transformer.	**N/A**
	- insulation between primary and secondary windings complies with 8.8.2	--	**P**
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4	--	**P**
16	**ME SYSTEMS**		**N/A**
16.1	**After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK**	EUT is medical direct plug-in power supply. EUT is a single components and therefore not treated as ME system.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM..... : (ISO 14971 Cl. 4.2-4.4, 5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered	--	**N/A**
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard	--	**N/A**
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards	--	**N/A**
	– tests performed in NORMAL CONDITION, except as specified	--	**N/A**
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM	--	**N/A**
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	--	**N/A**
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR	--	**N/A**
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	--	**N/A**
16.2	**ACCOMPANYING DOCUMENTS of an ME SYSTEM**		**N/A**
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM	--	**N/A**
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	--	**N/A**
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	--	**N/A**
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	--	**N/A**
	c) the required information is provided:	--	**N/A**
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	--	**N/A**
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	--	**N/A**
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM	--	**N/A**
	– additional safety measures to be applied during installation of ME SYSTEM	--	**N/A**
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	--	**N/A**
	– additional measures to be applied during preventive maintenance	--	**N/A**
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	--	**N/A**
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	--	**N/A**
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM	--	**N/A**
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM	--	**N/A**
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer	--	**N/A**
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET	--	**N/A**
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage	--	**N/A**
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT	--	**N/A**
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	--	**N/A**
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES	--	**N/A**
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard	--	**N/A**
16.3	**Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements**	--	**N/A**
	Transient currents restricted to allowable levels for the specified IPS or UPS ..... :	--	**N/A**
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified	--	**N/A**
16.4	**Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)**	--	**N/A**
16.5	**Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed**	--	**N/A**
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V) ..... :	--	**N/A**
16.6	**LEAKAGE CURRENTS**		**N/A**
16.6.1	**TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA ..... :**	See appended Table 16.6.1	**N/A**
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR ..... :	See appended Table 16.6.1	**N/A**
16.6.2	**Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA ... :**	--	**N/A**
16.6.3	**PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values ..... :**	See appended Tables 8.7 8.7.4.7 and 16.6.1	**N/A**
16.7	**ME SYSTEM complied with applicable requirements of Clause 9 ..... :**	See applicable appended Tables in section 9	**N/A**
16.8	**Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**	--	**N/A**
16.9	**ME SYSTEM connections and wiring**		**N/A**
16.9.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result .....:**	--	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.__)	**N/A**
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results	--	**N/A**
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable	--	**N/A**
16.9.2	**MAINS PARTS, components and layout**	--	**N/A**
16.9.2.1	**a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or**	--	**N/A**
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or	--	**N/A**
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and	--	**N/A**
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or	--	**N/A**
	– marked to indicate the equipment or equipment parts it may safely be attached to	--	**N/A**
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT	--	**N/A**
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	--	**N/A**
	– CREEPAGE and CLEARANCES complied with 8.9	--	**N/A**
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets	--	**N/A**
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:	--	**N/A**
	– ENCLOSURE complied with 8.4.2 d)	--	**N/A**
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable	--	**N/A**
	– RATINGS of components are not in conflict with conditions of use ..... :	See appended Table 8.10	**N/A**
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL	--	**N/A**
	– POWER SUPPLY CORD complied with 8.11.3	--	**N/A**
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	--	**N/A**
	– Separating transformer complied with this standard or IEC 61558-2-1, ... :	See appended Table 8.10	**N/A**
	– Separating transformer is CLASS I	--	**N/A**
	– Degree of protection against ingress of water specified as in IEC 60529	--	**N/A**
	– Separating transformer assembly marked according to 7.2 and 7.3	--	**N/A**
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
16.9.2.2	**The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ**	--	**N/A**
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part	--	**N/A**
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	--	**N/A**
16.9.2.3	**Conductors connecting different items within an ME SYSTEM protected against mechanical damage**	--	**N/A**
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**P**
	RISKS associated confirmed by review .....:	EUT is medical power supply unit. Electromagnetic compatibility shall be evaluated during end medical product approval.	**P**
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS.....:	End product consideration.	**N/A**
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003) (Risk No.: 10) (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems	See IEC 60601-1-2 Report.	**P**
ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		**N/A**
G.2	**Locations and basic requirements**		**N/A**
G.2.1	**Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5**	EUT was not tested against hazard of ignition of flammable anaesthetic mixtures.	**N/A**
G.2.2	**FLAMMABLE AESTHETIC MIXTURE WITH**	--	**N/A**
G.2.3	**A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
G.2.4	**ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5**	--	**N/A**
G.2.5	**ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6**	--	**N/A**
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7	--	**N/A**
G.3	**Marking, ACCOMPANYING DOCUMENTS**		**N/A**
G.3.1	**CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1)..... :**	See copies of Marking Labels	**N/A**
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case	--	**N/A**
	When above marking not possible, relevant information included in instructions for use... :	--	**N/A**
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	--	**N/A**
G.3.2	**CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1)..... :**	See copies of Marking Labels	**N/A**
	Marking is as large as possible for the particular case	--	**N/A**
	When above marking not possible, the relevant information included in instructions for use... :	--	**N/A**
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	--	**N/A**
G.3.3	**The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts**	--	**N/A**
G.3.4	**ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts**	--	**N/A**
G.3.5	**Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG**	--	**N/A**
G.4	**Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT**		**N/A**
G.4.1	**a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION**	--	**N/A**
	b) Connections protected against accidental disconnection	--	**N/A**
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,	--	**N/A**
G.4.2	**Construction details**		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL	--	**N/A**
	b) ENCLOSURE complies with .....:	See appended Table 8.10	**N/A**
	– no openings on top covers of ENCLOSURE,	--	**N/A**
	– openings in side-covers prevented penetration of a solid cylindrical test rod	--	**N/A**
	– openings in base plates prevented penetration of a solid cylindrical test	--	**N/A**
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION	--	**N/A**
G.4.3	**a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures**	--	**N/A**
	– Use of antistatic materials with a limited electrical resistance.....:	See appended Table 8.10	**N/A**
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor	--	**N/A**
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882 .....:	--	**N/A**
G.4.4	**Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5**	--	**N/A**
G.5	**Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components**		**N/A**
G.5.1	**ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5**	--	**N/A**
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 .....:	--	**N/A**
G.5.2	**Temperature limits.....:**	See appended Tables 11.1.1 and 11.2.2.1	**N/A**
G.5.3	**ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1 ..... :	--	**N/A**
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ... :	--	**N/A**
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :	--	**N/A**
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :	--	**N/A**
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1	--	**N/A**
	No extrapolation made for voltages above 42 V	--	**N/A**
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2	--	**N/A**
	No extrapolation made for voltages above 242V	--	**N/A**
	U_{max} determined using actual resistance R	--	**N/A**
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3	--	**N/A**
	No extrapolation made for inductances larger than 900 mH	--	**N/A**
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open	--	**N/A**
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed	--	**N/A**
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks	--	**N/A**
	– Peak value considered when a.c. supplied	--	**N/A**
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit... :	--	**N/A**
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3 .. :	See appended Table 11.1.1	**N/A**
	Alternatively, compliance was verified by examination of design data .....:	--	**N/A**
G.5.4	**External ventilation with internal overpressure**		**N/A**
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,	--	**N/A**
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa) .....:	--	**N/A**
	Overpressure maintained at the site of potential ignition	--	**N/A**
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE	--	**N/A**
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present	--	**N/A**
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa).....:	--	**N/A**
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C.....:	--	**N/A**
G.5.5	**ENCLOSURES with restricted breathing**		**N/A**
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:	--	**N/A**
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing	--	**N/A**
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h.:	See appended Table 8.10	**N/A**
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained	--	**N/A**
	Cords are fitted with adequate anchorages to limit stresses as determined by test	--	**N/A**
	Overpressure not reduced below 200 Pa	--	**N/A**
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)	--	**N/A**
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C).....:	--	**N/A**
	Steady state operating temperature of ENCLOSURE also measured (°C).....:	--	**N/A**
G.6	**CATEGORY APG ME EQUIPMENT, parts and components thereof**		**N/A**
G.6.1	**ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION**	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test	--	**N/A**
G.6.2	**Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :**	--	**N/A**
G.6.3	**Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :**	--	**N/A**
	a) no sparks produced and temperatures did not exceed 90 °C, or	See Tables 11.1.1, 11.2.2.1 and 13.2	**N/A**
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:	See Tables 11.1.1 and 13.2	**N/A**
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 .... :	--	**N/A**
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5... :	--	**N/A**
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :	--	**N/A**
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :	--	**N/A**
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated	--	**N/A**
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10	--	**N/A**
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10	--	**N/A**
	– C_{max} and L_{max} are values occurring in relevant circuit	--	**N/A**
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω	--	**N/A**
	– Peak value considered when a.c. supplied	--	**N/A**
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components	--	**N/A**
	- requirement not applied to transformers complying with this standard	--	**N/A**
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture	--	**N/A**
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or	--	**N/A**
	Temperature measurements made in accordance with 11.1 .....:	See Table 11.1.1	**N/A**
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6.....:	--	**N/A**
	Alternatively, compliance verified by comparison with design data .....:	--	**N/A**
G.6.4	**ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 .....:**	See appended Table 8.10	**N/A**
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	--	**N/A**
G.7	**Test apparatus for flammable mixtures according to this Clause and Fig G.7**	--	**N/A**

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		**N/A**
L.1	**BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex**	--	**N/A**
L.2	**Wire construction**		**N/A**
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component	--	**N/A**
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap	--	**N/A**
L.3	**Type Test**		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	--	**N/A**
	Temperature (°C) ..... :	--	**—**
	Humidity (%)..... :	--	**—**
L.3.1	**Dielectric strength**		**N/A**
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:	--	**N/A**
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	--	**N/A**
	– 6000 V for REINFORCED INSULATION (V) ..... :	--	**N/A**
L.3.2	**Flexibility and adherence**		**N/A**
	Sample subjected to flexibility and adherence	--	**N/A**
	Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown	--	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:	--	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	--	**N/A**
	– 3000 V for REINFORCED INSULATION (V) ..... :	--	**N/A**
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :	--	**N/A**
L.3.3	**Heat Shock**		**N/A**
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3	--	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	--	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	--	**N/A**
	– 3000 V for REINFORCED INSULATION (V) ..... :	--	**N/A**
	Oven temperature based on Table L.2 (°C)..... :	--	**—**
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2)..... :	--	**N/A**
	Dielectric strength test conducted at room temperature after removal from the oven	--	**N/A**
L.3.4	**Retention of electric strength after bending**		**N/A**
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	--	**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :	--	**N/A**
	– 3000 V for REINFORCED INSULATION (V)..... :	--	**N/A**
	Test voltage applied between the shot and conductor	--	**N/A**
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2)..... :	--	**N/A**
L.4	**Tests during manufacture**		**N/A**
L.4.1	**Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3 ..... :**	--	**N/A**
L.4.2	**Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:**	--	**N/A**
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V) ..... :	--	**N/A**
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :	--	**N/A**
L.4.3	**Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)..... :**	--	**N/A**
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:	--	**N/A**
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION ..... :	--	**N/A**
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION..... :	--	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.1	Risk management process	—	Risk Management Process (excluding production and post-production) Procedure describing the risk management process Procedure: GTQPR05000: Risk management procedure	P
3.2	Risk management process	—	Adequate Resources Top management has defined and established a system method to do the risk management. Procedure: GTQPR05000: Risk management procedure	P
3.2	Risk management process	—	Assignment of qualified personnel Top management has defined and established a system method to do the risk management. Procedure: GTQPR05000: Risk management procedure	P
3.2	Risk management process	—	Policy for determining criteria for risk acceptability Top management has defined and established a system method to do the risk management. Procedure: GTQPR05000: Risk management procedure	P
3.3	—	Risk management plan for device GTM3T41-12-150R-3	Qualification of personnel The risk management team has been trained and qualified.	P
3.4a	—	Risk management plan for device GTM3T41-12-150R-3	- Procedure for plan development - Description of the device - Verification plan - Allocation of responsibilities - Summary of review activities - Evidence of risk acceptability criteria	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.4b	—	Risk management plan for device GTM3T41-12-150R-3	- Procedure for plan development - Description of the device - Verification plan - Allocation of responsibilities - Summary of review activities - Evidence of risk acceptability criteria	P
3.4c	—	Risk management plan for device GTM3T41-12-150R-3	- Procedure for plan development - Description of the device - Verification plan - Allocation of responsibilities - Summary of review activities - Evidence of risk acceptability criteria	P
3.4d	—	Risk management plan for device GTM3T41-12-150R-3	- Procedure for plan development - Description of the device - Verification plan - Allocation of responsibilities - Summary of review activities - Evidence of risk acceptability criteria	P
3.4e	—	Risk management plan for device GTM3T41-12-150R-3	- Procedure for plan development - Description of the device - Verification plan - Allocation of responsibilities - Summary of review activities - Evidence of risk acceptability criteria	P
3.5	—	Evidence of file structure for all risk management activities	Risk management report Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
4.1	—	Procedure for risk analysis	Procedure: GTQPR05000: Risk management procedure Risk management plan for device GTM3T41-12-150R-3	P
4.2	—	Record of safety issue analysis	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
4.3	—	Record of hazard analysis	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
4.4	—	- Definition of methods used for estimating risks Description of method(s) used Record of risk estimation activities	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
5	—	Record of risk evaluation activities Method(s) for dealing with non-quantifiable risks	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
6.2	—	Record of risk control option analysis (including risk-benefit analysis, if appropriate)	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
6.3	—	Design inputs from risk management activities	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
6.4	—	Evidence, e.g. from design verification activities	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
6.5	—	See 6.2	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
6.6a	—	Record of review of all risk controls for impact on new hazards	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
6.6b	—	Risk management plan GT-RMPLAN2018-003	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
6.7	—	Risk management plan GT-RMPLAN2018-003	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
7	—	Procedure for generating a risk management report Summary of risk management activities Traceability of hazards to residual risks Clearances	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P
8	—	Procedure for linking information into risk management review a) Manufacturing b) CAPA c) Servicing d) Purchasing Records implementing procedures	Risk analysis, risk assessment and Risk control according to ISO 14971:2007 (GT-RM2018-003)	P

Supplementary Information:

Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.

4.3	TABLE: ESSENTIAL PERFORMANCE		N/A
List of ESSENTIAL PERFORMANCE functions	**MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)**	**Remarks**	

Supplementary Information:

ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.

No essential performance defined by the manufacturer. End medical product approval.

4.11	TABLE: Power Input				P
Operating Conditions / Ratings	**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W or VA)**	**Power factor (cos φ)**
Rated output load	207	50	22,5	3,3	--
Rated output load	230	50	28,9	3,9	--

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Clause	Requirement + Test	Result - Remark	Verdict

4.11	TABLE: Power Input					P
Operating Conditions / Ratings		**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W or VA)**	**Power factor (cos φ)**
Rated output load		253	50	49,9	4,1	--

Supplementary Information:

Rated input voltage: 230 Vac

Rated supply frequency: 50Hz

Rated input current: 34 mA

See copy of marking plate for details.

5.9.2	TABLE: Determination of ACCESSIBLE parts	P
Location	**Determination method (NOTE1)**	**Comments**
Power supply enclosure	Visual	Live parts not accessible. Enclosure without openings provided to cover all live parts. No doubts; therefore only visual inspection performed.

Supplementary information:

[1)] NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.

7.1.2	TABLE: Legibility of Marking	P
Markings tested	**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2) ..... :	950 lx	Marking plate
Inside Markings (Clause 7.3) ..... :	--	No markings to be read inside
Controls & Instruments (Clause 7.4) ..... :	--	No controls & instruments
Safety Signs (Clause 7.5)..... :	--	No safety signs
Symbols (Clause 7.6) ..... :	950 lx	Present on Marking plate

Supplementary information:

Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			**Remarks**
Material of Marking Label .....:		Ink-print method.	Pass

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Clause	Requirement + Test	Result - Remark	Verdict

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			**Remarks**
Ink/other printing material or process ..... :		Ink-print method.	Pass
Material (composition) of Warning Label ..... :		--	N/A
Ink/other printing material or process ..... :		--	N/A
Other..... :		--	N/A
Marking Label Tested:			**Remarks**

Supplementary information:

Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

Marking provided on the outer side of the PSU. See copy of marking plate and enclosed pictures of the unit for details.

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					P
Test supply voltage/frequency (V/Hz)[1] ..... :						230 Vac / 50 Hz
Location From/To	**Measured values**					**Remarks**
	Vrms	**Vpk or Vdc**	**Peak-to-peak ripple[2]**	**Power W/VA**	**Energy (J)**	
Measured between output minus and output plus	--	11,94 Vdc	--	17,0 VA	--	Maximum output current achieved: 1,423 A

Supplementary Information:

[1] The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.
[2]. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

8.4.3	TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply	N/A
Maximum allowable voltage (V) ..... :		**60**

Voltage measured (V)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--

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Clause	Requirement + Test	Result - Remark	Verdict

Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--
Maximum allowable stored charge when measured voltage exceeded 60 v (μc) .....:	**45**									
Calculated stored charge (μc)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--
Supplementary information: /										

8.4.4	**TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT**	**N/A**
Maximum allowable residual voltage (V) .....:	**60 V**	
Maximum allowable stored charge when residual voltage exceeded 60 V .....:	**45 μC**	

Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	**Measured residual voltage (V)**	**Calculated stored charge (μC)**	**Remarks**
Supplementary information: /			

8.5.5.1a	**TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies**				**N/A**
Test Condition: Figs. 9 & 10	**Measurement made on accessible part**	**Applied part with test voltage**	**Test voltage polarity**	**Measured voltage between Y1 and Y2 (mV)**	**Remarks**
Supplementary information: /					

8.5.5.1b	**TABLE: defibrillation-proof applied parts – verification of recovery time**			**N/A**
Applied part with test voltage	**Test voltage polarity**	**Recovery time from documents (s)**	**Measured recovery time (s)**	**Remarks**
Supplementary information: /				

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Clause	Requirement + Test	Result - Remark	Verdict

8.5.5.2	**TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load**	N/A

Test Voltage applied to	Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth			
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth			

Supplementary information:

For compliance: E1 must at least 90% of E2
E1= Measured energy delivered to 100 Ω with ME Equipment connected;
E2= Measured energy delivered to 100 Ω without ME equipment connected.

8.6.4	**TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS**	N/A

Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)

Supplementary information:

Permanently installed me equipment, impedance between protective earth terminal and a protectively earthed part - Limit 100 mΩMe equipment with an appliance inlet, impedance between earth pin in the appliance inlet and a protectively earthed part - Limit 100 mΩ
Me equipment with an appliance inlet, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a protectively earthed part - Limit 200 mΩ
Me equipment with a non-detachable power supply cord, impedance between the protective earth pin in the mains plug and a protectively earthed part - Limit 200 mΩ

8.7	**TABLE: leakage current**	P

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC

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Clause	Requirement + Test	Result - Remark	Verdict

Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
Normal condition, normal polarity, before humidity treatment	264	60	3,7	Measured on output
Normal condition, reverse polarity, before humidity treatment	264	60	3,8	Measured on output
Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	5,5	Measured on output
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	5,5	Measured on output
Normal condition, normal polarity, before humidity treatment	264	60	2,8	Measured on plastic enclosure (metal foil used).
Normal condition, reverse polarity, before humidity treatment	264	60	2,9	Measured on plastic enclosure (metal foil used).
Single fault condition (supply interruption), normal polarity, before humidity treatment	264	60	4,2	Measured on plastic enclosure (metal foil used).
Single fault condition (supply interruption), reverse polarity, before humidity treatment	264	60	4,2	Measured on plastic enclosure (metal foil used).
Normal condition, normal polarity, after humidity treatment	264	60	3,9	Measured on output
Normal condition, reverse polarity, after humidity treatment	264	60	4,2	Measured on output
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	6,2	Measured on output
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	6,0	Measured on output
Normal condition, normal polarity, after humidity treatment	264	60	2,9	Measured on plastic enclosure (metal foil used).
Normal condition, reverse polarity, after humidity treatment	264	60	3,1	Measured on plastic enclosure (metal foil used).
Single fault condition (supply interruption), normal polarity, after humidity treatment	264	60	4,4	Measured on plastic enclosure (metal foil used).
Single fault condition (supply interruption), reverse polarity, after humidity treatment	264	60	4,5	Measured on plastic enclosure (metal foil used).
Revision 1.0				
Frequency weighted				

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Clause	Requirement + Test	Result - Remark	Verdict

Normal condition, normal polarity, before humidity treatment	253	50	4,1	Measured on output +
Normal condition, reverse polarity, before humidity treatment	253	50	4,1	Measured on output +
Single fault condition (supply interruption), normal polarity, before humidity treatment	253	50	7,1	Measured on output +
Single fault condition (supply interruption), reverse polarity, before humidity treatment	253	50	7,1	Measured on output +
Normal condition, normal polarity, before humidity treatment	253	50	4,0	Measured on output -
Normal condition, reverse polarity, before humidity treatment	253	50	4,0	Measured on output -
Single fault condition (supply interruption), normal polarity, before humidity treatment	253	50	7,0	Measured on output -
Single fault condition (supply interruption), reverse polarity, before humidity treatment	253	50	7,1	Measured on output -
Normal condition, normal polarity, before humidity treatment	253	50	3,7	Measured on plastic enclosure (metal foil used)
Normal condition, reverse polarity, before humidity treatment	253	50	3,7	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), normal polarity, before humidity treatment	253	50	4,4	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), reverse polarity, before humidity treatment	253	50	4,4	Measured on plastic enclosure (metal foil used)
Normal condition, normal polarity, after humidity treatment	253	50	6,5	Measured on output +
Normal condition, reverse polarity, after humidity treatment	253	50	6,5	Measured on output +
Single fault condition (supply interruption), normal polarity, after humidity treatment	253	50	8,2	Measured on output +
Single fault condition (supply interruption), reverse polarity, after humidity treatment	253	50	8,2	Measured on output +
Normal condition, normal polarity, after humidity treatment	253	50	6,5	Measured on output -
Normal condition, reverse polarity, after humidity treatment	253	50	6,5	Measured on output -

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Clause	Requirement + Test	Result - Remark	Verdict

Single fault condition (supply interruption), normal polarity, after humidity treatment	253	50	8,4	Measured on output -
Single fault condition (supply interruption), reverse polarity, after humidity treatment	253	50	8,4	Measured on output -
Normal condition, normal polarity, after humidity treatment	253	50	3,8	Measured on plastic enclosure (metal foil used)
Normal condition, reverse polarity, after humidity treatment	253	50	3,8	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), normal polarity, after humidity treatment	253	50	4,3	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), reverse polarity, after humidity treatment	253	50	4,3	Measured on plastic enclosure (metal foil used)
Frequency weighted				
Normal condition, normal polarity, before humidity treatment	253	50	10,4	Measured on output +
Normal condition, reverse polarity, before humidity treatment	253	50	10,4	Measured on output +
Single fault condition (supply interruption), normal polarity, before humidity treatment	253	50	11,6	Measured on output +
Single fault condition (supply interruption), reverse polarity, before humidity treatment	253	50	11,7	Measured on output +
Normal condition, normal polarity, before humidity treatment	253	50	10,6	Measured on output -
Normal condition, reverse polarity, before humidity treatment	253	50	10,6	Measured on output -
Single fault condition (supply interruption), normal polarity, before humidity treatment	253	50	11,7	Measured on output -
Single fault condition (supply interruption), reverse polarity, before humidity treatment	253	50	11,7	Measured on output -
Normal condition, normal polarity, before humidity treatment	253	50	9,3	Measured on plastic enclosure (metal foil used)
Normal condition, reverse polarity, before humidity treatment	253	50	9,3	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), normal polarity, before humidity treatment	253	50	9,7	Measured on plastic enclosure (metal foil used)

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Clause	Requirement + Test	Result - Remark	Verdict

Single fault condition (supply interruption), reverse polarity, before humidity treatment	253	50	9,7	Measured on plastic enclosure (metal foil used)
Normal condition, normal polarity, after humidity treatment	253	50	16,3	Measured on output +
Normal condition, reverse polarity, after humidity treatment	253	50	16,3	Measured on output +
Single fault condition (supply interruption), normal polarity, after humidity treatment	253	50	17,3	Measured on output +
Single fault condition (supply interruption), reverse polarity, after humidity treatment	253	50	17,3	Measured on output +
Normal condition, normal polarity, after humidity treatment	253	50	17,3	Measured on output -
Normal condition, reverse polarity, after humidity treatment	253	50	17,3	Measured on output -
Single fault condition (supply interruption), normal polarity, after humidity treatment	253	50	19,0	Measured on output -
Single fault condition (supply interruption), reverse polarity, after humidity treatment	253	50	19,0	Measured on output -
Normal condition, normal polarity, after humidity treatment	253	50	17,3	Measured on plastic enclosure (metal foil used)
Normal condition, reverse polarity, after humidity treatment	253	50	17,3	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), normal polarity, after humidity treatment	253	50	19,0	Measured on plastic enclosure (metal foil used)
Single fault condition (supply interruption), reverse polarity, after humidity treatment	253	50	19,0	Measured on plastic enclosure (metal foil used)
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA

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Clause	Requirement + Test	Result - Remark	Verdict

Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA

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Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current	A - After humidity conditioning
TC – Touch current	B - Before humidity conditioning
P - Patient leakage current	1 - Switch closed or set to normal polarity
PA – Patient auxiliary current	0 - Switch open or set to reversed polarity
TP – Total Patient current	NC - Normal condition
PM - Patient leakage current with mains on the applied parts	SFC - Single fault condition
MD - Measuring device	

8.8.3	**TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)**	**P**

Insulation under test (area from insulation diagram)	**Insulation Type (1 or 2 MOOP/MOPP)**	**Reference Voltage**		**A.C. test voltages in V r.m.s[1)]**	**Dielectric breakdown after 1 minute Yes/No[2)]**
		PEAK WORKING VOLTAGE (U) V peak	**PEAK WORKING VOLTAGE (U) V d.c.**		
Area C (primary to plastic enclosure (metal foil used)	2 x MOOP	330 V peak	--	3000 Vac	No
Area D (primary to secondary)	2 x MOOP	330 V peak	--	3000 Vac	No
Area D (primary to secondary – mains transformer)	2 x MOOP	330 V peak	--	3000 Vac	No
Revision 1.0					
Area C (primary to plastic enclosure (metal foil used)	2x MOOP	330 V peak	--	3000 Vac	No

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Area D (primary to secondary)	2x MOOP	330 V_{peak}	--	3000 Vac	No
Area D (primary to secondary – mains transformer)	2x MOOP	330 V_{peak}	--	3000 Vac	No

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.
[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

8.8.4.1	**TABLE: Resistance to heat - Ball pressure test of thermoplastic parts**		**P**
	Allowed impression diameter (mm) ..... :	≤ 2 mm	—
	Force (N) ..... :	20	—

Part/material	**Test temperature (°C)**	**Impression diameter (mm)**
Enclosure/External insulating parts		
Plastic enclosure	75	1,2 mm
Insulating material supporting un-insulated Mains Parts		
Transformer bobbin Manufacturer EI Dupont Model PA66 (Zytel 101FNC010)	125	1,4 mm
Supplementary information: /		

8.9.2	**TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4**	**N/A**

Specific areas of circuits short-circuited and test conditions	**Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1)]**	**HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No**	**Remarks**

Supplementary information:

[1)] Note: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

8.9.3.2	**Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**			**N/A**
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts			N/A
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**
	68 h at T1 ± 2 °C = ___°C [1)]			
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			

Supplementary information:

[1)] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

8.9.3.3	Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)			N/A
Part tested	**Sample**	**Each test duration and temperature**	**Dielectric test voltage**	**Dielectric strength test Breakdown: Yes/No**
	1	10 Cycles conducted of the following:		
		1 - 68 h at T1 ± 2 °C = ___°C[1]		
		2 - 1 h at 25 °C ± 2 °C		
		3 - 2 h at 0 °C ± 2 °C		
		4 - 1 or more h at 25 °C ± 2 °C		
	2	Humidity Conditioning per 5.7		
	3	Humidity Conditioning per 5.7		

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Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.3	Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)				N/A
Part tested	**Sample**	**Each test duration and temperature**	**Dielectric test voltage**	**Dielectric strength test Breakdown: Yes/No**	
Supplementary information: [1)] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.					

8.10	TABLE: List of critical components				P
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity[1)]**
Enclosure (Electrical, Fire)	Plastic, overall 73,5 x 52 mm x 40,5 mm (without pins) Min. thickness: 2,3 mm Top and bottom parts are fixed together with 4 screws. Dimensions of the mains plug complying with the requirements of EN 50075.			IEC/EN 60601-1	Checked with appliance.
Plastic Enclosure material	CHI MEI Corporation	PA-765	V-0 at minimum thickness 1,5 mm 80°C	IEC/EN 60601-1 (QMFZ2)	Checked with appliance. UL E56070
Plastic Enclosure material (alternative)	CHI MEI Corporation	PA-765A	V-0 at minimum thickness 2,1 mm 80°C	IEC/EN 60601-1 (QMFZ2)	Checked with appliance. UL E56070
PCB	TECHNI Technology Ltd.	T2-A	Min. 130°C V-0 Dim.: 40 x 22 mm Min. thickness: 1,6 mm	IEC/EN 60601-1 (ZPMV2)	Checked with appliance. UL E154355
Primary fuse (Fuse 2, 3)	WALTER ELECTRONIC Co., Ltd.	TAP	3,6 x 10 mm 0,3 A / 250 Vac	IEC/EN 60601-1 (JDYX)	Checked with appliance. UL E56092
U-shape	Aluminium Length: 40,5 x 28,0 x 28,0 Width: 16,8 mm Min. thickness: 2,2 mm			IEC/EN 60601-1	Checked with appliance.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Electrolytic capacitor (EC1)	Various	Various	2200 µF Min. 105°C Min. 25 V	IEC/EN 60601-1	Checked with appliance
Electrolytic capacitor (EC2)	Various	Various	10 µF Min. 105°C Min. 16 V	IEC/EN 60601-1	Checked with appliance
Voltage regulator (IC)	Various	Various	7812 12 Vdc output voltage	IEC/EN 60601-1	Checked with appliance
Primary wires	Sheng Yu	Style 1015	Min. 600 V Min. 105°C 22 AWG	IEC/EN 60601-1 (AVLV2)	Checked with appliance UL E219726
Transformer	Open type construction Separated primary and secondary with addition partition wall (DTI: 0,71 mm minimum). IRON laminated EI core (Size: 41 x 33 x 21 mm). Transformer core considered as secondary.			IEC/EN 60601-1	Checked with appliance
Thermal cut-out	AUPO Electronics Ltd.	A4-F	Cut-out temperature: 130°C 2 A / 250 Vac	IEC/EN 60601-1 (XCMQ2)	VDE 40005418 UL E140847
Insulation tape	+ Jingjiang Yahua Pressure Sensitive Glue Co., Ltd.	+ CT	Min. 130°C	IEC/EN 60601-1 (OANZ2)	Checked with appliance UL E165111
Transformer bobbin	EI Dupont	PA66 (Zytel 101FNC010)	Min. V-2 0,71 mm minimum thickness Min. 130°C	IEC/EN 60601-1 (QMFZ2)	Checked with appliance UL E41938
Output cable (polarized output) (Interchangeable)	Sheng Yu	VW-1	Min. 300 V Min. 80°C 22 AWG	IEC/EN 60601-1 (AVLV2)	Checked with appliance UL E219726
Supplementary information: 1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

8.10 b	**TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS**				**N/A**
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity[1)]**

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Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

8.11.3.5	**TABLE: Cord anchorages**			**N/A**
Cord under test	**Mass of equipment (kg)**	**Pull (N)**	**Torque Nm)**	**Remarks**

Supplementary information: /

8.11.3.6	**TABLE: Cord guard**		**N/A**
Cord under test	**Test mass**	**Measured curvature**	**Remarks**

Supplementary information: /

9.2.2.2	**TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)**			**N/A**
Part of body	**Allowable adult gap[1)], mm**	**Measured adult gap, mm**	**Allowable children gap[1)], mm**	**Measured children gap, mm**
Body	> 500		> 500	
Head	> 300 or < 120		> 300 or < 60	
Leg	> 180		> 180	
Foot	> 120 or < 35		> 120 or < 25	
Toes	> 50		> 50	
Arm	> 120		> 120	
Hand, wrist, fist	> 100		> 100	
Finger	> 25 or < 8		> 25 or < 4	

Supplementary information:

[1)] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.

9.2.3.2	**TABLE: Over-travel End Stop Test**	**N/A**
ME EQUIPMENT end stop	**Test Condition (cycles, load, speed)**	**Remarks**

Supplementary information: /

9.4.2.1	**TABLE: Instability—overbalance in transport position**	**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict

ME EQUIPMENT preparation	Test Condition (transport position)	Remarks
Supplementary information: /		

9.4.2.2	TABLE: Instability—overbalance excluding transport position		N/A
ME EQUIPMENT preparation	**Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)**	**Remarks**	
Supplementary information: /			

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces		N/A
ME EQUIPMENT preparation	**Test Condition (force used, direction of force, weight of equipment, location of force)**	**Remarks**	
Supplementary information: /			

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion		N/A
ME EQUIPMENT preparation	**Test Condition (force location and height)**	**Remarks**	
Supplementary information: /			

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold		N/A
ME EQUIPMENT preparation	**Test Condition (speed of movement)**	**Remarks**	
Supplementary information: /			

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position		N/A
ME EQUIPMENT Preparation	**Test Condition (transport position, working load, locking device(s), caster position)**	**Remarks**	
Supplementary information: /			

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Clause	Requirement + Test	Result - Remark	Verdict

9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position	N/A

ME EQUIPMENT Preparation	Test Condition (working load, locking device(s), caster position, force, force location, force direction)	Remarks

Supplementary information: /

9.4.4	TABLE: Grips and other handling devices	N/A

Clause and Name of Test	Test Condition	Remarks

Supplementary information: /

9.7.5	TABLE: Pressure vessels	N/A

Hydraulic, Pneumatic or Suitable Media and Test Pressure	Vessel Burst	Permanent Deformation	Leaks	Vessel fluid substance	Remarks

Supplementary Information: /

9.8.3.2	TABLE: PATIENT support/suspension system - Static forces	N/A

ME EQUIPMENT part or area	Position	Load	Area	Remarks

Supplementary Information: /

9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons	N/A

ME EQUIPMENT part or area	Position	Safe Working Load	Area	Remarks

Supplementary Information: /

10.1.1	TABLE: Measurement of X - radiation	N/A

Maximum allowable radiation pA/kg (µSv/h) (mR/h)	36 (5 µSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description[1)]	Measured Radiation, pA/kg (µSv/h) (mR/h)	Remarks

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

[1)] Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access

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Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT					P
Model No. .....:		Model 1	Model 2	Model 3	Model 4	--
Test ambient (°C) .....:		27,7	28,3	40,0	40,0	--
Test supply voltage/frequency (V/Hz)[4] ..:		207/50	253/50	207/50	253/50	--

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Model 1	1	PCB	44,2	130	--
Model 1	2	PCB near to diode D1, D2	50,4	130	--
Model 1	3	Plastic enclosure top side	38,9	71 *)	--
Model 1	4	PCB near to linear regulator	45,9	130	--
Model 1	5	Transformer core	44,1	95	--
Model 1	6	Primary windings of the transformer	44,1	95	--
Model 1	7	Electrolytic capacitor EC2	44,1	105	--
Model 1	8	Secondary windings of the transformer	45,4	95	--
Model 1	9	Plastic enclosure inside	32,9	80	--
Model 1	10	Electrolytic capacitor EC1	44,1	105	--
Model 1	11	Plastic enclosure bottom side	34,8	71 *)	--
Model 2	1	PCB	61,6	130	--
Model 2	2	PCB near to diode D1, D2	66,1	130	--
Model 2	3	Plastic enclosure top side	48,4	71 *)	--
Model 2	4	PCB near to linear regulator	65,8	130	--
Model 2	5	Transformer core	62,3	95	--
Model 2	6	Primary windings of the transformer	65,0	95	--
Model 2	7	Electrolytic capacitor EC2	59,7	105	--
Model 2	8	Secondary windings of the transformer	63,3	95	--
Model 2	9	Plastic enclosure inside	40,1	80	--
Model 2	10	Electrolytic capacitor EC1	60,9	105	--
Model 2	11	Plastic enclosure bottom side	41,4	71 *)	--
Model 3	1	PCB	56,5	130	--
Model 3	2	PCB near to diode D1, D2	62,7	130	--

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Clause	Requirement + Test	Result - Remark	Verdict

Model 3	3	Plastic enclosure top side	51,2	71 *)	--
Model 3	4	PCB near to linear regulator	58,2	130	--
Model 3	5	Transformer core	56,4	95	--
Model 3	6	Primary windings of the transformer	56,4	95	--
Model 3	7	Electrolytic capacitor EC2	56,4	105	--
Model 3	8	Secondary windings of the transformer	57,7	95	--
Model 3	9	Plastic enclosure inside	45,2	80	--
Model 3	10	Electrolytic capacitor EC1	56,4	105	--
Model 3	11	Plastic enclosure bottom side	47,1	71 *)	--
Model 4	1	PCB	73,3	130	--
Model 4	2	PCB near to diode D1, D2	77,8	130	--
Model 4	3	Plastic enclosure top side	60,1	71 *)	--
Model 4	4	PCB near to linear regulator	77,5	130	--
Model 4	5	Transformer core	74,0	95	--
Model 4	6	Primary windings of the transformer	76,7	95	--
Model 4	7	Electrolytic capacitor EC2	71,4	105	--
Model 4	8	Secondary windings of the transformer	75,0	95	--
Model 4	9	Plastic enclosure inside	51,8	80	--
Model 4	10	Electrolytic capacitor EC1	72,6	105	--
Model 4	11	Plastic enclosure bottom side	53,1	71 *)	--

Supplementary information:

1) Maximum allowable temperature on surfaces of test corner is 90 °C
2) Max temperature determined in accordance with 11.1.3e)
3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4) Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.

- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

5) **APPLIED PARTS** intended to supply heat to a **PATIENT - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Information from Risk Management, as applicable:

Output load: 12 Vdc / 150 mA (rated output load)

*) Duration of the contact of the external enclosure is assumed to be between 1 and 10 seconds (normal time needed for disconnecting direct plug-in adapter from the mains) for top side of the enclosure.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				P
Model No. .....:	Model 5	Model 6	--	--	--
Test ambient (°C) .....:	29,8	40,0	--	--	--
Test supply voltage/frequency (V/Hz)[4] ..:	230/50	230/50	--	--	--

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Model 5	1	PCB	54,7	130	--
Model 5	2	PCB near to diode D1, D2	60,0	130	--
Model 5	3	Plastic enclosure top side	45,1	71 *)	--
Model 5	4	PCB near to linear regulator	57,7	130	--
Model 5	5	Transformer core	54,8	95	--
Model 5	6	Primary windings of the transformer	55,0	95	--
Model 5	7	Electrolytic capacitor EC2	53,8	105	--
Model 5	8	Secondary windings of the transformer	56,0	95	--
Model 5	9	Plastic enclosure inside	38,0	80	--
Model 5	10	Electrolytic capacitor EC1	54,4	105	--
Model 5	11	Plastic enclosure bottom side	40,5	71 *)	--
Model 6	1	PCB	64,9	130	--
Model 6	2	PCB near to diode D1, D2	70,2	130	--
Model 6	3	Plastic enclosure top side	55,3	71 *)	--
Model 6	4	PCB near to linear regulator	67,9	130	--
Model 6	5	Transformer core	65,0	95	--
Model 6	6	Primary windings of the transformer	65,2	95	--
Model 6	7	Electrolytic capacitor EC2	64,0	105	--
Model 6	8	Secondary windings of the transformer	66,2	95	--
Model 6	9	Plastic enclosure inside	48,2	80	--
Model 6	10	Electrolytic capacitor EC1	64,6	105	--
Model 6	11	Plastic enclosure bottom side	50,7	71 *)	--

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Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

1) Maximum allowable temperature on surfaces of test corner is 90 °C

2) Max temperature determined in accordance with 11.1.3e)

3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

4) Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.

- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

5) **APPLIED PARTS** intended to supply heat to a **PATIENT - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Information from Risk Management, as applicable: Risk No.

Output load: 12 Vdc / 150 mA (rated output load)

*) Duration of the contact of the external enclosure is assumed to be between 1 and 10 seconds (normal time needed for disconnecting direct plug-in adapter from the mains) for top side of the enclosure.

11.1.3d	**TABLE: Temperature of windings by change-of-resistance method**						**P**
Temperature T of winding:	**t_1 (°C)**	**R_1 (Ω)**	**t_2 (°C)**	**R_2 (Ω)**	**T (°C)**	**Allowed T_{max} (°C)**	**Insulation class**
Supply voltage: 207 V~ / 50 Hz							
Primary windings	24,9	475,66 kΩ	24,4	509,70 kΩ	59,1 (Calculate to max. ambient 40°C)	105	Class A
Supply voltage: 230 V~ / 50 Hz							
Primary windings	24,9	475,66 kΩ	28,3	529,32 kΩ	65,9 (Calculate to max. ambient 40°C)	105	Class A
Supply voltage: 253 V~ / 50 Hz							
Primary windings	24,9	475,66 kΩ	25,7	546,60 kΩ	77,9 (Calculate to max. ambient 40°C)	105	Class A
Supplementary information: /							

11.2.2.1	**TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source**	**N/A**
Areas where sparking might cause ignition:		**Remarks**
1.		

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Clause	Requirement + Test	Result - Remark	Verdict

2.	
3.	
4.	
5.	
6.	
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):	**Remarks**
1.	
2.	
3.	
4.	
5.	
6.	

Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**
Oxygen concentration (%) ..... :		
Fuel ..... :		
Current (A) ..... :		
Voltage (V) ..... :		
Capacitance (μF) ..... :		
Inductance or resistance (h or Ω) ..... :		
No. of trials (300 Min) ..... :		
Sparks resulted in ignition (Yes/No) .... :		

Supplementary information:

Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.

Information from Risk Management, as applicable:

11.6.1	**TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances**	**N/A**

Clause / Test Name	**Test Condition**	**Part under test**	**Remarks**

Supplementary information:

Information from Risk Management, as applicable: N/A

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Clause	Requirement + Test	Result - Remark	Verdict

13.1.2	**TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances**	**N/A**
Power dissipated less than (W).....:	15	
Energy dissipated less than (J).....:	900	

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks

Supplementary information: /

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**		**P**
Clause No.	**Description of SINGLE FAULT CONDITION**	**Results observed**	**HAZARDOUS SITUATION (Yes/No)**
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:**	**—**	**—**
	1) Output overload Supply voltage: 253 Vac	After 14 minutes, thermal cut-out operated. No hazard. Measured temperatures: Primary windings: 119,2°C Secondary windings: 141,0°C Transformer core: 99,8°C Ambient: 23,8°C	NO
	2) Output short Supply voltage: 253 Vac	Duration: 2 hours No defect, no hazard. Measured temperatures: Primary windings: 116,9°C Secondary windings: 110,2°C Transformer core: 96,8°C Ambient: 25,6°C	NO
	3) Short circuit of capacitor EC1 Supply voltage: 240 Vac	Output voltage immediately dropped to 0 V. No hazard, no fire. Unit damaged. Measured temperatures: Primary windings: 82,3°C Secondary windings: 110,5°C Transformer core: 67,8°C Ambient: 24,8°C	NO

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Clause	Requirement + Test	Result - Remark	Verdict
	4) Short circuit of diode D2 Supply voltage: 240 Vac	After 2 minutes, output voltage dropped to 0 V. Thermal cut-out operated. No hazard, no fire. No high temperature rises observed.	NO
13.2.3	**Overheating of transformers per Clause 15.5:**	—	—
	Transformer short circuit test	Refer to Table 15.5.1.2 for details.	NO
	Transformer overload test	Refer to table 15.5.1.3 for details.	NO
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	—	—
13.2.5	**Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:**	—	—
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	—	—
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	—	—
	Single ventilation fans locked consecutively		
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		
13.2.8	**Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:**	—	—
13.2.9	**Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1)] – Also see 13.10**	—	—
		V measured =	
13.2.10	**Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:**	—	—

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time:		
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
13.2.11	**Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:**	**—**	**—**
13.2.12	**Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):**	**—**	**—**

Supplementary information:

1) Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

Information from Risk Management, as applicable: N/A

15.3	**TABLE: Mechanical Strength tests 1)**		**P**
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	Test performed on external parts of the enclosure. No damage of the enclosure, no cracks.
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	Test performed on top and sides of the enclosure (not performed on exchangeable plug). No damage of the enclosure, no cracks.
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1 meter	EUT is direct plug-in equipment. No damage of the enclosure, no cracks.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 71°C	Whole equipment placed into the circulating air oven for 7 hours. Maximum temperature measured on the enclosure during normal use of the equipment: 60,1°C. No damage of the enclosure.

Supplementary information:

1) As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).

15.4.6	**TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests**				**N/A**
Rotating control under test	**Gripping diameter "d" of control knob (mm)1)**	**Torque from Table 30 (Nm)**	**Axial force applied (N)**	**Unacceptable RISK occurred Yes/No**	**Remarks**

Supplementary information:

1) Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

15.5.1.2	**TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION**						**P**
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)1) ..... :					253 Vac		—
RATED input frequency (Hz) ..... :					50 Hz		—
Winding tested	**Class of insulation (A, B, E, F, or H)**	**Type of protective device (fuse, circuit breaker) /Ratings**	**Protective device operated Yes/No**	**Time to THERMAL STABILITY (when protective device did not operate)(Min)**	**Maximum allowed temp from Table 31 (ºC)**	**Maximum winding temp measured (ºC)**	**Ambient (ºC)**
Secondary windings	A	Thermal cut-out	Yes	N/A	150 See 1)	102,2°C (pri.) 148,0°C (sec.) See 1)	27,0
Primary windings	A	Primary fuses	Yes	N/A	See 2)	See 2)	--

Supplementary information:

1) Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

1) After 2 min 10 sec primary thermal cut-out operated.

2) Primary fuse opened immediately. No high temperature rises observed. No hazard.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.3	**TABLE: transformer overload test – conducted only when protective device under short-circuit test operated**	**P**
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1)] ..... :		253 Vac
RATED input frequency (Hz)..... :		50 Hz
Test current just below minimum current that would activate protective device and achieve THERMAL STABILITY under method a) (A)..... :		--
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A) ..... :		--

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
Secondary windings	A	Thermal cut-out	150	119,2 (pri.) 141,0 (sec.) See 1)	23,8

Supplementary information:

[1)] Loads on other windings between no load and their NORMAL USE load.
Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.
Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

1) Overload performed on the output to verify transformer overload. After 14 minutes, thermal cut-out opened.

15.5.2	**TABLE: Transformer dielectric strength after humidity preconditioning of 5.7**				**P**
Transformer Model/Type/ Part No	**Test voltage applied between**	**Test voltage, (V)**	**Test frequency (Hz)**	**Breakdown Yes/No**	**Deterioration Yes/No**
Mains transformer	Primary windings	1150 Vac	250	No	No
Mains transformer	Secondary windings	60 Vac	250	No	No

Supplementary information:

Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

16.6.1	**TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS**				**N/A**
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	**Allowable TOUCH CURRENT in NORMAL CONDITION (µA)**	**Measured TOUCH CURRENT in NORMAL CONDITION (µA)**	**Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)**	**Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)**	
	100		500		
	100		500		
	100		500		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

	100		500	
	100		500	
Supplementary information: /				

SP	**TABLE: Additional or special tests conducted**		**N/A**
Clause and Name of Test	**Test type and condition**	**Observed results**	
Supplementary information:			
No additional or special tests conducted.			

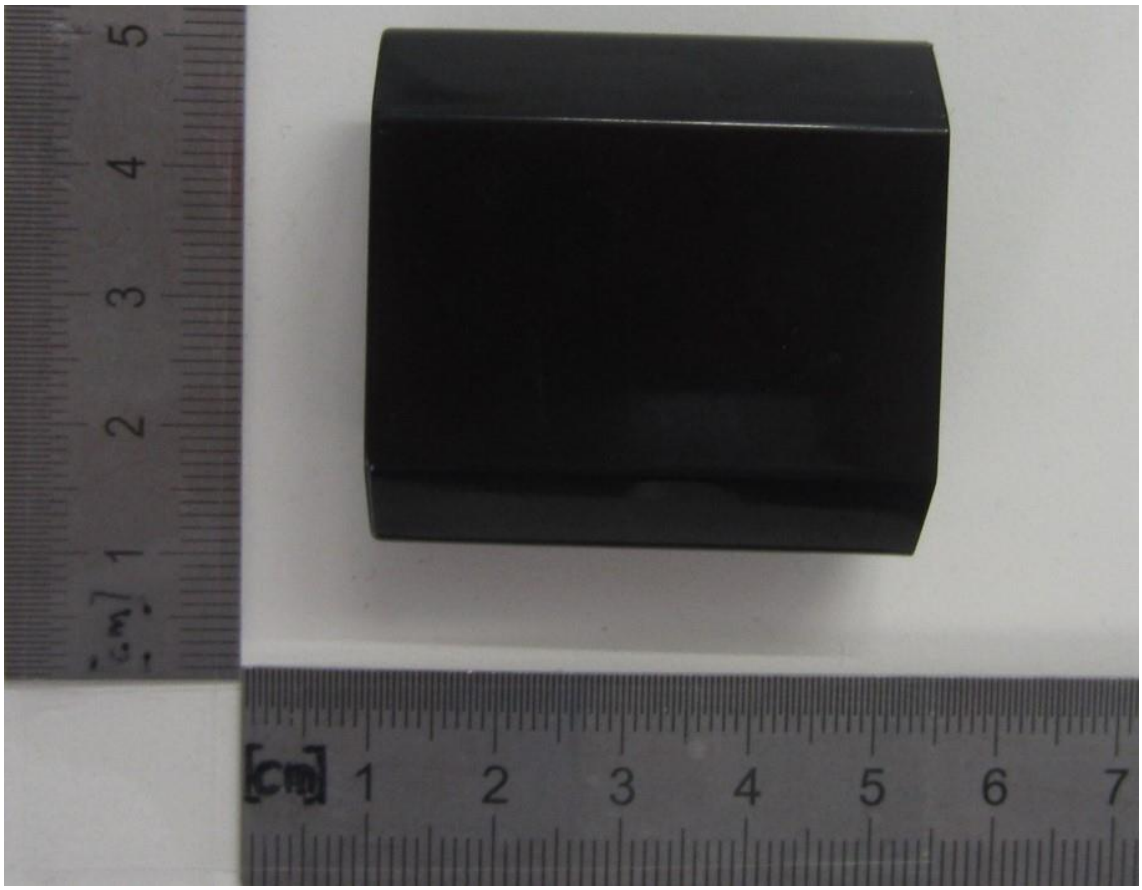
Enclosure No. 1

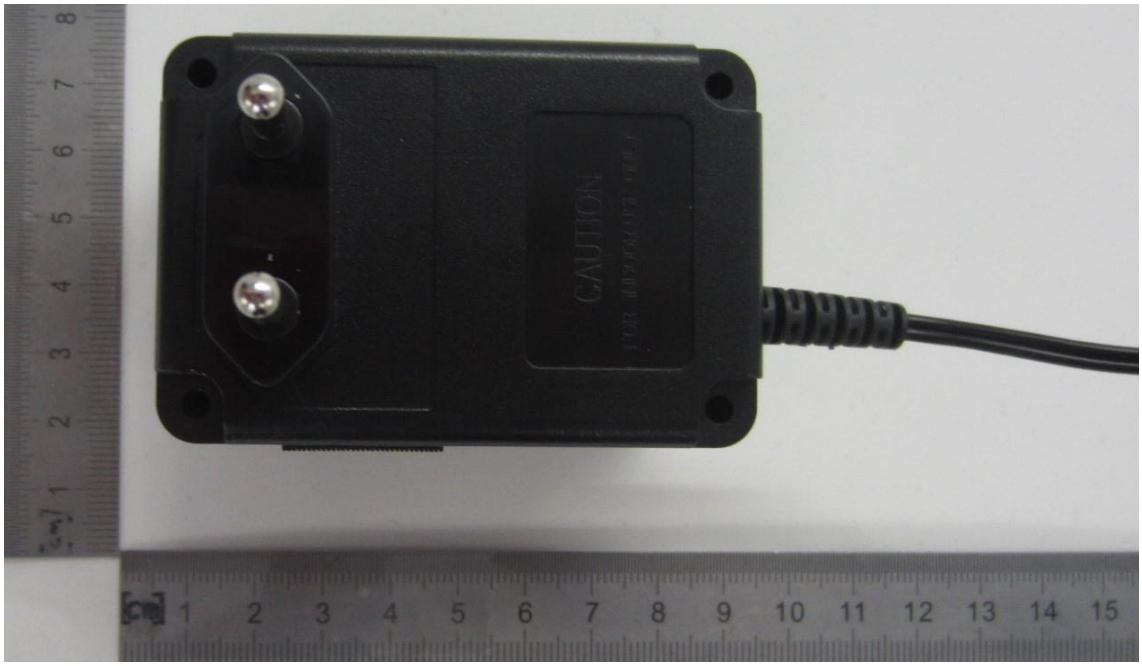
Photo documentation

(9 pages including this cover page)

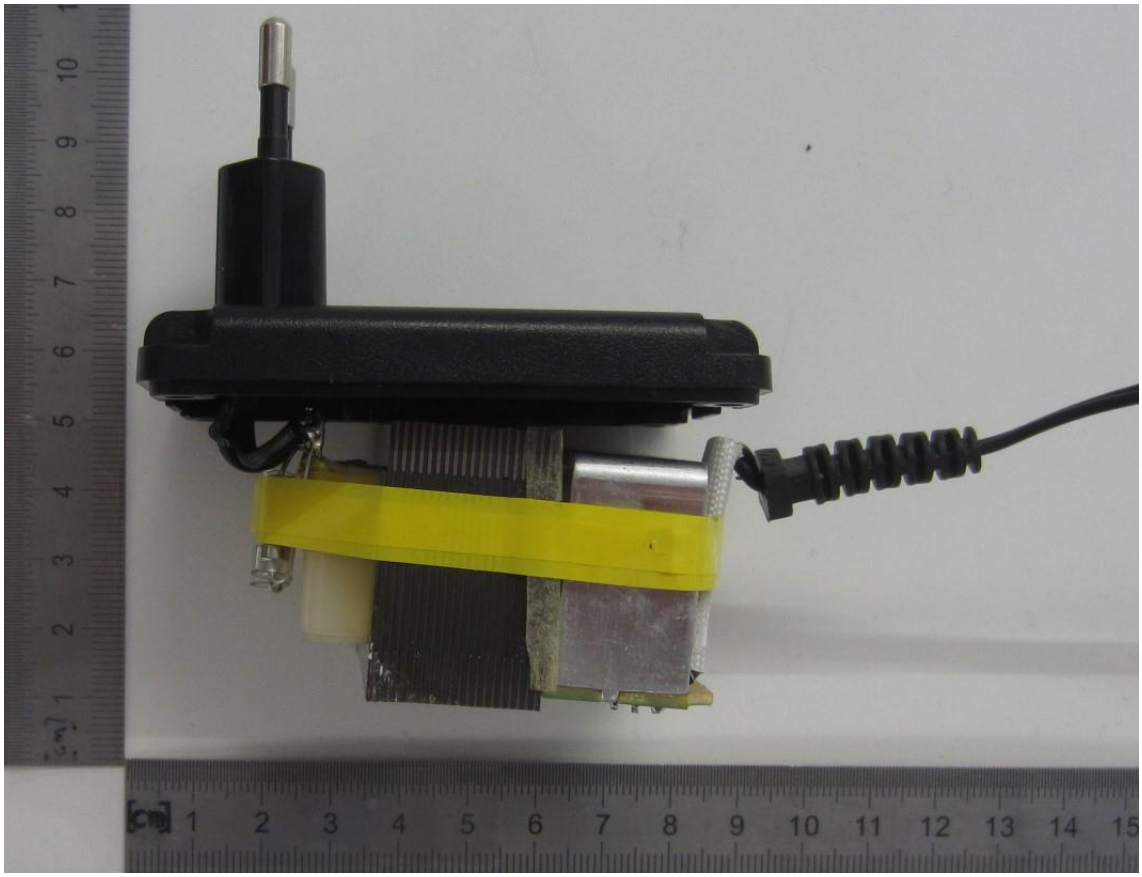
Outside

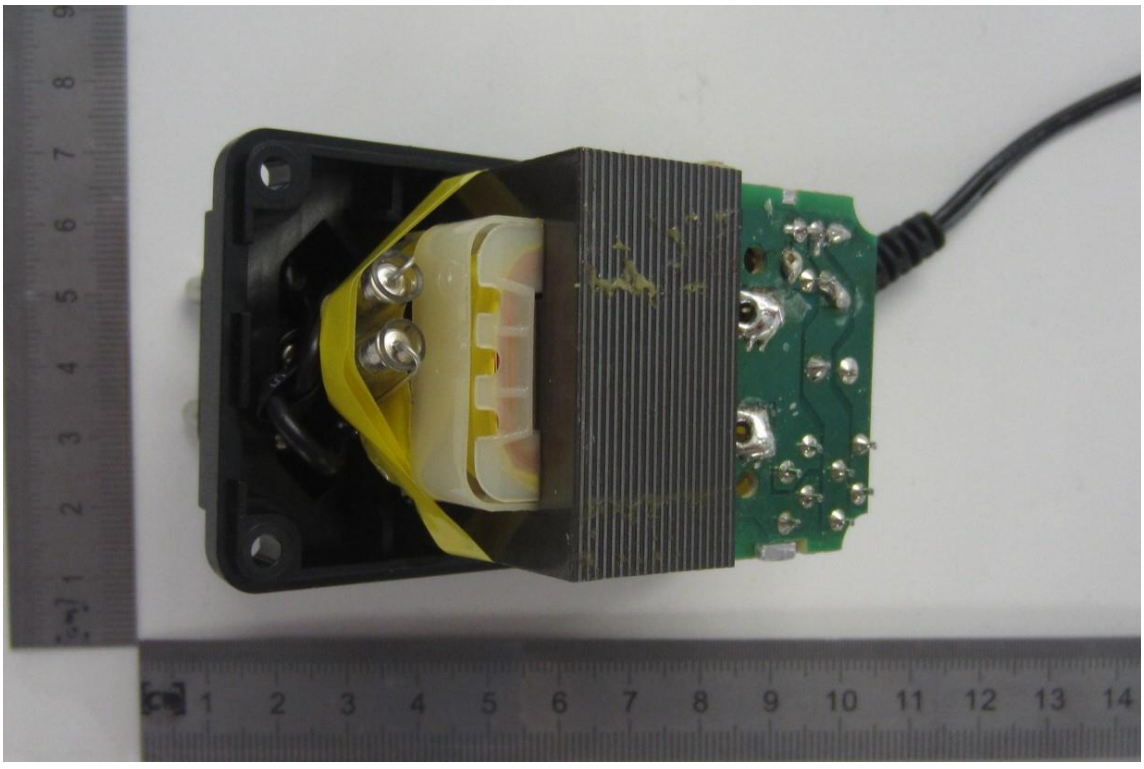

S20189845
seca

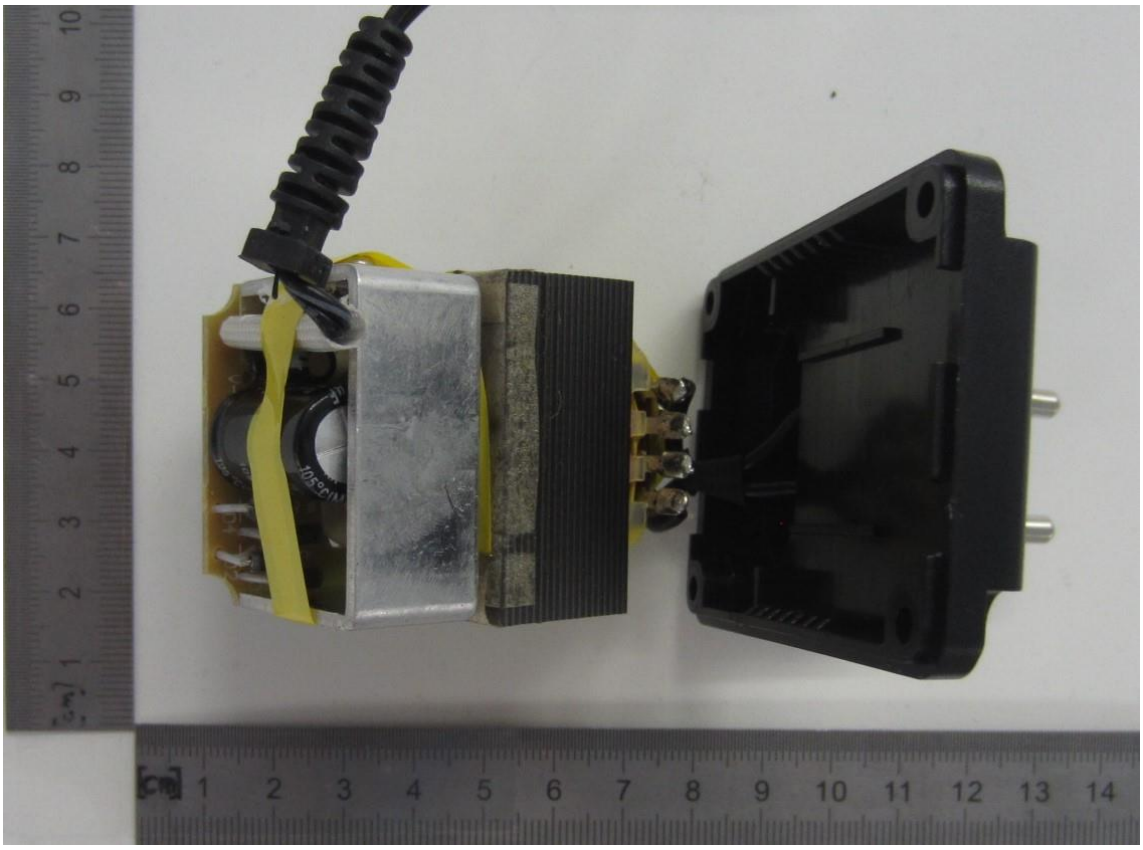


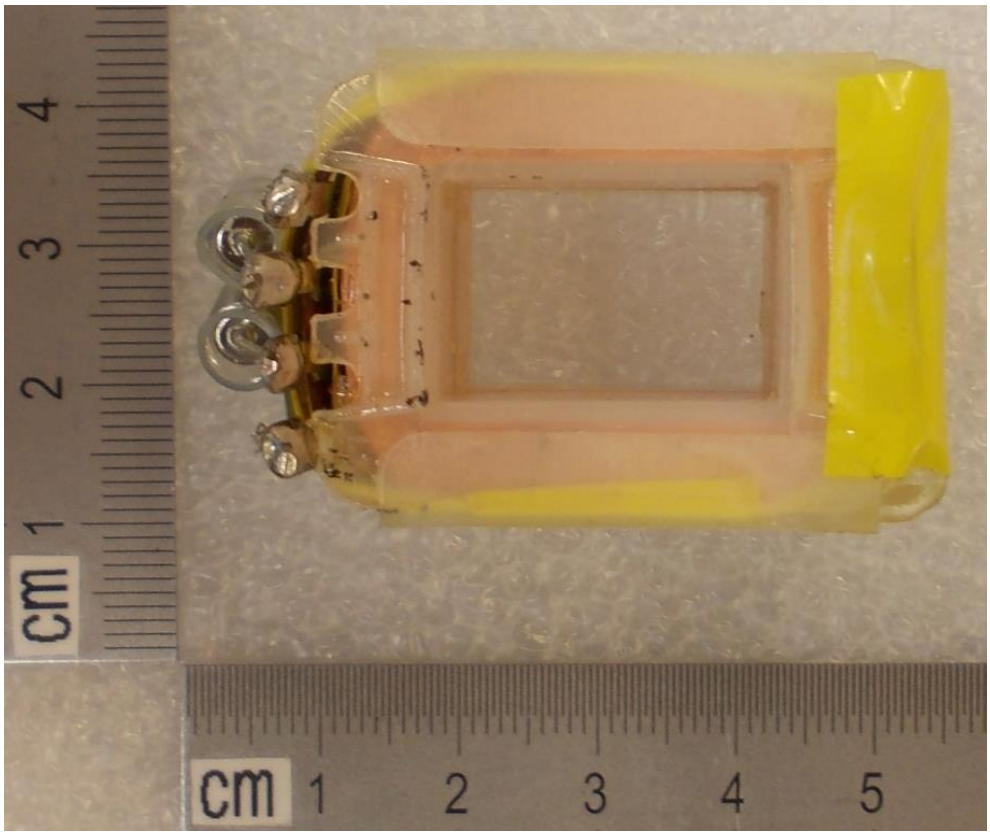

CAUTION

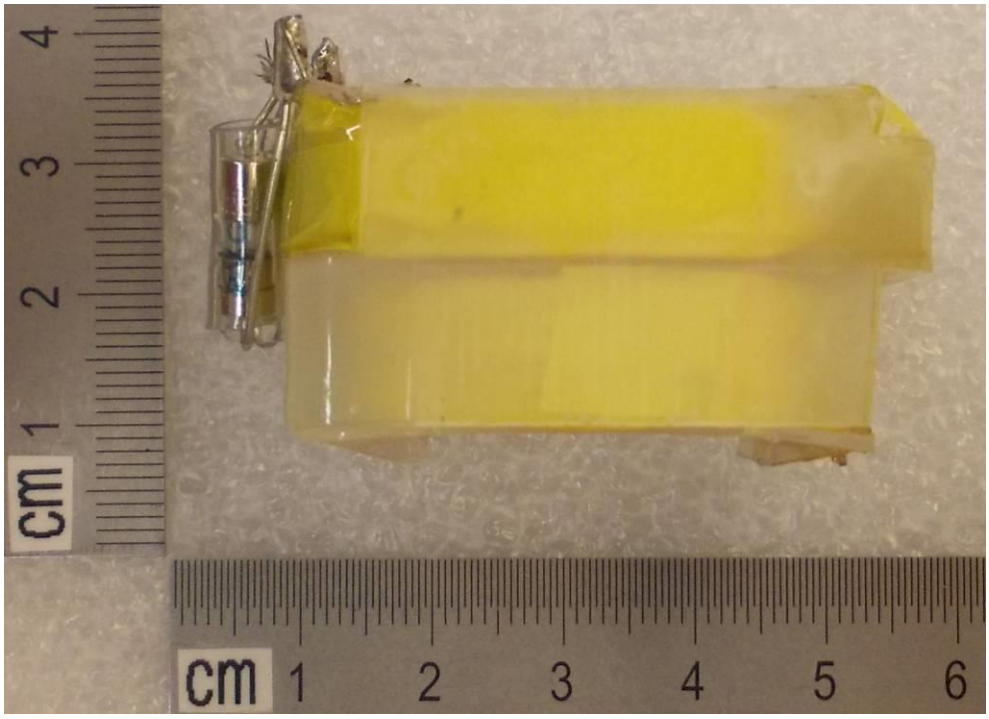
Inside








cm 1 2 3 4 5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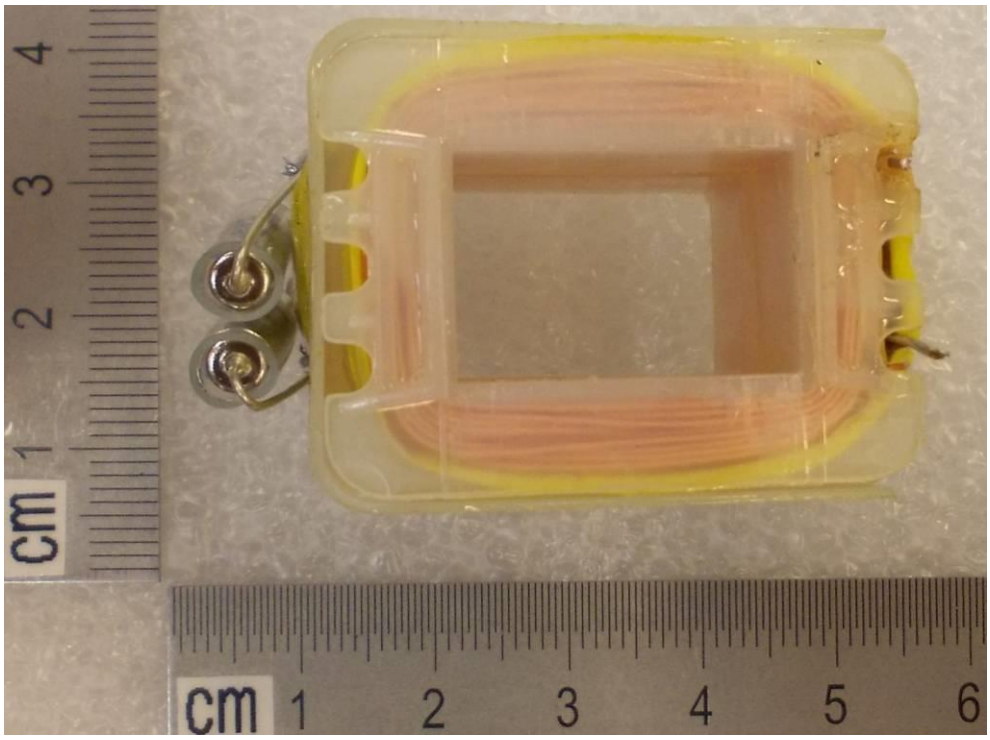
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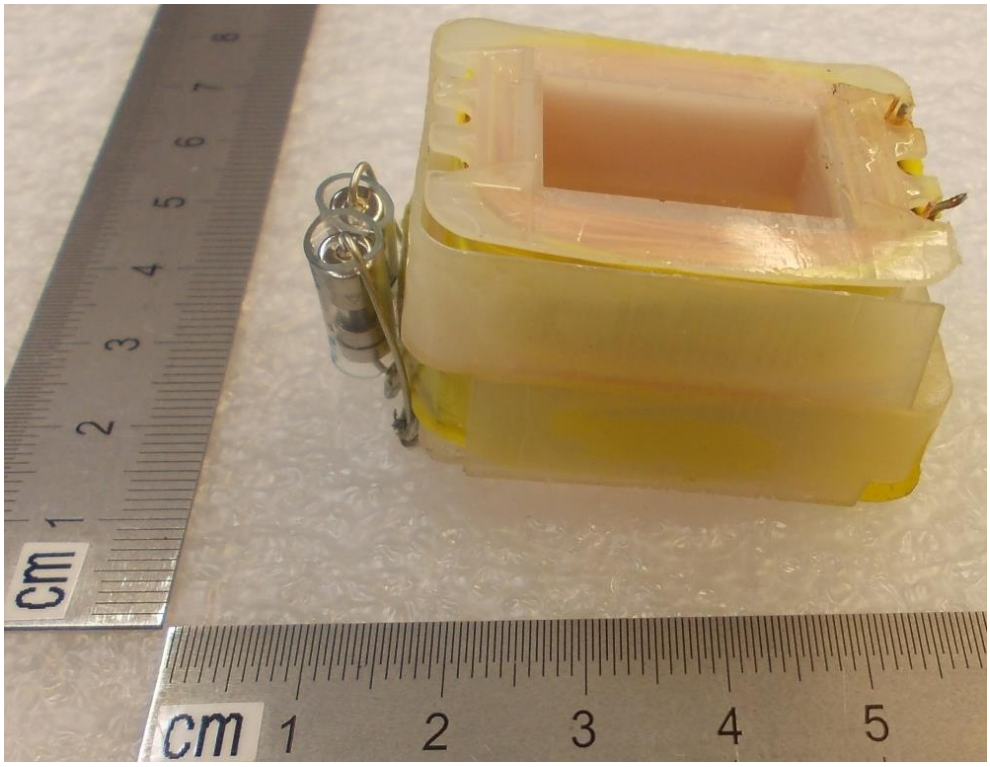
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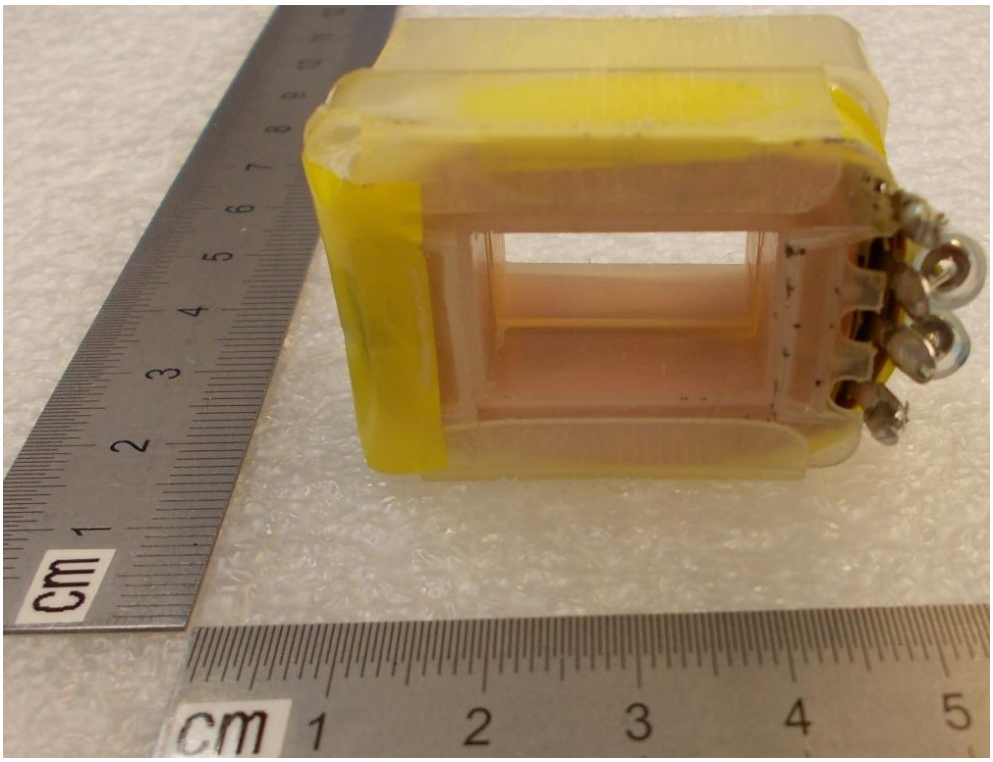
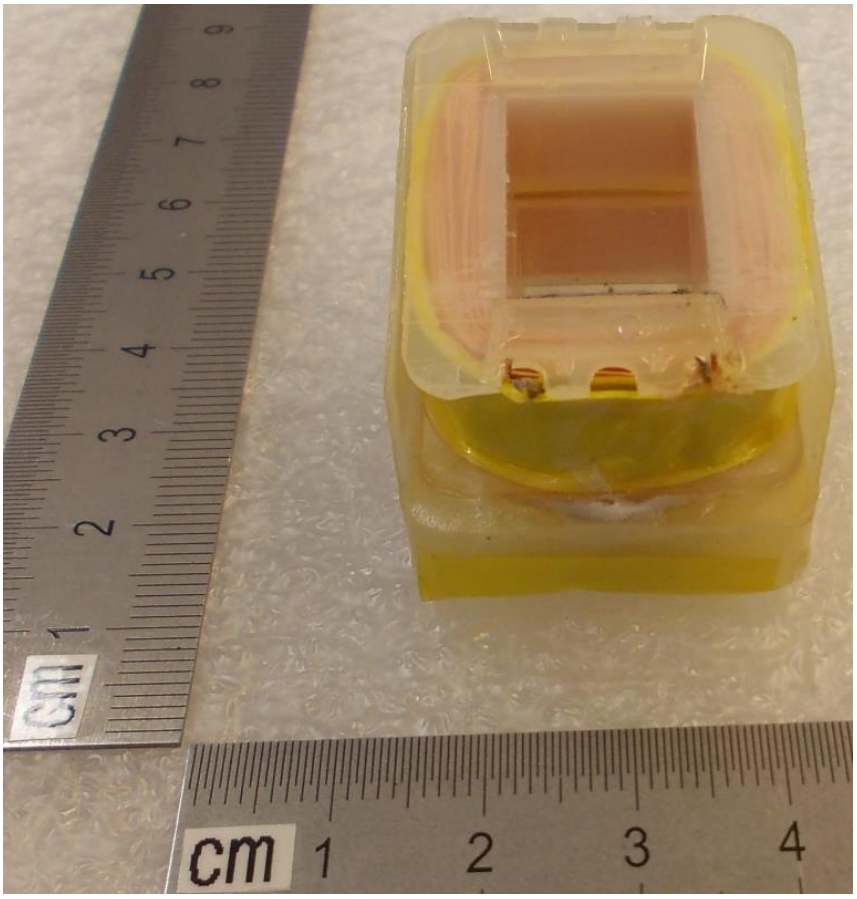
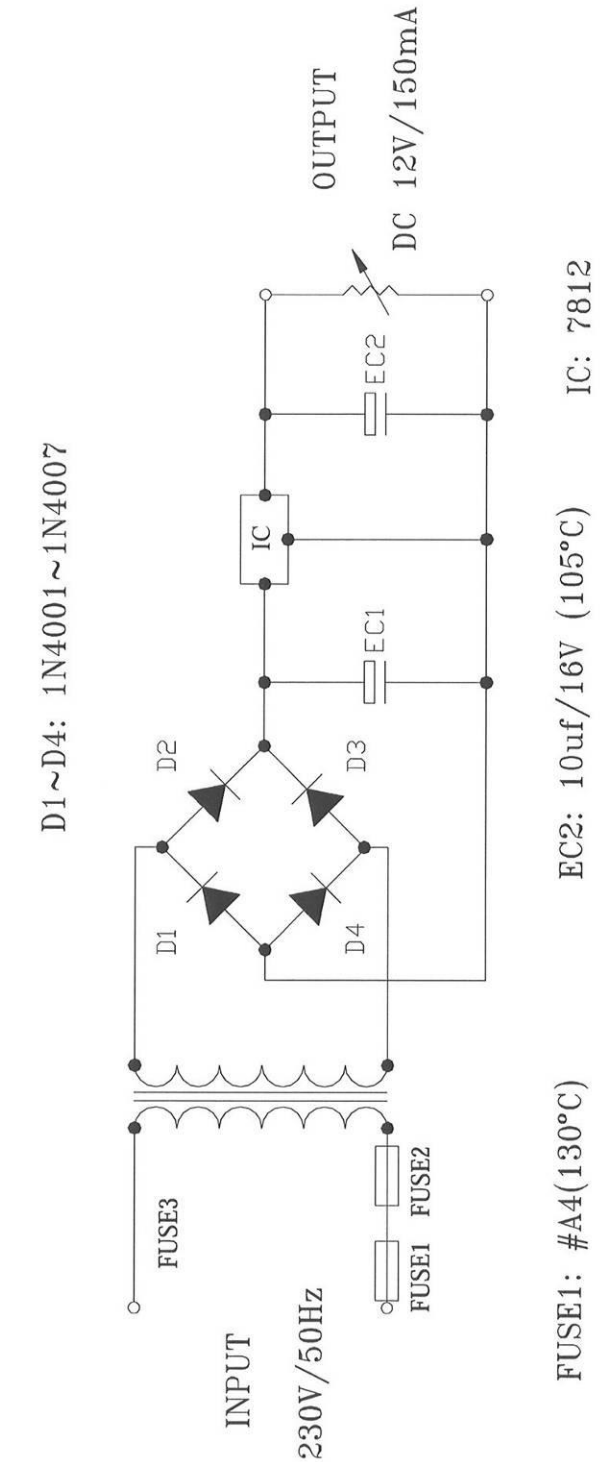

cm
1
2
3
4
5

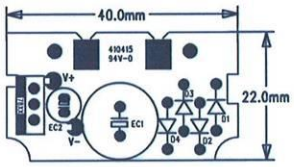

cm
1
2
3
4

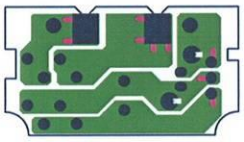
Enclosure No. 2

Schematics, layouts and documentation

(15 pages including this cover page)


D1~D4: 1N4001~1N4007
OUTPUT
DC 12V/150mA
EC2
IC
EC1
D2
D3
D1
D4
FUSE3
FUSE1 FUSE2
INPUT
230V/50Hz
FUSE1: #A4(130°C)
EC2: 10uf/16V (105°C)
IC: 7812
FUSE2/3: 0.3A/250V
f/25V (105°C) 200


40.0mm
22.0mm
V+
V-
EC1
EC2
D1
D2
D3
D4



CHIMEI
奇美實業股份有限公司
CHI MEI CORPORATION
59-1 SAN CHIA, JEN TE, TAINAN COUNTY, TAIWAN.
TEL: 886-6-266-5000 FAX: 886-6-266-5555~7

Flame Retardant ABS, POLYLAC® PA-765 *December 22, 2011 V1W*

Typical Characteristics

Properties	Test Method	Test Condition	Unit	PA-765
Tensile Strength	ASTM D638	1/8", 6 mm/min	$Kg/cm^2(lb/in^2)$	390 (5,530)
Tensile Elongation	ASTM D638	1/8", 6 mm/min	%	15
Flexural Strength	ASTM D790	1/4", 2.8 mm/min	$Kg/cm^2(lb/in^2)$	620 (8,800)
Flexural Modulus	ASTM D790	1/4", 2.8 mm/min	$Kg/cm^2(lb/in^2)$	21,000 (300,000)
Izod Impact Strength (Notched)	ASTM D256	1/4", 23℃ 1/8", 23℃	Kg-cm/cm(ft-lb/in) Kg-cm/cm(ft-lb/in)	18(3.3) 22(4.0)
Melt Flow Index	ASTM D1238	200℃, 5Kg	g/10min	5.0
Hardness	ASTM D785	1/2"	R Scale	100
Specific Gravity	ASTM D792	23℃	-	1.19
Vicat Softening Temp.	ASTM D1525	1/8", 50℃/hr	℃(℉)	90(194)
H.D.T. Annealed(85℃X8hr) Unannealed	ASTM D648	1/4", 120℃/hr	℃(℉)	 83(181) 73(163)
Flammability	UL 94	-	-	1.6mm, V-0 2.5mm, 5VA

The data are intended as a general guide only and do not necessarily represent results that may be obtained elsewhere.

For further information, please contact your local agent or fax to Chi Mei Technical Services Dept. at 886-6-2665555.

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Flame Retardant ABS, POLYLAC® Characteristics

December 22, 2011 VIW

Properties	ISO	DIN	Test Condition	Unit	PA-763	PA-763A	PA-765	PA-765A	PA-765B	PA-764	PA-764B
MVI	1133	-	220℃×10kg	ml/10min	30	28	49	46	45	30	25
Vicat Softening Temp.	306	53460	50℃/hr;1kg	℃	103	104	92	94	95	97	99
			50℃/hr;5kg	℃	96	97	78	79	80	83	85
			120℃/hr;1kg	℃	104	105	90	91	92	98	99
			120℃/hr;5kg	℃	97	98	80	82	82	87	88
H.D.T / A	75	53461	1.8 MPa, unanneal	℃	86	87	74	76	77	74	83
			1.8 MPa, anneal	℃	96	97	90	91	91	96	97
Izod Impact Strength	180/1A	-	Notched	KJ/m^2	20	22	17	19	20	13	14
	180/1C	-	Unnotched	KJ/m^2	NB	NB	NB	NB	NB	NB	NB
Charpy Impact	179		Notched	KJ/m^2	20	22	20	20	20	14	17
			Unnotched	KJ/m^2	NB	NB	NB	NB	NB	NB	NB
Impact Flexual Test	179/2C	53453	Notched	KJ/m^2	13	14	12	12	13	9	11
	179/2D	53453	Unnotched	KJ/m^2	NB	NB	NB	NB	NB	NB	NB
Tensile Strength	527	53455	50mm/min, yield	MPa	41	42	39	40	41	39	40
			50mm/min, break	MPa	32	33	34	28	30	29	30
Tensile Elongation	527	53455	50 mm/min	%	15	20	10	10	10	10	10
Flexural Strength	178	53452	2 mm/min	MPa	59	60	55	54	57	55	57
Flexural Modulus	178	53452	2 mm/min	GPa	2.0	2.1	1.8	1.7	1.8	1.7	1.8
Ball Indentation Hardness	2039-1	53456	H358/30		80	80	79	81	82	75	78
Flammability	-		-	UL-94	1.5mm V-0 2.5mm 5VA	1.5mm V-1 3.0mm 5VA	1.0mm V-1 2.5mm 5VA	1.5mm V-1 2.5mm 5VA	1.5mm V-2 3.0mm 5VA	1.5mm 5VB 2.5mm 5VA	2.5mm 5VB 3.0mm 5VA
Mass Density	1183	53479-A	23℃	-	1.19	1.17	1.19	1.17	1.16	1.19	1.16

The data are intended as a general guide only and do not necessarily represent results that may be obtained elsewhere.

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Component - Plastics E56070

CHI MEI CORPORATION

59-1 SAN CHIA, JEN TE, TAINAN HSIEN 717 TW

PA-765(+)

Acrylonitrile Butadiene Styrene (ABS), "Polylac", furnished as pellets

Color	Min Thk (mm)	Flame Class	HWI	HAI	RTI Elec	RTI Imp	RTI Str
ALL	1.0	V-1	4	0	80	80	80
	1.5	V-0, 5VB	2	0	80	80	80
	2.5	V-0, 5VA	2	0	80	80	80
	3.0	V-0, 5VA	0	0	80	80	80

Comparative Tracking Index (CTI): 1

High-Voltage Arc Tracking Rate (HVTR): 0

Dielectric Strength (kV/mm): -

Dimensional Stability (%): -

High Volt, Low Current Arc Resis (D495): 7

Volume Resistivity (10^X ohm-cm): 15

(+) - Optional prefix or suffix; may be used to denote usage of 0-0.5 percent acid scavengers.

UL94 small-scale test data does not pertain to building materials, furnishings and related contents. UL94 small-scale test data is intended solely for determining the flammability of plastic materials used in the components and parts of end-product devices and appliances, where the acceptability of the combination is determined by Underwriters Laboratories Inc.

Report Date: 1983-06-23

Last Revised: 2008-07-03

Underwriters Laboratories Inc®

c UL us

Product Information

DUPONT

Zytel®

nylon resin

Zytel® 101F NC010

Zytel® 101F NC010 is an internally lubricated PA 66 resin that has been developed for fast cycles and high productivity.

Property	Test Method	Units	Value	
			50%RH	DAM
Mechanical				
Yield Stress	ISO 527-1 2	MPa		
50mm/min			53	83
Nominal Strain at Break	ISO 527-1 2	%		
50mm/min			>50	18
Yield Strain	ISO 527-1 2	%		
50mm/min			25	4,4
Tensile Modulus	ISO 527-1 2	MPa		
1mm/min			1200	3100
Tensile Creep Modulus	ISO 899	MPa		
1000h			930	
1h			1450	
Notched Charpy Impact	ISO 179/1eA	kJ/m2		
-30C			3	4
23C			13	5
Unnotched Charpy Impact	ISO 179/1eU	kJ/m2		
-30C			NB	NB
23C			NB	NB
Thermal				
Deflection Temperature	ISO 75-1 2	C		
0,45MPa				200
1,80MPa				70
CLTE, Flow	ASTM E 831	E-4 C		1
CLTE, Transverse	ASTM E 831	E-4 C		1,1
Melting Temperature	ISO 3146C	C		
10C/min				263
Heat Softening Temperature	ISO 306	°C		
50N				238

Properties measured at 23°C unless otherwise stated.
Please refer to the Safety Data Sheet, general guides and/or additional information about ventilation, handling, purging, drying, etc.

970d01UA20

The information provided in this documentation corresponds to our knowledge on the subject at the date of its publication. This information may be subject to revision as new knowledge and experience becomes available. The data provided fall within the normal range of product properties and relate only to the specific material designated; these data may not be valid for such material used in combination with any other materials or additives or in any process, unless expressly indicated otherwise. The data provided should not be used to establish specification limits nor used alone as the basis of design; they are not intended to substitute for any testing you may need to conduct to determine for yourself the suitability of a specific material for your particular purposes. Since DuPont cannot anticipate all variations in actual end-use conditions DuPont makes no warranties and assumes no liability in connection with any use of this information. Nothing in this publication is to be considered as a license to operate under or a recommendation to infringe any patent rights. CAUTION: Do not use this product in medical applications involving permanent implantation in the human body. For other medical applications see "DuPont Medical Caution Statement", H-51459.

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Engineering Polymers

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Zytel® 101F NC010

Property	Test Method	Units	Value	
			50%RH	DAM
Electrical				
Surface Resistivity	IEC 93	ohm	1E12	1E12
Relative Permittivity	IEC 250			
23C, 1E2 Hz				3,9
1E6 Hz			4,6	3,6
Volume Resistivity	IEC 93	ohm cm	1E13	1E15
Dissipation Factor	IEC 250	E-4		
1E2 Hz				80
1E6 Hz			1000	200
Electric Strength	IEC 243-1	kV/mm	26	31,5
Flammability				
Flammability at 1.6mm Nominal UL94	UL94			V-2
UL94 Rating at Min. Thickness	UL94			V-2
UL94 Min. Thickness Tested	UL94	mm		0,7
Limited Oxygen Index	ISO 4589	%		28
Other				
Density	ISO 1183	kg/m3		1140
Humidity Absorption	ISO 62, Similar to	%		2,8
Water Absorption	ISO 62, Similar to	%		
Equilibrium 50%RH				8,5
Mould Shrinkage	ISO 2577	%		
Flow				1,4
Transverse				1,3
Processing				
Melt Temperature Range		°C		280-305
Mould Temperature Range		°C		40-95
Drying Time, Dehumidified Dryer		h		2-4
Drying Temperature		°C		80
Physical				
Viscosity Number				147

Properties as moulded at 23°C unless otherwise stated
Please refer to the Safety Data Sheet, general guides and/or additional information about ventilation, handling, purging, drying, etc

970601UA20

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Component - Plastics E41938

E I DUPONT DE NEMOURS & CO INC

ENGINEERING POLYMERS, CHESTNUT RUN PLAZA, PO BOX 80713, WILMINGTON DE 19880

101(r9)(f1), 101F(r9)(f1), 101L(r9)(f1), E101(r9)(f1), E101L(r9)(f1)

Polyamide 66 (PA66), "Zytel", furnished as pellets

Color	Min Thk (mm)	Flame Class	HWI	HAI	RTI Elec	RTI Imp	RTI Str
ALL	0.71	V-2	4	0	130	75	85
	1.5	V-2	3	0	130	75	85
	3.0	V-2	2	0	130	75	85
	6.0	V-2	2	0	130	75	85

Comparative Tracking Index (CTI): 0

Inclined Plane Tracking (IPT): -

Dielectric Strength (kV/mm): 13

Volume Resistivity (10^x ohm-cm) : 14

High-Voltage Arc Tracking Rate (HVTR): 0

High Volt, Low Current Arc Resis (D495): 6

Dimensional Stability (%): -

(f1) - Suitable for outdoor use with respect to exposure to Ultraviolet Light, Water Exposure and Immersion in accordance with UL 746C.

NOTE - (1) Material designations that are color pigmented may be followed by suffix letters and numbers. (2) Material designations may be prefixed by "ZYT" for Zytel or "MIN" for Minlon or "DEL" for Delrin or "CRA" for Crastin or "RYN" for Rynite or "ETPV" for ETPV or "SOR" for Sorona grades.

r9 - Virgin and regrind up to 50% by weight inclusive, have the same basic material characteristics for ALL colors down to 0.71mm. For thickness 0.40mm to 0.70mm the same basic material characteristics exist with the exception of generic RTIs for all properties and Regrind exceeding 25% is limited to V-2 Flammability for WT, RD, BK.

ANSI/UL 94 small-scale test data does not pertain to building materials, furnishings and related contents. ANSI/UL 94 small-scale test data is intended solely for determining the flammability of plastic materials used in the components and parts of end-product devices and appliances, where the acceptability of the combination is determined by UL.

Report Date: 1996-07-29

Last Revised: 2010-07-27

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IEC and ISO Test Methods

Test Name	Test Method	Units	Thickness Tested (mm)	Value
Flammability	IEC 60695-11-10	Class (color)	0.71	V-2 (ALL)
			1.5	V-2 (ALL)
			3.0	V-2 (ALL)
			6.0	V-2 (ALL)
Glow-Wire Flammability (GWFI)	IEC 60695-2-12	C	0.71	960
			1.5	960
			3.0	960
			6.0	960
Glow-Wire Ignition (GWIT)	IEC 60695-2-13	C	0.71	725
			1.5	750
			3.0	800
			6.0	800
IEC Comparative Tracking Index	IEC 60112	Volts (Max)	-	-
IEC Ball Pressure	IEC 60695-10-2	C	-	-
ISO Heat Deflection (1.80 MPa)	ISO 75-2	C	-	-
ISO Tensile Strength	ISO 527-2	MPa	-	-
ISO Flexural Strength	ISO 178	MPa	-	-
ISO Tensile Impact	ISO 8256	kJ/m^2	-	-
ISO Izod Impact	ISO 180	kJ/m^2	-	-
ISO Charpy Impact	ISO 179-2	kJ/m^2	-	-

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The materials covered in this database are incomplete in certain constructional features or restricted in performance capabilities and are intended for use as components of complete equipment submitted for investigation rather than for direct separate installation in the field. THE FINAL ACCEPTANCE OF THE COMPONENT IS DEPENDENT UPON ITS INSTALLATION AND USE IN COMPLETE PRODUCTS SUBMITTED TO UNDERWRITERS LABORATORIES.

Notice of Disclaimer

ONLINE CERTIFICATIONS DIRECTORY

OANZ2.E165111
Insulating Tape - Component

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Insulating Tape - Component

See General Information for Insulating Tape - Component

JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD E165111
SOUTHWEST AROUND RD
JINGJIANG, JIANGSU 214500 CHINA

Flame retardant copper foil tape, Cat. No. CP-3002#.

Nonwoven cloth/polyethylene terepthalate film insulating tape, Cat. No. WF with suffixes, rated 130 C* (c) (h).

Polyimide film insulating tape, Cat. No. PF with suffixes, rated 180 C* (d) (g).

Polyethylene terephthalate film insulating tape, Cat. No. CT with suffixes, yellow color, rated 130 C*(c) (e) (g).

Polyethylene terephthalate film insulating tape, Cat. No. CT with suffixes, all colors except yellow, rated 130 C(b)(f) (g).

Polyethylene terephthalate film insulating tape, Cat. No. PZ with additional suffixes, rated 130 C*(b).

PET film with acrylic adhesive insulating tape, Cat. No. CT-280B, yellow color only, rated 130C.

*Complies with flame retardant requirements when so marked.

Markings shall include "Flame Retardant".

(b)Comparative Tracking Index (CTI) performance indicates material Group IIIa, PLC=2, CTI equal to or greater than 250 but less than 400 v.

(c)Comparative Tracking Index (CTI) performance indicates material Group I, PLC=0, CTI equal to or greater than 600 v.

(d)Comparative Tracking Index (CTI) performance indicates material Group IIIb, PLC=4, CTI equal to or greater than 100 v but less than 175v.

(e) - Yellow color only

(f) - All colors except yellow

(g) - The CTI test was conducted per IEC 112, 3rd Edition 1979 and the assigned level is based on the testing of both film and adhesive sides.

(h) - The CTI test was conducted per IEC 60112, 4th Edition 2003 and the assigned level is based on the testing of both film and adhesive sides.

Marking: Company name or file number "E165111" and catalog designation printed on the carton, wrapper or core.
Last Updated on 2012-03-19

Questions? Print this page Notice of Disclaimer Page Top

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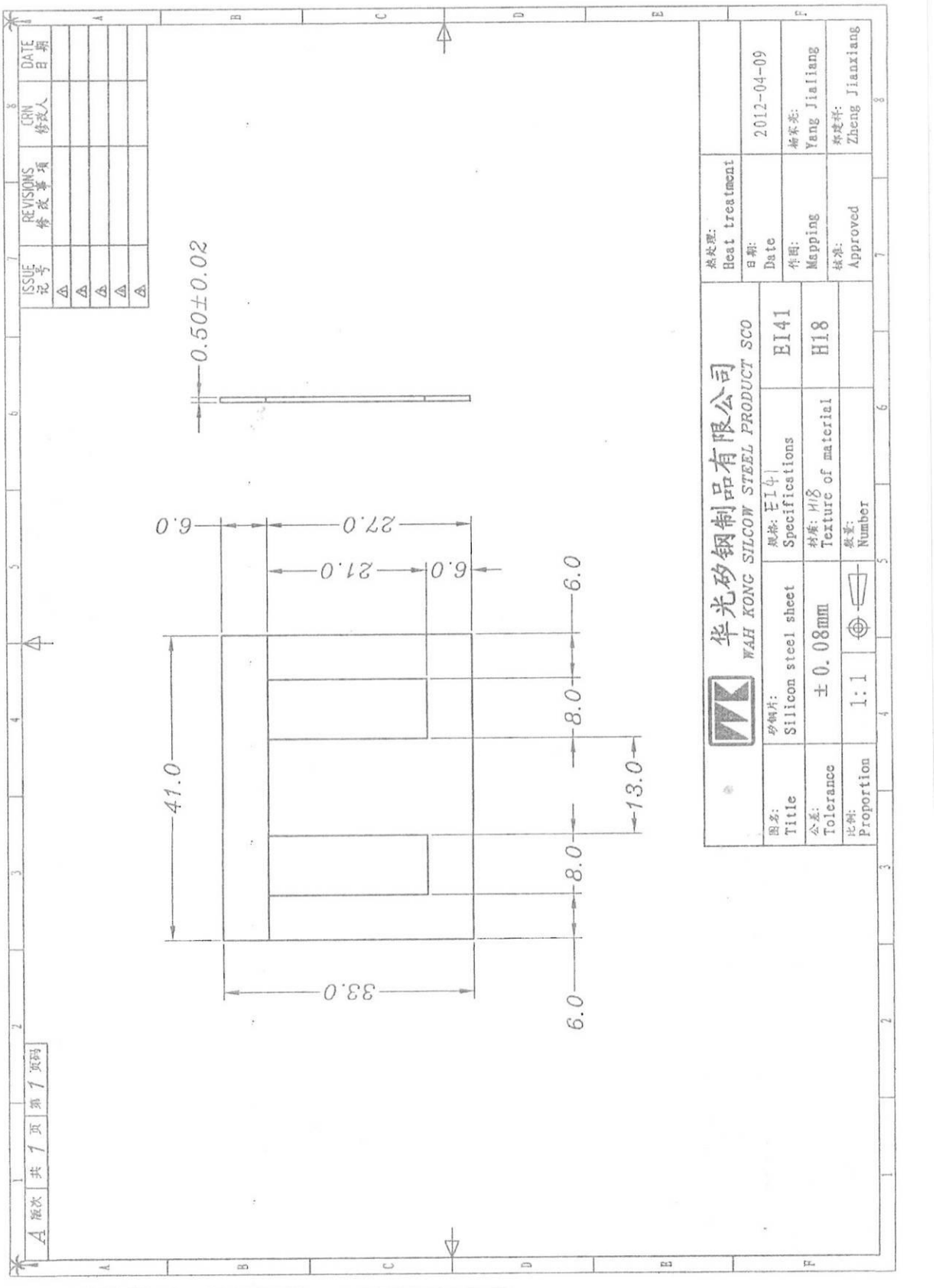
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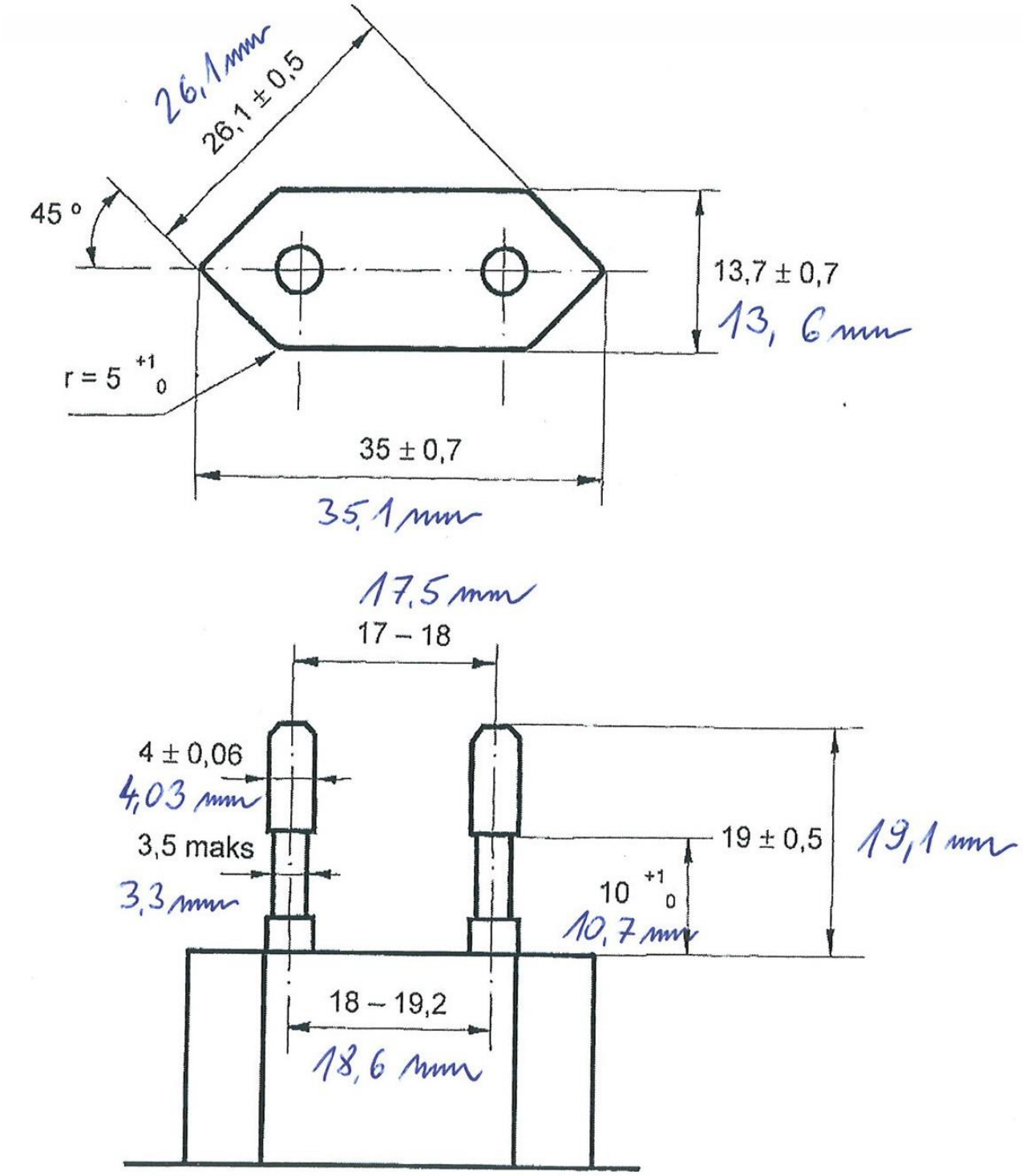
26,1 mm
26,1 ± 0,5
45 °
13,7 ± 0,7
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18,6 mm

Enclosure No. 3

National Differences to
IEC 60601-1:2005 + A1:2012

(24 pages including this cover page)

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict

US NATIONAL DIFFERENCES to IEC 60601-1 Third edition National standard ANSI/AAMI ES60601-1: 2005			
4.8	**Components of ME EQUIPMENT**	--	**P**
	When no relevant US ANSI standard existed, the requirements of this standard applied	--	**P**
4.10.2.	**SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**	Considered	**P**
	Replacement: Reference to "500 V" replaced with "600 V" in the second and third dashes to agree with the National Electrical Code (NEC) "and the NEC" added after the reference to "IEC 60364-4-41" in the text of the second-to-last dash of this sub-clause to agree with NEC	--	**P**
8.2	**Requirements related to power sources**	--	**N/A**
	Addition to agree with NEC: The requirement, "ALL FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT"	Not fixed or permanently installed equipment.	**N/A**
8.7.3	**Allowable values:**	--	**P**
	Deleted the second sentence and note to sub-clause 8.7.3 d) to read as follows to agree with NFPA 99 which does not permit for allowances larger than the stated values:	--	**P**
	d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION	Considered.	**P**
8.11.	**MAINS PARTS, components and layout**	--	**N/A**
	Addition to agree with NEC:	--	**N/A**
	The requirement, "Permanently connected ME EQUIPMENT shall have provision for the connection of one of the wiring systems that is in accordance with the NEC" **Fixed and stationary X-ray ME EQUIPMENT supplied from a branch circuit rated at 30 A or less, and ME EQUIPMENT not strictly portable but obviously intended to be stationary, considered acceptable when supply connection provided with a length of attached Type S hard service flexible cord, or equivalent:**	Not fixed or permanently installed equipment.	**N/A**
	Installation of connecting cords between EQUIPMENT parts comply with NEC, as applicable	--	**N/A**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	Cable used as external interconnection between units was: **1) Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord when exposed to abuse, or similar multiple-conductor appliance-wiring material such as computer cable:** **2) The cable was as in item 1) above when not exposed to abuse, or it was** **i) Type SPT-2, SP-2, or SPE-2, or equivalent** **ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material,** **Or, ii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more.**	--	**N/A**
	Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of pediatric wards, rooms, or areas are listed (e.g., UL Certified) tamper resistant or employ a listed (e.g., UL Certified) tamper resistant cover in accordance with NEC	--	**N/A**
8.11.3.2.	**Addition to agree with NEC:**	--	**P**
	The flexible cord is a type acceptable for the particular application, and it is acceptable for use at a voltage not less than the rated voltage of the appliance and has an ampacity as in NEC, not less than the current rating of the appliance.	Power supply cord with mains plug.	**P**

CANADA NATIONAL DIFFERENCES to IEC 60601-1 Third edition National standard CAN/CSA-C22.2 No. 60601-1:08			
1.1	**Scope**	--	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32. **NOTE 1A: In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.**	--	**P**
1.3	**Collateral standards**	--	**P**
	Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard. **NOTE 1: When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards**	--	**P**
1.4	**Particular standards**	--	**P**
	A requirement of a Canadian-particular safety standard takes precedence over this standard.	Considered.	**P**
2	**Normative references** **The following referenced documents are indispensable for the application of this document.** **For dated references, the applicable corresponding Canadian adopted IEC standards shall take precedence. For undated references, the latest edition of the referenced document (including any amendments) applies. All Canadian adopted IEC part 2 standards are referenced with the date of publication.**	--	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	CSA (Canadian Standards Association) **B51-03: Boiler, pressure vessel, and pressure piping code** **C22.1-06: Canadian Electrical Code, Part I** **CAN/CSA-C22.2 No. 0-M91 (R2006): General requirements — Canadian Electrical Code, Part II** **C22.2 No. 21-95 (R2004): Cord sets and power supply cords** **C22.2 No. 42-99 (R2004): General use receptacles, attachment plugs, and similar wiring devices** **C22.2 No. 49-06: Flexible cords and cables** **CAN/CSA-E61558-2-1:03: Safety of power transformers, power supply units and similar — Part 2: Particular requirements for separating transformers for general use** **CAN/CSA-Z32-04: Electrical safety and essential electrical systems in health care facilities**	--	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	Z305 series of Standards: **CAN/CSA-Z305.1-92 (R2001): Non-flammable medical gas piping systems** **CAN/CSA-Z305.6-92 (R2007): Medical oxygen concentrator central supply system for use with non-flammable medical gas piping systems** **CAN/CSA-Z305.8-03. Medical supply units** **CAN/CSA-Z305.12-98 (R2004): Guide for the safe storage, handling and use of portable oxygen systems in home, domiciliary and healthcare settings** **CAN/CSA-Z5359-04: Low pressure hose assemblies for use with medical gases** **CAN/CSA-Z9170-1-00 (R2005): Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum** **CAN/CSA-Z9170-2-00 (R2005): Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems** **CAN/CSA-Z9170-2-00 (R2005): Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems** **CAN/CSA-Z15002-02 (R2007): Flow-metering devices for connection to terminal units of medical gas pipeline systems** **ASME International (American Society of Mechanical Engineers)** **PTC 25-2001: Pressure Relief Devices** **CGA (Compressed Gas Association):** **V-1-2005: Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections** **V-5-2005: Diameter Index Safety System (Non interchangeable Low Pressure Connections for Medical Gas Applications)**	--	**P**
	ISO (International Organization for Standardization) **32:1977: Gas cylinders for medical use — Marking for identification of content** **407:2004: Small medical gas cylinders — Pin-index yoke-type valve connections**	--	**N/A**
3.41	**HIGH VOLTAGE**	No high voltage present in the EUT.	**N/A**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	any voltage above 750 V, 1 050 V peak, as defined in the Canadian Electrical Code (CEC), Part I	Only voltages below 750V, 1050 Vpeak are present.	**N/A**
4.8	**Components of ME EQUIPMENT**	--	**P**
	a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; **NOTE 1: For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.**	--	**P**
	b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied **NOTE 2: If there are neither requirements in this standard nor in a CSA, IEC, or ISO standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.**	--	**P**
4.10.2	**SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**	--	**P**
	and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1:	--	**P**
7.7.1 to 7.7.5	**A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49.**	--	**P**
8.7.3	**Allowable values** **Allowable values shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1.**	--	**P**
8.11.3.2	**POWER SUPPLY CORDS Types**	--	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be **i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;** **j) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or** **k) Class II equipment having fuses on the line side/sides and neutral and may use a non-polarized attachment plug or a polarized attachment plug — CSA configuration type 1-15P shall be required and shall meet all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the POWER SUPPLY CORD shall be connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:** **1- the centre contact of an Edison base lamp holder;** **2- a single pole switch;** **3- an automatic control with a marked off position;** **4- a solitary fuse/fuse holder; or** **5- any other single pole over-current protective device**	--	**P**
	b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that **i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;** **j) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and** **k) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION**	--	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	c) A detachable POWER SUPPLY CORD shall **i) comply with the applicable requirements of CSA C22.2 No. 21; and** **j) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than** **1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and** **2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature).** **NOTE 1A: See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).**	--	**P**
	d) Power supply cords shall meet the requirements of the Canadian Electrical Code, Part I, as applicable. **Connecting cords between equipment parts shall meet the requirements of the Canadian Electrical Code, Part I, as applicable.**	--	**P**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES** **Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1.**	Refer to Table 8.10: List of critical components.	**P**
9.7.5	**Pressure vessels** **Pressure vessels shall comply with the requirements of CSA B51, as applicable.**	--	**N/A**
9.7.7	**Pressure-relief device** **A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements.**	--	**N/A**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.1	**Construction of connectors** **The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be** **i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or** **DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359.** **NOTE 1A: Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke-type valve connections; and ISO 32 for colour coding.**	No gas connections used.	**N/A**
15.4.8	**Internal wiring of ME EQUIPMENT** **Internal wiring of ME EQUIPMENT shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1.**	--	**P**
16.1	**MULTIPLE SOCKET OUTLET** **The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements.** - **The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding** - **1 kVA for single-phase transformers; and** - **5 kVA for polyphase transformers** **The separating transformer shall also have a degree of protection not exceeding IPX4.**	No MSO used.	**N/A**

JAPAN NATIONAL DIFFERENCES to IEC 60601-1 Third edition **National standard: JIS T0601-1:2012**			
1.1	**At the end, add the following:** **JIS T0601-1:1999 is applicable until 2017.05.31.**	Considered.	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
1.3	**In NOTE 3, add the following:** **In Japan, to check the concerned JIS standard is required.**	--	**P**
1.4	**At the end of NOTE, add the following:** **In Japan, application of the concerned JIS standard(s) is required.**	--	**P**
2	**Except the part of the first paragraph, Attention and NOTE, replace the existing part listing standards with the following, and apply these properly in the following clauses if any:** **JIS B7761-3, Hand-transmitted vibration-Part 3: General requirements for measurement and evaluation** **NOTE: ISO 5349-1, Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements (IDT)** **JIS B9707, Safety of machinery-Safety distances to prevent danger zones being reached by the upper limbs** **NOTE: ISO 13852, Safety of machinery - Safety distances to prevent danger zones being reached by the upper limbs (IDT)** **JIS B9711, Safety of machinery-Minimum gaps to avoid crushing of parts of the human body** **NOTE: ISO 13854, Safety of machinery - Minimum gaps to avoid crushing of parts of the human body (IDT)** **JIS C0445, Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system** **NOTE: IEC 60445, Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system (IDT)** **JIS C0447, Man-machine interface (MMI) - Actuating principles** **NOTE: IEC 60447, Basic and safety principles for man-machine interface, marking and identification - Actuating principles (IDT)** **JIS C0920:2003, Degrees of protection provided by enclosures (IP Code)** **NOTE: IEC 60529:2001, Degrees of protection provided by enclosures (IP Code) (IDT)** **JIS C1509-1, Electroacoustitcs - Sound level meters- Part 1: Specifications** **NOTE: IEC 61672-1, Electroacoustics - Sound level meters - Part 1: Specifications (IDT)** **JIS C1509-2, Electroacoustics -Sound level meters - Part 2: Pattern evaluation tests** **NOTE: IEC 61672-2, Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests (IDT)** **JIS C2134, Method for the determination of the proof and the comparative tracking indices of solid insulating materials** **NOTE: IEC 60112, Method for the determination of the proof and the comparative tracking indices of solid insulating materials (IDT)**	--	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	JIS C3301:2000, Rubber insulated flexible cords **NOTE: IEC 60245-4:1994, Rubber insulated cables of rated voltages up to and including 450/750 V - Part 4: Cords and flexible cables, Amendment 1:1997 (NEQ)** **JIS C3306:2000, Polyvinyl chloride insulated flexible cords** **NOTE: IEC 60227-5:1997, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V - Part 5: Flexible cables (cords) (NEQ)** **JIS C4003, Electrical insulation-Thermal evaluation and designation** **NITE: IEC 60085, Electrical insulation - Thermal evaluation and designation (MOD)** **JIS C5101-14:2009, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains** **NOTE: IEC 60384-14:2005, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains (IDT)** **JIS C6065:2007, Audio, video and similar electronic apparatus-Safety requirements** **NOTE: IEC 60065:2001, Audio, video and similar electronic apparatus - Safety requirements (MOD)** **JIS C6802:2005, Safety of laser products** **NOTE: IEC 60825-1:1993, Safety of laser products - Part 1: Equipment classification, requirements and user's guide, Amendment 1:1997 and Amendment 2 :2001 (IDT)** **JIS C6965, Mechanical safety of cathode ray tubes** **NOTE: IEC 61965, Mechanical safety of cathode ray tubes (IDT)** **JIS C8282-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements** **NOTE: IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements (MOD)** **JIS C8303, Plugs and receptacles for domestic and similar general use** **NOTE: No corresponding JIS exists. This standard has been listed as normative reference corresponding to IEC60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC, which has been listed in IEC 60601-1:2005. Refer to JIS T1021, too.** **JIS C60068-2-2:1995, Environmental testing - Part 2-2:Tests -Test B: Dry heat** **NOTE: IEC 60068-2-2:1974, Environmental testing - Part 2: Tests. Tests B: Dry heat, Amendment 1:1993 and Amendment 2:1994 (IDT)** **JIS C60079-0, Explosive atmospheres-Part 0: Equipment-General requirements** **NOTE: IEC 60079-0, Electrical apparatus for explosive gas atmospheres - Part 0: General requirements (IDT)** **JIS C60079-2, Electrical apparatus for explosive gas atmospheres - Part 2: Pressurized enclosures "p"** **NOTE: IEC 60079-2, Electrical apparatus for explosive gas atmospheres - Part 2: Pressurized enclosures “p” (IDT)** **JIS C60079-6, Electrical apparatus for explosive gas atmospheres - Part 6:Oil immersion "o"**		

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	NOTE: IEC 60079-6, Electrical apparatus for explosive gas atmospheres - Part 6: Oil-immersion "o" (IDT) **JIS C60364-4-41, Low-voltage electrical installations-Part 4-41: Protection for safety - Protection against electric shock** **NOTE: IEC 60364-4-41, Electrical installations of buildings - Part 4-41: Protection for safety - Protection against electric shock (IDT)** **JIS C60664-1:2009, Insulation coordination for equipment within low-voltage systems - Part 1:Principles, requirements and tests** **NOTE: IEC 60664-1:2007, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests (IDT)** **JIS C60695-11-10, Fire hazard testing-Part11-10:Test flames-50W horizontal and vertical flame test methods** **NOTE: IEC 60695-11-10, Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods (IDT)** **JIS T0307, Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied** **NOTE: ISO 15223, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied (IDT)** **JIS T0601-1-3, Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment** **NOTE: IEC60601-1-3, Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (IDT)** **JIS T14971:2003, Medical devices-Application of risk management to medical devices** **NOTE: ISO 14971:2000, Medical devices - Application of risk management to medical devices (IDT)** **JIS Z8202 (all parts), Quantities and units** **NOTE: ISO 31 (all parts), Quantities and units (IDT)** **JIS Z8203, SI units and recommendations for the use of their multiples and of certain other units** **NOTE: ISO 1000, SI units and recommendations for the use of their multiples and of certain other units (IDT)** **JIS Z8736-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1 : Measurement at discrete points** **NOTE: ISO 9614-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points (IDT)** **JIS Z9101:2005, Safety colours and safety signs-Design principles for safety signs in workplaces and public areas** **NOTE: ISO 3864-1:2002, Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs in workplaces and public areas (IDT)** **ISO 780, Packaging - Pictorial marking for handling of goods** **NOTE: The corresponding JIS standard is JIS Z0150**		

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	Packaging-Pictorial marking for handling of goods (MOD) **ISO 1853, Conducting and dissipative rubbers, vulcanized or thermoplastic－Measurement of resistivity** **NOTE: The corresponding JIS standard is JIS K6271 Rubber, vulcanized or thermoplastic-Determination of volume and surface resistivity (MOD)** **ISO 2878, Rubber - Antistatic and conductive products - Determination of electrical resistance** **ISO 2882, Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance** **Limits** **ISO 3746, Acoustics - Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane** **ISO 7000-DB:2004, Graphical symbols for use on equipment - Index and synopsis** **ISO 7010:2003, Graphical symbols - Safety colours and safety signs - Safety signs used in workplaces and public areas** **ISO 10993 (all parts), Biological evaluation of medical devices** **NOTE: The corresponding JIS standard is JIS T0993-1 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (MOD). However, other Parts than Part 1 and Part 7 have still not been published as JIS.** **ISO 11134, Sterilization of health care products - Requirements for validation and routine control -Industrial moist heat sterilization** **NOTE: At present, as the corresponding JIS or international standards, the following exist:** **JIS T0816-1:2010 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices** **ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (IDT)** **ISO 11135, Medical devices - Validation and routine control of ethylene oxide sterilization** **NOTE: At present, as the corresponding JIS or international standards, the following exist:** **JIS T0801-1:2010 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices** **ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT)** **ISO 11137, Sterilization of health care products - Requirements for validation and routine control – Radiation Sterilization** **NOTE: At present, as the corresponding JIS or international standards, the following exist:** **JIS T0806-1:2010 Sterilization of health care products - Radiation - Part 1: Requirements for development,**		

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Clause	Requirement + Test	Result - Remark	Verdict
	validation and routine control of a sterilization process for medical devices **ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT)** **ISO 23529, Rubber - General procedures for preparing and conditioning test pieces for physical test methods** **NOTE: The corresponding JIS standard is JIS K6250 Rubber-General procedures for preparing and conditioning test pieces for physical test methods (MOD)** **IEC 60079-5, Explosive gas atmospheres－Part 5: Equipment protection by powder filling "q"** **IEC/TR 60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC** **IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries** **NOTE: The corresponding JIS standard is JIS C8513 Safety of primary lithium batteries (MOD)** **IEC 60127-1, Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links** **NOTE: The corresponding JIS standard is JIS C6575-1 Miniature fuses-Part 1: Definitions of miniature fuses and general requirements for miniature fuse-links (MOD)** **IEC 60227-1:1993, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements, Amendment 1:1995 and Amendment 2:1998** **NOTE: The corresponding JIS standard is JIS C3662-1:2009 Polyvinyl chloride insulated cables of rated voltages up to and including 450/750V - Part 1: General requirements (MOD)** **IEC 60245-1:2003, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements** **NOTE: The corresponding JIS standard is JIS C3663-1:2007 Rubber insulated cables-Rated voltages up to and including 450/750 V-Part 1: General requirements (MOD)** **IEC 60252-1, AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements -Guide for installation and operation** **IEC 60320-1, Appliance couplers for household and similar general purposes - Part 1: General requirements** **NOTE: The corresponding JIS standard is JIS C8283-1 Appliance couplers for household and similar general purposes-Part 1: General requirements (MOD)** **IEC 60335-1:2001, Household and similar electrical appliances - Safety - Part 1: General requirements** **NOTE: The corresponding JIS standard is JIS C9335-1:2003 Household and similar electrical appliances - Safety - Part 1 : General requirements (MOD)** **IEC 60417-DB:2002, Graphical symbols for use on equipment** **IEC 60601-1-2, Medical electrical equipment -**		

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	Part 1 - 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests **NOTE: The current "JIS T0601-1-2:2012 Medical electrical equipment - Part 1-2: General requirements for safety - Electromagnetic compatibility - Requirements and tests" corresponds to IEC 60601-1-2:2001 and Amendment 1:2004.** **IEC 60601-1-6, Medical electrical equipment - Part 1 - 6: General requirements for basic safety and essential performance - Collateral standard: Usability** **NOTE: As the corresponding international standard, IEC 62336 is applicable.** **IEC 60601-1-8, Medical electrical equipment - Part 1 - 8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems** **NOTE: The corresponding JIS standard is now under drafting.** **IEC 60730-1:1999, Automatic electrical controls for household and similar use - Part 1: General requirements, Amendment 1:2003 and Amendment 2:2007** **NOTE: The corresponding JIS standard is JIS C9730-1:2010 Automatic electrical controls for household and similar use-Part 1:General requirements (MOD)** **IEC 60851-3:1996, Winding wires - Test methods - Part 3: Mechanical properties, Amendment 1:1997 and Amendment 2:2003** **IEC 60851-5:1996, Winding wires - Test methods - Part 5: Electrical properties, Amendment 1:1997 and Amendment 2:2004** **IEC 60851-6:1996, Winding wires - Test methods - Part 6: Thermal properties and Amendment 1:1997** **IEC 60878:2003, Graphical symbols for electrical equipment in medical practice** **IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements** **IEC 60950-1:2001, Information technology equipment – Safety - Part 1: General requirements** **NOTE: The corresponding JIS standard is JIS C 6950-1:2009 Information technology equipment - Safety - Part 1: General requirements (MOD)** **IEC 61058-1:2000, Switches for appliances - Part 1: General requirements and Amendment 1:2001** **NOTE: The corresponding JIS standard is JIS C4526-1:2005 Switches for appliances - Part 1: General requirements (MOD)** **IEC 61558-1:1997, Safety of power transformers, power supply units and similar products - Part 1: General requirements and**		

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	tests and Amendment 1:1998 **NOTE: No corresponding JIS exists. However, as the standard corresponding to IEC 61558-1:2005, the following exists:** **JIS C 61558-1:2008 Safety of power transformers, power supplies, reactors and similar products - Part 1: General requirements and tests (MOD)** **IEC 61558-2-1, Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications** **NOTE: The corresponding JIS standard is JIS C61558-2-1 Safety of power transformers, power supplies, reactors and similar products-Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications (MOD)**		
3.61	**Add NOTE as follows:** **NOTE In this standard, MECHANICAL HAZARD is understandable suitably by replacing with mechanical HAZARD, mechanical HADARDOUS SITUATION, HARM or unacceptable RISK.**	--	**P**
3.70	**Replace the existing text with:** **condition in which all means provided for protection against HAZARDOUS SITUATION or HAZARDS are intact**	--	**P**
4.2	**Replace the existing NOTE 2 with the following:** **NOTE 2 Conditions or faults that can give rise to HAZARDOUS SITUATIONS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDOUS SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS do not arise in the specified circumstances.**	--	**P**
4.10.1	**In the existing text, replace "a separate power supply" with "a separate power supply (e.g., a power supply of other equipment)".**	Mains operated equipment.	**N/A**
7.3.3	**In the third paragraph, replace "could result in a HAZARD" with "could result in a HAZARDOUS SITUATION".**	--	**N/A**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
7.4.3	**Replace the existing first paragraph with the following:** **Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to JIS Z8202 (ISO 31 (IDT)) except the base quantities listed in Table 1 may be expressed in the indicated units, which are used in conjunction with the SI units system or as the approved combination.** **Replace the title of Table 1 with the following:** **Units which are used in conjunction with the SI units system or as the approved combination**	--	**N/A**
7.7.4	**Under the existing text, add the following:** **If polyvinyl chloride insulated flexible cord of JIS C3306 or rubber insulated flexible cord of JIS C3301 is used, the conductor may be coloured "white".**	--	**N/A**
7.7.5	**Under the existing text, add the following:** **If polyvinyl chloride insulated flexible cord of JIS C3306 or rubber insulated flexible cord of JIS C3301 is used, conductors may be of the colour specified in the said standards.**	--	**N/A**
7.9.3.2	**In the fourth dash, replace "the nature of the HAZARD" with "the HAZARDOUS SITUATION".**	--	**N/A**
8.4.2	**For Item c), at the end of the paragraph of "For such parts, the voltage to earth or --," replace "at a potential up to 2 V" with "at a potential of 2 V or more".** **For Item c), replace the existing NOTE with NOTE 1, and add the following new NOTE 2:** **NOTE 2 – The corresponding international standard specifies as "not exceed 20 J at a potential up to 2 V". However, 1.2.8.9 of IEC 60950-1, which was quoted by the said international standard, specifies as "2 V or more". Therefore, this JIS standard was harmonized to IEC 60950-1.**	--	**N/A**
8.8.2	**For a), add the following NOTE:** **NOTE – Generally, "distance through insulation" means the thickness of insulation. However, for example, if a transformer installed into a metal case is insulated by filler, the thickness is always not uniformly. Therefore, such expression was used.**	--	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
8.8.3	**Between the third dash and the paragraph of "Initially, not more than --", add the following new paragraph.** **During the above-mentioned tests, the state of the power switch shall be kept with closed circuit.**	--	**P**
8.9.1.2	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**N/A**
8.9.1.3	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**N/A**
8.9.1.4	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**P**
8.9.1.5	**At the end of the title of this sub-clause, add "(Apply to MOOP and MOPP)".**	--	**P**
8.9.1.6	**At the end of the title of this sub-clause, add "(Apply to MOOP and MOPP)".**	--	**P**
8.9.1.7	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**P**
8.9.1.8	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**P**
8.9.1.9	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**P**
8.9.1.10	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**P**
8.9.1.11	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**P**
8.9.1.12	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**P**
8.9.1.13	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**N/A**
8.9.1.14	**At the end of the title of this sub-clause, add "(Apply to MOOP)".**	--	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.2	**Add the following between the first paragraph and the second paragraph:** **And, rubber insulated flexible cords of JIS C3301, polyvinyl chloride insulated flexible cords of JIS C3306 or cords of which the robustness is equal to or more than those are usable.** **Add the following between the second paragraph and the last paragraph:** **And, in the case of cords of JIS C3306, shall not use;** - **for polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 60 °C, and;** - **for grade heat-resistant polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 75 °C.**	Power supply cord not part of investigation.	**N/A**
9.2.2.2	**In the bottom column of Table 20, replace the existing text with the following:** **[a] The values in this table are taken from JIS B9711 (ISO 13854 (IDT)).**	--	**N/A**
9.2.2.4.4	**In the second dash, replace "no HAZARD or damage shall result" with "no HAZARDOUS SITUATION or unacceptable RISK shall result".**	--	**N/A**
9.2.4	**In e), replace "no HAZARD or damage shall result" with "no HAZARDOUS SITUATION or unacceptable RISK shall result".**	--	**N/A**
9.4.4	**In the first paragraph of a), replace "and no HAZARDS can develop" with "and no HAZARDOUS SITUATION can develop".**	--	**P**
9.7.5	**In the last paragraph, delete "unmarked".**	--	**N/A**
9.8.4.1	**Replace the existing NOTE with the following:** **NOTE The upper carriage of the human body test mass apparatus is formed of wood or a similar material. The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) has not been specified. The foam is cylindrical, rather than spherical.**	--	**N/A**
10.1.1	**In the paragraph, replace "0,5 mR/h" with "0,5 mR/h ≈ 5 µGy/h"; and in NOTE 2, "0,1 mR/h" with "0,5 mR/h ≈ 1 µGy/h".**	--	**N/A**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
11.1.1	**To the existing text of a in the Table 22, add the following:** **(For example, the maximum temperature limit of a transformer with three insulating materials of Class A, Class B and Class E shall be 105 °C of Class A of the lowest limit.)**	--	**N/A**
13.2.7	**In the title of this sub-clause, replace "in a HAZARD" with "in a HAZARDOUS SITUATION".**	--	**N/A**
13.2.10	**In Table 26, replace the existing NOTE with the following:** **NOTE The temperature limits in this table were derived from Table B.1 of IEC 60950-1:2001 (in the corresponding international standard, IEC 61010-1:2001 [22]).**	--	**N/A**
15.4.2.1	**In c), replace "could constitute a HAZARD" with "could constitute a HAZARDOUS SITUATION".**	--	**N/A**
15.4.3.4	**In the first paragraph, replace "could become a HAZARD" with "could become a HAZARDOUS SITUATION".**	--	**N/A**
16.1	**Replace the last two paragraphs with the following:** **Otherwise, non-medical equipment shall be those which are in compliance with relevant JIS standards or the Technical Requirements of the Electrical Appliance and Material Safety Act or which ensure safety equivalent to the said standards/technical requirements.** **Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM.** **For the measures for ensuring safety, e.g., the case combined with a separating transformer with DOUBLE INSULATION or RAINFORCED INSULATION, equipment only with BASIC INSULATION may be used.** ***Compliance is checked by inspection of appropriate documents or certificates.***	--	**N/A**
16.6.4.1	**In NOTE, replace "no possibility of any HAZARD" with "no possibility of any HAZARDOUS SITUATION".**	--	**N/A**
16.9.2.1	**In the text of c), replace "IEC 60884-1" with "IEC 60884-1 or JIS C8282-1".**	--	**N/A**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
Annex D	**In Table D.2, replace the sign of No. 10, which is shown as "IEC 60878 Safety 01 [b]", with the sign of "ISO 7010-M002 [b]".** **In the bottom column if Table D.2, replace the existing a and b with the following:** **[a] The description of this commonly used safety sign appeared in Annex B of ISO 3864:1984.** **[b] In accordance with the corrigendum of IEC 60601-1, Replaced "IEC 60878 Safety 01 " with "ISO 7010-M002**	--	**P**
Annex I	**In 1.1.3, replace the first dash with the following:** **- PATIENTS should only be connected to APPLIED PARTS of ME EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards or comply with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or ensure safety equivalent to the said standards/technical requirements.** **Replace the existing NOTE 2 with the following:** **NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601 (all parts) or JIS T0601 (all parts).** **Replace the existing NOTE 3 with the following:** **NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards. Include non-medical equipment in compliance with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or non-medical equipment ensuring safety equivalent to the said standards/technical requirements.**	--	**P**
Annex L	**In the first paragraph, replace "wound components" with "wound components (e.g., transformers, motors, etc.)"**	No wires in accordance with Annex L provided.	**N/A**
Bibliography	**Add the following at the end:** **[55] JIS T1021, "Hospital grade" outlet-sockets and plugs** **[56] JIS Q13485, Medical devices - Quality management systems - Requirements for regulatory purposes**	--	**P**

REPUBLIC OF KOREA NATIONAL DIFFERENCES to IEC 60601-1 Third edition **National standard KS C IEC 60601-1**		
	LIMITATIONS	**P**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	<Supply voltage rating> **National supply voltages are 110,220V and 380V**	--	**P**
	<Frequency> **Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted.**	--	**P**
	<Instruction> **Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417.**	Instructions shall be evaluated during Korea national approval.	**N/A**
	Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300) **More details are available from KTR on request.**	Power supply cord with Korean mains plug not part of the investigation.	**N/A**

SWITZERLAND NATIONAL DIFFERENCES to IEC 60601-1 Third edition **National standard SN EN 60601-1:06**			
4	**Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7,** **Mercury - Annex 1.7 of SR 814.81 applies for mercury.**	--	**N/A**
	Switches containing mercury such as thermostats, relays and level controllers are not allowed.	--	**N/A**
	Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15: Batteries	--	**N/A**
	Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury.	--	**N/A**
	Note: Ordinance relating to environmentally hazardous substances, SR 814.013 of 1986-06-09 is not longer in force and superseded by SR 814.81 of 2009-02-01 (ChemRRV).	--	**N/A**
	Supply cords of portable electrical appliances having a rated current not exceeding 10 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: **- SEV 6533-2:2009 Plug type 11, L + N, 250V 10A** **- SEV 6534-2:2009 Plug type 12, L + N + PE, 250V 10A** **- SEV 6532-2:2009 Plug type 15, 3L + N + PE, 250/400V 10A**	Power supply cord not part of investigation.	**N/A**

National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Supply cords of portable electrical appliances having a rated current not exceeding 16 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1,** **SEV 1011 and one of the following dimension sheets:** **- SEV 5933-2:2009 Plug type 21 L + N, 250 V, 16A** **- SEV 5934-2:2009 Plug type 23 L + N + PE, 250 V, 16A** **- SEV 5932-2:2009 Plug type 25 3L + N + PE, 250/400V 16A**	--	**N/A**
	NOTE 16 A plugs are not often used in Swiss domestic installation system.	--	**N/A**
	See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates.	--	**N/A**

Enclosure No. 4

European Differences

(35 pages including this cover page)

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

EU DIFFERENCES **Standard: EN 60601-1:2006 + A1:2013 + A12:2014**		
Annex ZA	**Annex ZA** **(normative)** **Normative references to international publications with their corresponding European publications**	**–**
	The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.	**–**
	NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.	**–**

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 60065 (mod)	2001	Audio, video and similar electronic apparatus - Safety requirements	EN 60065 + corr. March	2002
A1 (mod)	2005		A1 + corr. August A11	2006 2007 2008
A2 (mod	2010		A2 A12	2010 2012
IEC 60068-2-2	2007	Environmental testing Part 2: Tests - Test B: Dry heat	EN 60068-2-2	2007
IEC 60079-0 (mod)	- [1)]	Explosive atmospheres - Part 0: Equipment - General requirements	EN 60079-0	2012
IEC 60079-2	- [1)]	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"	EN 60079-2	2007
IEC 60079-5	- [1)]	Explosive atmospheres - Part 5: Equipment protection by powder filling "q"	EN 60079-5	2007
IEC 60079-6	- [1)]	Explosive atmospheres - Part 6: Equipment protection by oil immersion "o"	EN 60079-6	2007
IEC 60083	- [1)]	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	IEC 60083	2009
IEC 60085	- [1)]	Electrical insulation - Thermal evaluation and designation	EN 60085	2008
IEC 60086-4	- [1)]	Primary batteries Part 4: Safety of lithium batteries	EN 60086-4	2007
IEC 60112	- [1)]	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	2003
IEC 60127-1	2006	Miniature fuses Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links	EN 60127-1	2006

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 60227-1 [2)]	1993	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V		
A1	1995			
A2	1998	Part 1: General requirements	HD 21.1 S4	2002
IEC 60245-1 [3)]	2003	Rubber insulated cables - Rated voltages up to and including 450/750 V Part 1: General requirements	IEC 60245-1	2003
IEC 60252-1	- [1)]	AC motor capacitors Part 1: General - Performance, testing and rating - Safety requirements - Guidance for installation and operation	EN 60252-1	2011
IEC 60320-1	- [1)]	Appliance couplers for household and similar general purposes Part 1: General requirements	EN 60320-1	2001
IEC 60335-1 (mod)	2010	Household and similar electrical appliances - Safety Part 1: General requirements	EN 60335-1	2012
IEC 60364-4-41 (mod)	2005	Low-voltage electrical installations Part 4-41: Protection for safety - Protection against electric shock	HD 60364-4-41	2006
IEC 60384-14	2005	Fixed capacitors for use in electronic equipment Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains	EN 60384-14	2005
IEC 60417	Data base	Graphical symbols for use on equipment available from http://www.graphical-symbols.info/equipment	IEC 60417	2004
IEC 60445	- [1)]	Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals, conductor terminations and conductors	EN 60445	2010
IEC 60447	- [1)]	Basic and safety principles for man-machine interface, marking and identification - Actuating principles	EN 60447	2004
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
A1	1999		A1	2000
IEC 60601-1-2	- [1)]	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
IEC 60601-1-3	- [1)]	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3 + corr. March	2008 2010
A1	- [1)]		A1	2013

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 60601-1-6	-[1)]	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
IEC 60601-1-8	-[1)]	Medical electrical equipment Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8 + corr. March	2007 2010
A1	-[1)]		A1	2013
IEC 60664-1	2007	Insulation coordination for equipment within low-voltage systems Part 1: Principles, requirements and tests	EN 60664-1	2007
IEC 60695-11-10	-[1)]	Fire hazard testing Part 11-10: Test flames - 50 W horizontal and vertical flame test methods	EN 60695-11-10	1999
A1				2003
IEC 60730-1 (mod)	2010	Automatic electrical controls for household and similar use Part 1: General requirements	EN 60730-1	2011
IEC 60825-1	2007	Safety of laser products Part 1: Equipment classification and requirements	EN 60825-1	2007
IEC 60851-3	2009	Winding wires - Test methods Part 3: Mechanical properties	EN 60851-3	2009
IEC 60851-5	2008	Winding wires - Test methods Part 5: Electrical properties	EN 60851-5	2008
IEC 60851-6 A1	1996 1997	Winding wires - Test methods Part 6: Thermal properties	EN 60851-6 A1	1996 1997
IEC/TR 60878	2003	Graphical symbols for electrical equipment in medical practice	IEC/TR 60878	2003
IEC 60884-1	-[1)]	Plugs and socket-outlets for household and similar purposes Part 1: General requirements	IEC 60884-1	2013
IEC 60950-1 (mod)	2001	Information technology equipment - Safety Part 1: General requirements	EN 60950-1 + corr. April A11	2001 2004 2004
IEC 61058-1 (mod) A1 A2	2000 2001 2007	Switches for appliances Part 1: General requirements	EN 61058-1 A2	2002 2008
IEC 61558-2-1	-[1)]	Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications	EN 61558-2-1	2007
IEC 61672-1	-[1)]	Electroacoustics - Sound level meters Part 1: Specifications	EN 61672-1	2003
IEC 61672-2	-[1)]	Electroacoustics - Sound level meters Part 2: Pattern evaluation tests	EN 61672-2	2003

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 61965	- [1)]	Mechanical safety of cathode ray tubes	EN 61965	2003
IEC 62133	- [1)]	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	EN 62133	2013
IEC 62304	2006	Medical device software – Software lifecycle processes	EN 62304 + corr. November	2006 2008
ISO 780	- [1)]	Packaging - Pictorial marking for handling of goods	EN ISO 780	1999
ISO 1853	- [1)]	Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity	ISO 1853	2011
ISO 2878	- [1)]	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance	ISO 2878	2011
ISO 2882	- [1)]	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	ISO 2882	1997
ISO 3746	- [1)]	Acoustics - Determination of sound power levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane	EN ISO 3746	2010

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Publication	Year	Title	EN/HD and IEC/ISO	Year
ISO 3864-1	2002	Graphical symbols - Safety colours and safety signs Part 1: Design principles for safety signs in workplaces and public areas	ISO 3864-1	2011
ISO 7000	2004	Graphical symbols for use on equipment – Collection of symbols	ISO 7000	2004
ISO 7010	2011	Graphical symbols – Safety colours and safety signs – Registered safety signs	EN ISO 7010	2012
ISO 9614-1	- [1)]	Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points	EN ISO 9614-1	2009
ISO 10993 all parts	- [1)]	Biological evaluation of medical devices	See list below	
ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1	2009
+ corr June	2010			
ISO 10993-2	2006	Biological evaluation of medical devices - Part 2: Animal welfare requirements	EN ISO 10993-2	2006
ISO 10993-3	2003	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3	2003
ISO 10994-4	2002	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood		
A1	2006		EN ISO 10993-4	2009
ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5	2009
ISO 10993-6	2007	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	EN ISO 10993-6	2009
ISO 10993-7	2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7	2008
+ corr November	2009		+ AC	2009
ISO 10993-9	2009	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	EN ISO 10993-9	2009
ISO 10993-10	2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10	2010
ISO 10993-11	2006	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11	2009
ISO 10993-12	2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12	2012
ISO 10993-13	2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	EN ISO 10993-13	2010
ISO 10993-14	2001	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	EN ISO 10993-14	2009
ISO 10993-15	2000	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	EN ISO 10993-15	2009
ISO 10993-16	2010	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	EN ISO 10993-16	2010

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Publication	Year	Title	EN/HD and IEC/ISO	Year
ISO 10993-17	2002	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17	2009
ISO 10993-18	2005	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	EN ISO 10993-18	2009
ISO/TS 10993-19	2006	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials	ISO/TS 10993-19	2006
ISO/TS 10993-20	2006	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices	ISO/TS 10993-20	2006
ISO 11135-1	2007	Sterilization of health care products – Ethylene oxide – Part 1:Requirements for development, validation and routine control of a sterilization process formedical devices	EN ISO 11135-1	2007
ISO 11137-1	2006	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	EN ISO 11137-1	2006
ISO 13857	2008	Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs	EN ISO 13857	2008
ISO 14971	2007	Medical devices – Application of risk management to medical devices	EN ISO 14971	2012
ISO 15223-1	2012	ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	EN ISO 15223-1	2012
ISO 17665-1	2006	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 17665-1	2006
ISO 23529	- [1)]	Rubber – General procedures for preparing and conditioning test pieces for physical test methods	ISO 23529	2010
ISO 80000-1	2009	Quantities and units – Part 1: General	EN ISO 80000-1	2013

1) Undated reference, converted to dated reference in this European Standard.

2) HD 21.1 S4:2002, *Cables of rated voltages up to and including 450/750 V and having thermoplastic insulation -*

Part 1: General requirements, which is related to, but not directly equivalent with, IEC 60227-1, applies instead.

3) HD 22.1 S4:2002, *Cables of rated voltages up to and including 450/750 V and having cross-linked insulation - Part 1:General requirements*, which is related to, but not directly equivalent with, IEC 60245-1, applies instead.

Annex ZZA	**Annex ZZA** (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices**	**–**
	This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of the EC Directives 93/42/EEC as amended by 2007/47/EC.	**–**

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

	General Guidance:	**-**
	Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.	**–**
	NOTE 1 This standard is intended to be applied in its entirety only. Selected clauses or subclauses may be not applicable due to the specific type of equipment under consideration. It is necessary to understand and apply Clauses 1 to 5. It is also recommended to understand and apply those clauses which contain general requirements related to a specific subclause. Elements of the standard that are not cited in Table ZZA.1 may be relevant for the appropriate fulfilment of certain essential requirements through indirect reference, and for safety and performance aspects of the device, that are not addressed through essential requirements.	**–**
	NOTE 2 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the MDD (Directive 93/42/EEC amended by 2007/47/EC). This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.	**–**
	NOTE 3 With respect to note 4 of clause 4.2.2 General requirement for risk management, the manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.	**–**
	NOTE 4 References in the clauses 3 to 17 or in the Annexes of this standard specify whether the normative references listed in Clause 2 as cited in Annex ZA are to be applied in whole or in part.	**–**
	NOTE 5 This Annex ZZA is based on Normative References according to Annex ZA, replacing the references in the core text.	**–**
	WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.	**–**

Table ZZA.1	**Relationship between Essential Requirements of Directive 93/42/EEC amended by 2007/47/EC, and Clauses and Subclauses of this standard**	
I.	**--**	
1.	**General Guidance note 2 and 3 shall be observed**	
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include:	Not completely covered But If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER for equipment in the scope of this standard.

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	- reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	Not covered See EN/IEC 60601-1-6, EN/IEC 62366, EN/IEC 60601-1-11 and EN/IEC 60601-1-12	
	- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	Covered only for accompanying documents by: 7.9.1 Paragraphs 4 and 5, intended operator	
2.	**General Guidance note 2 and 3 shall be observed**		
2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	1st paragraph: Covered only in respect of the following and under the condition that 2nd paragraph (including the following 3 bullets) is taken into account: 8 Protection against electrical hazards from ME equipment 9 Protection against mechanical hazards of ME equipment and ME systems 15 Construction of me equipment 2nd paragraph (including the following 3 bullets) Not covered in the normative text.	
	- eliminate or reduce risks as far as possible (inherently safe design and construction),	--	
	- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	--	
	- inform users of the residual risks due to any shortcomings of the protection measures adopted.	--	
3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	Not covered.	
4	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	Not covered However, the standard provides a procedure for the generation of information that is necessary to document that the device is in compliance with this ER.	
5.	**General Guidance note 2 and 3 shall be observed**		

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

5	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Covered only in respect of the following: Instructions and information provided by the manufacturer 7.2.17 Marking on protective packaging 7.9.3.1 Technical description 15.3.7 Environmental influences
6.	**General Guidance note 2 and 3 shall be observed**	
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	Not covered.
6a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	Not covered.
II		
7.	**Chemical, physical and biological properties**	**General Guidance note 2 and 3 shall be observed**
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I (3) on the 'General requirements'. Particular attention must be paid to:	Not covered.
	- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	Partially covered in respect of the following: Toxicity: 11.7 Biocompatibility, the manufacturer should apply the appropriate part of the EN ISO 10993 series 13.1.2 Emissions, deformation of Enclosure or exceeding maximum temperature Flammability: 11.2 Fire prevention 11.3 Constructional requirements for fire enclosures 11.4 ME equipment and ME systems intended for use with flammable anaesthetics Annex G Protection against hazards of ignition of flammable anaesthetic mixtures
	- the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,	Not covered The manufacturer should apply the appropriate part of the EN ISO 10993 series
	- where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand.	Not covered

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
7.2	The devices must be designed, manufactured and packed in such a way as to minimize the risks posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	Not covered.	
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures;	Covered only for the physical properties dealt with in Subclauses: 11.2.2 ME equipment and ME systems used in conjunction with oxygen rich environments 11.2.3 Single fault conditions related to oxygen rich environments and 11.6.1, 11.6.2, 11.6.3, 11.6.4, 11.6.6, 11.6.7, 11.6.8 (Overflow, spillage, leakage, cleaning, disinfection, sterilization and compatibility with substances used)	
	if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	Not covered.	
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.	Not covered.	
	For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body.	Not covered.	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.		
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.	Covered in respect of the following: 9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure, 11.6.1 Protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, compatibility with substances 11.6.2 Overflow 15.4.9 Oil containers	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

	Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances.	Not covered.
	If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.	Not covered.
	If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	Not covered.
7.6	Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	Not covered.
8	**Infection and microbial contamination**	**General Guidance note 2 and 3 shall be observed**
8.1	The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	Not covered.
8.2	Tissues of animal origin must originate from animals that have been subject to veterinary controls and surveillance adapted to the intended use of the tissues.	Not covered

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

	Notified Bodies shall retain information on the geographical origin of the animals.	Not covered
	Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other *transmissible* agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	Not covered
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	Not covered
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	Not covered
8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	Not covered
8.6	Packaging system for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination;	Covered in respect of 7.2.17 Marking aspects of protective packaging
	the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Not covered
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Not covered
9	**Construction and environmental properties**	**General Guidance note 2 and 3 shall be observed**
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices.	Covered in respect of the following: 9.1 Mechanical hazards 16.3 Power supply 16.5 Separation devices 16.6 Leakage currents 16.8 Interruption of power supply
	Any restrictions on use must be indicated on the label or in the instructions for use.	Covered by 16.2 Accompanying documents of an ME system

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:	--	
	- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	Covered in respect of the following: 8.1 Electric shock 9.1 Mechanical Hazards 10 Radiation (all types) 11.1 Excessive temperatures 11.2 Fire prevention 11.4 Flammable anaesthetics 11.5 Flammable agent 11.6.3 Spillage 11.8 Interruption of power supply 12.4 Hazardous output 13.1 Hazardous situations 13.2 Single Fault condition 15.3 Mechanical strength 15.4 Components and general assembly 15.5.3 Construction of transformers 16.3 Power supply 16.5 Separation devices 16.6 Leakage currents 16.8 Interruption of power supply	
	- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration;	Not covered. See for EMC EN 60601-1-2 as referenced in Annex ZA See for acceleration EN 60601-1-11 and EN 60601-1-12 as referenced in Annex ZA Covered in respect of the following: pressure, temperature: test in 5.3 according to manufacturers' specification in 7.9.3.1	
	- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	Not covered. See for EMC EN 60601-1-2 as referenced in annex ZA	
	- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	Not covered.	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
9.3	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition.	Covered in respect of the following: Normal use 9.7.5 Pressure vessels, Single fault condition: 11.2 Fire prevention 11.3 Fire enclosures 11.4 Flammable anaesthetics Annex G ignition of flammable anaesthetic mixtures	
	Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	Covered in respect of the following: 11.4 Flammable anaesthetics Annex G ignition of flammable anaesthetic mixtures	
10	**Devices with a measuring function**		
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device.	Not covered. See particular standards EN 60601-2-xx See 12.1 in respect of risks associated with accuracy of controls and instruments	
	The limits of accuracy must be indicated by the manufacturer.	Covered by 7.9.3.1 technical description	
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	Not covered. See EN IEC 60601-1-6 and EN IEC 62366	
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	Covered in respect of the following: 7.4.3 Units of measurement cmH2O is not included in 80/181/EEC	
11	**Protection against radiation**	**General Guidance note 2 and 3 shall be observed**	
11.1	**General**	**--**	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	For unintended radiation, covered in respect to the following: 10.1.1 (ionizing radiation), 10.3 (microwave), 10.4 (lasers). For intended radiation, covered in respect to the following: 10.3 (microwave), 10.4 (lasers). Other types of radiation of these devices and other devices not covered. For devices intended to produce radiation see EN 60601-1-3 for diagnostic x-radiation. For other radiation see particular standards EN 60601-2-xx.	
11.2	**Intended radiation**	**--**	
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	1st and 2nd sentence covered in respect of the following: 10.3, Microwave 10.4 Lasers First sentence covered by subclauses 15.4.6, Actuating parts of controls and 15.4.7 hand or foot switches See particular standards EN 60601-2-xx See EN 60601-1-3 for diagnostic x-radiation	
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	Not covered.	
11.3	**Unintended radiation**	**--**	
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	Covered in respect to the following: 10.1.1 (ionizing radiation), 10.3 (microwave), 10.4 (lasers). Other types of radiation of these devices and other devices not covered.	
11.4	**Instructions**	**--**	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Covered in respect of information relating to the nature of the emitted radiation: 7.9.2.17 – ME equipment emitting radiation
11.5	**Ionizing radiation**	**--**
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	Not covered. For diagnostic x-radiation see EN 60601-1-3. For other devices see particular standards EN 60601-2-xx
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	Not covered For diagnostic x-radiation see EN 60601-1-3. For other devices see particular standards EN 60601-2-xx
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	Not covered.
12	**Requirements for medical devices connected to or equipped with an energy source**	**General Guidance note 2 and 3 shall be observed**
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	Covered by 14 Programmable electrical medical systems (PEMS)
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	Covered in respect of devices which incorporate SW by 14 Programmable electrical medical systems (PEMS)
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	Not covered.
12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	Not covered.

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	Not covered
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	Not covered EMC: see EN 60601-1-2 as referenced in annex ZA
12.6	**Protection against electrical risks**	**--**
12.6.1	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	Covered in respect of the following: 6.2 Protection against electric shock 7.2.10 Applied parts 7.9 Accompanying documents 8 Protection against electrical hazard 13.1 Specific hazardous situation 13.2 Single fault conditions 16.6 Leakage currents
12.7	**Protection against mechanical and thermal risks**	**--**
12.7.1	Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	Covered in respect of the following: 9.1 Mechanical Hazard 15.3 Mechanical strength
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	Covered in respect of the following: 9.6 Acoustic energy and vibration 9.8.1 Support systems
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	Covered in respect of 9.6 Acoustic energy and vibration

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

12.7.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	Covered in respect of the following: Electrical Risks: 8.1 Fundamental rule of protection against electric shock 8.2 Connection to power sources 8.4 Limitation of voltage current or energy 8,5 Separation of parts 8.6 Functional earthing 8.7 Leakage current 8.11.3 Power supply cords Gas or Hydraulic and Pneumatic: 9.7 Pressure vessels and parts
12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	Covered by 11.1 Excessive temperatures
12.8	**Protection against the risks posed to the patient by energy supplies or substances**	**--**
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	Covered in respect of the following: 15.4.2 Temperature and overload control devices 15.4.4 Indicators for standby and output 15.4.6 Actuating parts of controls 15.4.7 Cord-connected hand-held and foot-operated control devices
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.	Covered in respect of the following: 15.4.1 Construction of connectors 15.4.2 Temperature and overload control devices 15.4.4 indicators for standby and output 15.4.5 Pre-set controls 15.4.6 Actuating parts of controls 15.4.7 Cord-connected hand-held and foot-operated control devices

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	Covered in respect of the following: Energy Source: 12.4 Protection against hazardous output 14 In respect of programmable electrical medical systems (PEMS) 15.4.1 Construction of connectors 15.4.2 Temperature and overload control devices 15.4.4 Indicators for standby and output 15.4.5 Pre-set controls 15.4.6 Actuating parts of controls 15.4.7 Cord-connected hand-held and foot-operated control devices Substance Source: 9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure 12.4 Protection against hazardous output 14 In respect of programmable electrical medical systems (PEMS) 15.4.4 Indicators for standby and output 15.4.5 Pre-set controls 15.4.6 Actuating parts of controls	
12.9	The function of the controls and indicators must be clearly specified on the devices	Covered in respect of the following: 7.4 Marking of controls and instruments	
	Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	Covered in respect of the following: 7.5 Safety signs 7.9.1 General requirements for accompanying documents	
13	**Information supplied by the manufacturer**	**--**	
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use.	Covered in respect of the following: 7.2.2 Identification 7.2.4 Accessories 7.2.5 Power from other equipment 7.9 Accompanying documents	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.	Covered in respect of the following: 7.2.3 Consult accompanying documents 7.9 Accompanying documents	
	Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	Covered in respect of the following: 7.9.1 Accompanying documents, general 7.9.2 Instructions for use	
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colors must be described in the documentation supplied with the device.	Covered in respect of the following: 7.6 Symbols Annex D Symbols on marking – informative annex for information only	
13.3	The label must bear the following particulars: (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community; (b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (c) where appropriate, the word 'STERILE'; (d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number; (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month; (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; (g) if the device is custom-made, the words 'custom-made device'; (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations';	Covered in respect of the following: a) 7.2.2 Identification (partially covered: in order to comply with this ER, name and address must be used). Std. does not address the specifics of imported devices (authorized representative). b) 7.2.2 Identification (limited to details related to the identification of the device) c) 7.2.17 Protective packaging d) 7.2.2 Identification, 7.2.4 Accessories (the std. does not require to use the word LOT which has to be added) e) 7.2.2 Identification (std. does not specify the format, however, the note directs to a standard that specifies the format) f) 7.2.1 Marking (std. allows three options, manufacturer needs to limit himself on just one) g) Not covered h) Not covered i) 7.2.17 Protective packaging j) Covered: 7.2 Marking on the outside of equipment and parts 7.3 Marking on the inside of equipment and	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

	(i) any special storage and/or handling conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number; (m) where applicable, method of sterilization;	parts 7.5 Safety signs k) Covered: 7.2.2 Identification 7.2.20 Removable protective means 7.3 Marking on the inside of equipment and parts l) 7.2.2 Identification m) 7.2.17 Protective packaging
	(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	n) Not covered.
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Not covered.
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Covered. 7.2.2 Identification
13.6	Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; (e) where appropriate, information to avoid certain risks in connection with implantation of the device; (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-	a) Details referred to in Section 13.3, with the exception of (d) and (e): 13.3 a) Instructions for Use: authorized representative: not covered Instructions for Use: 7.9.2 Instructions for use 13.3 b) Instructions for Use: 7.9.1 General on accompanying documents (for electronic Instructions for Use adhere to EU legislation 2007/12) 13.3 c) Instructions for Use: 7.9.2.18 Equipment and accessories supplied sterile (partly covered, the word “sterile” is not required by the standard) 13.3 d) Exempted for Instructions for Use. 13.3 e) Exempted for Instructions for Use 13.3 f) Instructions for Use: not covered 13.3 g) Instructions for Use: not covered 13.3 h) Instructions for Use: not covered 13.3 i) Instructions for Use: Covered in respect of the following: 7.9.2.2 Warning and safety notices 7.9.2.18 Equipment and accessories supplied sterile

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	sterilization;	7.9.3.1 General on Technical description 9.4.4.a Grips and other handling devices Remark: handling is assumed to include installation, but to be different from operating use 13.3 k) Instructions for Use: Covered in respect of the following: 7.9.2.2 Warning and safety notices, first sentence 13.3 l) Instructions for Use: not covered 13.3 m) Instructions for Use: not covered 13.3 n) Instructions for Use: not covered b) Performances referred to in Section 3 Not covered c) If the device must be installed with or connected to other medical devices Covered in respect of the following: 7.9.1, General on accompanying documents 7.9.2.1 General on instructions for use 7.9.2.14 Accessories, supplementary equipment, used material 7.9.3, Technical description 14 Programmable electrical medical systems (PEMS) d) Covered in respect of the following: 7.9.2.9 Operating instructions 7.9.2.13 Maintenance e) Not covered f) Not covered g) Covered in respect of the following: 7.2.17 Protective packaging 7.9.2.18 ME equipment and accessories supplied sterile
	(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses.	h) Covered in respect of 7.9.2.12 Cleaning, disinfection and sterilization i) Covered in respect of 7.9 Accompanying documents

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I; If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; (i) details of any further treatment or handling needed before the device can be used (for example sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation. The instructions for use must also include details allowing the medical staff to brief the patient on any contraindications and any precautions to be taken. These details should cover in particular: (k) precautions to be taken in the event of changes in the performance of the device; (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; (n) precautions to be taken against any special, unusual risks related to the disposal of the device; (o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; (p) degree of accuracy claimed for devices with a measuring function; (q) date of issue or the latest revision of the instructions for use.	j) Covered in respect of 7.9.2.17 ME equipment emitting radiation k) Not covered l) Not covered m) Not covered n) Not covered o) Not covered p) Not covered q) Not covered	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Annex ZZB	**Annex ZZB** (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices**	**–**
	This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of the EC Directives 90/385/EEC as amended by 2007/47/EC.	-
	General Guidance:	**–**
	Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.	**–**
	NOTE 1 This standard is intended to be applied in its entirety only. Selected clauses or subclauses may be not applicable due to the specific type of equipment under consideration. It is necessary to understand and apply Clauses 1 to 16. It is also recommended to understand and apply those clauses which contain general requirements related to a specific subclause. Elements of the standard that are not cited in Table ZZB.1 may be relevant for the appropriate fulfilment of certain essential requirements through indirect reference, and for safety and performance aspects of the device, that are not addressed through essential requirements	**–**
	NOTE 2 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the AIMD (Directive 90/385/EEC amended by 2007/47/EC). This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.	**–**
	NOTE 3 With respect to Note 4 of clause 4.2.2 General requirement for risk management, the manufacturer’s policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.	**–**
	NOTE 4 References in the Clauses 3 to 17 or in the Annexes of this standard specify whether the normative references listed in Clause 2 as cited in Annex ZA are to be applied in whole or in part.	**–**
	NOTE 5 This Annex ZZB is based on Normative References according to Annex ZA, replacing the references in the core text.	**–**
	WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.	**–**

Table ZZB.1	**Relationship between Essential Requirements of Directive 90/385/EEC amended by 2007/47/EC, and Clauses and Subclauses of this standard**	
No.	Essential Requirement	Coverage
I	GENERAL REQUIREMENTS	
1.	General Guidance notes 2 and 3 shall be observed	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

1	The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.	Not covered This ER relates to the implanted part of the active implantable medical device.
2	The devices must achieve the performances intended by the manufacturer, viz. Be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a) as specified by him.	Not covered.
3	The characteristics and performances referred to in sections 1 and 2 must not be adversely affected to such a degree that the clinical condition and safety of the patients or, as appropriate, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.	Not covered. However, the standard provides a procedure for the generation of information that is necessary to document that the device is in compliance with this ER with regard to the external parts of an active implantable medical device.
4	General Guidance notes 2 and 3 shall be observed	
4	The devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacturer (temperature, humidity, etc.).	Covered for the external part of an active implantable medical device only in respect of the following: 7.2.17 Marking on protective packaging 7.9.3.1 Technical description 15.3.7 Environmental influences
5	General Guidance notes 2 and 3 shall be observed	
5	Any side effects or undesirable conditions must constitute acceptable risks when weighed against the performances intended.	Not covered.
5a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex 7.	Not covered.
II	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**	
6	The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles taking account of the generally acknowledged state of the art.	Covered for the external part of an active implantable medical device only in respect of the following: 8 Protection against electrical hazards from ME equipment 9 Protection against mechanical hazards of ME equipment and ME systems 15 Construction of ME equipment

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
7	Implantable devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted.	Not covered.	
8	General Guidance notes 2 and 3 shall be observed		
8	Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:	--	
	- the risk of physical injury in connection with their physical, including dimensional, features,	Covered for the external part of an active implantable medical device only in respect of the following: 8.1 Electric shock 9.1 Mechanical Hazards 10 Radiation (all types) 11.1 Excessive temperatures 11.2 Fire prevention 11.4 Flammable anaesthetics 11.5 Flammable agent 11.6.3 Spillage 11.8 Interruption of power supply 12.4 Hazardous output 13.1 Hazardous situations 13.2 Single Fault condition 15.3 Mechanical strength 15.4 Components and general assembly 15.5.3 Construction of transformers 16.3 Power supply 16.5 Separation devices 16.6 Leakage currents 16.8 Interruption of power supply	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	- risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,	Covered for the external part of an active implantable medical device only in respect of the following: 8.1 Electric shock 13.2 Single Fault condition 15.5.3 Construction of transformers 16.3 Power supply 16.5 Separation devices 16.6 Leakage currents 16.8 Interruption of power supply	
	- risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,	Not covered. See for EMC EN 60601-1-2 as referenced in Annex ZA See for acceleration EN 60601-1-11 and EN 60601-1-12 as referenced in Annex ZA Covered in respect of the following: pressure, temperature: test in 5.3 according to manufacturers' specification in 7.9.3.1	
	- risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,	Covered for the external part of an active implantable medical device only in respect of the following: For defibrillator protection 8.5.5 Defibrillation-proof applied parts	
	- risks connected with ionising radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (1) and Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (1),	Not covered.	
	- risks which may arise where maintenance and calibration are impossible, including: - excessive increase of leakage currents, - ageing of the materials used, - excess heat generated by the device, - decreased accuracy of any measuring or control mechanism.	Not covered.	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
9	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in I. 'General requirements', with particular attention being paid to:	**--**	
	- the choice of materials used, particularly as regards toxicity aspects,	Not covered. The manufacturer should apply the appropriate part of EN ISO 10993.	
	- mutual compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the device,	Not covered. The manufacturer should apply the appropriate part of EN ISO 10993.	
	- compatibility of the devices with the substances they are intended to administer,	Not covered.	
	- the quality of the connections, particularly in respect of safety,	Covered for the external part of an active implantable medical device only in respect of the following: Covered in respect of the following: 15.4.1 Construction of connectors	
	- the reliability of the source of energy,	Not covered.	
	- if appropriate, that they are leakproof,	Covered for the external part of an active implantable medical device only in respect of the following: 9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure, 11.6.1 Protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, compatibility with substances 11.6.2 Overflow 15.4.9 Oil containers	
	- proper functioning of the programming and control systems, including software. For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification	Covered for the external part of an active implantable medical device which incorporates software by 14 Programmable electrical medical systems (PEMS)	
10	- Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to	Not covered.	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (2) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance, including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance to the device or not. The notified body shall take the updated scientific opinion into		

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict

	account in reconsidering its assessment of the conformity assessment procedure.	
11	The devices and, if appropriate, their component parts must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.	Not covered.
12	Devices must bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.	Not covered.
13	When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	Covered for the external part of an active implantable medical device only in respect of the following: 7.5 Safety signs 7.9.1 General requirements for accompanying documents
14	On the sterile pack:	Not covered.
	- the method of sterilization,	Not covered.
	- an indication permitting this packaging to be recognized as such,	Not covered.
	- the name and address of the manufacturer,	Not covered.
	- a description of the device,	Not covered.
	- if the device is intended for clinical investigations, the words: ‘exclusively for clinical investigations	Not covered.
	- if the device is custom-made, the words ‘custom-made device’,	Not covered.
	- a declaration that the implantable device is in a sterile condition,	Not covered.
	- the month and year of manufacture,	Not covered.
	- an indication of the time limit for implanting a device safely.	Not covered.
14.2	On the sales packaging:	Not covered.
	- the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the Community,	Not covered.
	- a description of the device,	Not covered.
	- the purpose of the device,	Not covered.
	- the relevant characteristics for its use,	Not covered.

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	- if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',	Not covered.	
	- if the device is custom-made, the words: 'custom-made device',	Not covered.	
	- a declaration that the implantable device is in a sterile condition,	Not covered.	
	- the month and year of manufacture,	Not covered.	
	- an indication of the time limit for implanting a device safely,	Not covered.	
	- the conditions for transporting and staring the device,	Not covered.	
	- in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	Not covered.	
15	When placed on the market, each device must be accompanied by instructions for use giving the following particulars:	Not covered.	
	- the year of authorization to affix the CE mark,	Not covered.	
	- the details referred to in 14.1 and 14.2, with the exception of those referred to in the eighth and ninth indents,	Not covered.	
	- the performances referred to in section 2 and any undesirable side effects,	Not covered.	
	- information allowing the physician to select a suitable device and the corresponding software and accessories,	Not covered.	
	- information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures,	Not covered.	
	- information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided,	Not covered.	
	- information regarding the risks of reciprocal interference (1) in connection with the presence of the device during specific investigations or treatment,	Not covered.	
	- the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization,	Not covered.	

European Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	- an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.	Not covered.	
	The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken. These details should cover in particular:	Not covered.	
	- information allowing the lifetime of the energy source to be established,	Not covered.	
	- precautions to be taken should changes occur in the device's performance,	Not covered.	
	- precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, etc.,	Not covered.	
	- adequate information regarding the medicinal products which the device in question is designed to administer,	Not covered.	
	- date of issue or the latest revision of the instructions for use.	Not covered.	
16	Confirmation that the device satisfies the requirements in respect of characteristics and performances, as referred to in I. 'General requirements', in normal conditions of use, and the evaluation of the side effects or undesirable effects must be based on clinical data established in accordance with Annex 7.	Not covered.	