**Test Report issued under the responsibility of:**

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# TEST REPORT
# IEC 60601-1-6
# Medical electrical equipment - Part 1-6:
# General requirements for basic safety and essential performance - Collateral standard: Usability

| | |
|---|---|
| **Report Number. ..... :** | **230500749SHA-002** |
| **Date of issue ..... :** | **2023-06-07** |
| **Total number of pages ..... :** | **15** |
| **Name of Testing Laboratory preparing the Report ..... :** | Intertek Testing Services Shanghai<br>Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China |
| **Applicant's name ..... :** | GlobTek, Inc. |
| **Address ..... :** | 186 Veterans Drive Northvale NJ 07647, USA |
| **Test specification:** | |
| **Standard ..... :** | IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 for use in conjunction with IEC 62366-1:2015, AMD1:2020, and IEC 60601-1:2005, AMD1:2012, AMD2:2020 |
| **Test procedure ..... :** | CB Scheme |
| **Non-standard test method ..... :** | N/A |
| **TRF template used ..... :** | IECEE OD-2020-F1:2020, Ed.1.3 |
| **Test Report Form No. ..... :** | IEC60601_1_6K |
| **Test Report Form(s) Originator .... :** | TÜV Rheinland of North America |
| **Master TRF ..... :** | Dated 2020-11-23 |



If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

**This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.**

**General disclaimer:**

The test 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 Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

| | |
|---|---|
| **Test item description ..... :** | Medical Power Supply |
| **Trade Mark(s) ..... :** | GlobTek, Inc. |
| **Manufacturer ..... :** | GlobTek, Inc.<br>186 Veterans Drive Northvale NJ 07647, USA |
| **Model/Type reference ..... :** | GT*46101-*05*-USB, GT*46101-*06*-USB<br>(Refer to page 6 for details.) |
| **Ratings ..... :** | Input: 100-240V~, 50-60Hz, 0.3A;<br>Output :<br>GT*46101-*05*-USB: 5Vdc, 2A max.<br>GT*46101-*06*-USB: 5.1-5.5Vdc, 2.54A max. |

**Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):**

| | | | |
|---|---|---|---|
| ☒ | **CB Testing Laboratory:** | Intertek Testing Services Shanghai | |
| **Testing location/ address.....:** | | Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China | |
| **Tested by (name, function, signature).....:** | | Vivian Xu (Engineer) | Vivian Xu |
| **Approved by (name, function, signature)...:** | | Larry Zhong<br>(Mandated reviewer) | Larry Zhong |
| ☐ | **Testing procedure: CTF Stage 1:** | N/A | |
| **Testing location/ address.....:** | | | |
| **Tested by (name, function, signature).....:** | | | |
| **Approved by (name, function, signature)...:** | | | |
| ☐ | **Testing procedure: CTF Stage 2:** | N/A | |
| **Testing location/ address.....:** | | | |
| **Tested by (name + signature).....:** | | | |
| **Witnessed by (name, function, signature) .:** | | | |
| **Approved by (name, function, signature)...:** | | | |
| ☐ | **Testing procedure: CTF Stage 3:** | N/A | |
| ☐ | **Testing procedure: CTF Stage 4:** | N/A | |
| **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):**
ANNEX I – IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist (Pages: 11)

**Summary of testing:**

| **Tests performed (name of test and test clause):** | **Testing location:** |
|---|---|
| Process standard only, no testing | N/A |

**Summary of compliance with National Differences (List of countries addressed):**
None

☒ **The product fulfils the requirements of** IEC 60601-1-6:2010, AMD1:2013, AMD2:2020

**Statement concerning the uncertainty of the measurement systems used for the tests**

☒ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

**Procedure number, issue date and title:**

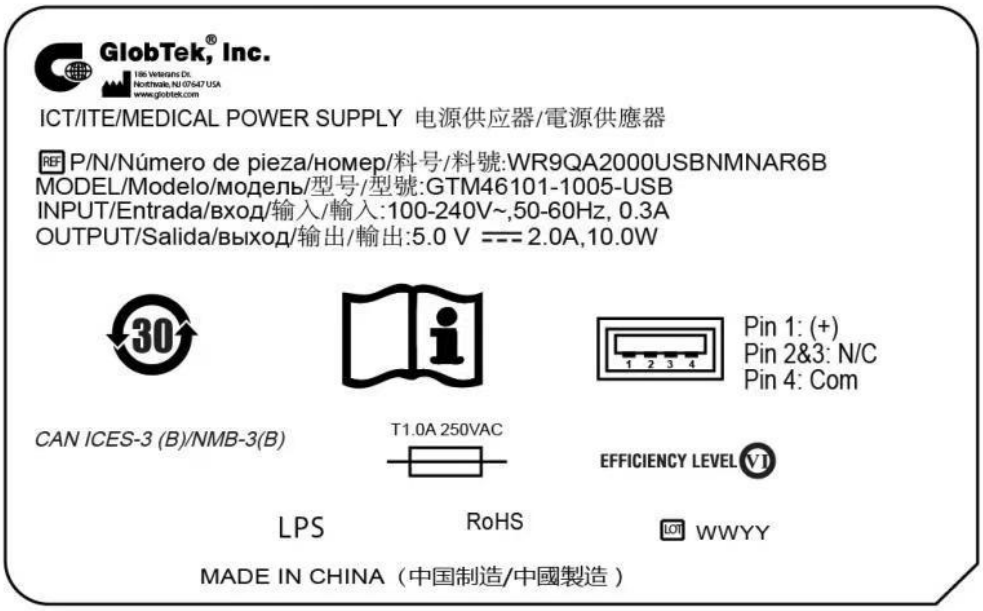
**GMS-QC-12 Estimation of Measurement Uncertainty, 19-April-2018 Initial Release.**

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

☐ **Statement not required by the standard used for type testing**

**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.**




Note:
The above markings are the minimum requirements required by the safety standard. For the final production samples, the additional markings which do not give rise to misunderstanding may be added.
Other models are with similar label as corresponding above models except different model name and output ratings.
When the equipment is vended to EU, the name and address of the importer or authorized representative within the EEA shall be added on the equipment;

| | |
|---|---|
| **Test item particulars.....:** | |
| **Classification of installation and use.....:** | Direct plug-in for power adapter model |
| **Supply Connection.....:** | Direct plug-in |
| **Possible test case verdicts:** | |
| **- test case does not apply to the test object.....:** | N/A |
| **- test object does meet the requirement.....:** | P (Pass) |
| **- test object does not meet the requirement.....:** | F (Fail) |
| **Testing.....:** | No test need |
| **Date of receipt of test item .....:** | N/A |
| **Date (s) of performance of tests.....:** | N/A |

**General remarks:**

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the 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:** | |
|---|---|
| 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**<br>☐ **Not applicable** |

**When differences exist; they shall be identified in the General product information section.**

| | |
|---|---|
| **Name and address of factory (ies).....:** | Factory 1<br>GlobTek, Inc.<br>186 Veterans Drive Northvale NJ 07647, USA<br>Factory 2<br>GlobTek (Suzhou) Co., Ltd<br>Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial Park, Suzhou, JiangSu 215021, China<br>Factory 3<br>Shenzhen ENG Electronics Co., Ltd.<br>Block B, Nuclear Group Industrial District, Baishixia, Fuyun Town, Bao'an, Shenzhen, China |

**General product information and other remarks:**

Product covered by this report is medical power supply module, which can be used as a part of medical equipment. All the models have the same structure except with or without led.

Transformers used in all models are the same. All models have same PCB, but some non-critical components may be adjusted according to different output voltage. The parameters of these components depend on output voltage.

All the types are designed for continuous operation and no applied part is defined.

The insulation construction of EUT is evaluated as 2MOPP in this report as customer's request.

Model Similarity:

GT*46101-*05*-USB , GT*46101-*06*-USB

The 1st "*" can be "M" or "-"or "H" for market identification and not related to safety.

The 2nd "*" can be "01" to "13", with interval of 1, denote the rated output wattage designation.

The 3rd "*" can be "-0.5" to "-0.9" with interval of 0.1, or blank indicate no voltage different, optional deviation, subtracted from standard output voltage.

The"05" or "06" and 3rd "*" together denote the output voltage, with a range of 5-5.5 volts.

Model list

| Model | Rated output voltage range | Max. rated output current | Max. rated output power |
|---|---|---|---|
| GT*46101-*05*-USB | 5Vdc | 2A | 10W |
| GT*46101-*06*-USB | 5.1-5.5Vdc | 2.54A | 13W |

**Technical Considerations:**

Models GTM46101-1005-USB, GTM46101-1306-0.9-USB and GTM46101-1306-0.5-USB are tested as typical models.
The products are not intended to use in environment which altitude exceed 5000m.

| IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **4.0** | **GENERAL REQUIREMENTS** | | P |
| 4.2 | USABILITY ENGINEERING PROCESS complies with IEC 62366-1 including amended definitions.<br>Excludes production and post-production monitoring, and maintenance of the USABILITY ENGINEERING PROCESS | See attached IEC 62366-1 ANNEX I | P |
| | Inspection of the USABILITY ENGINEERING FILE verified that the MANUFACTURER | | P |
| | – established a USABILITY ENGINEERING PROCESS | See QF-GT-DJD-7.3.2-4 Usability Engineering File P2/1.2 | P |
| | – established acceptance criteria for USABILITY; and | See QF-GT-DJD-7.3.2-4 Usability Engineering File P5/1.15 | P |
| | – demonstrated that the acceptance criteria for USABILITY have been met. | See QF-GT-DJD-7.3.2-4 Usability Engineering File P5/1.15 | P |
| **5** | **ME EQUIPMENT ACCOMPANYING DOCUMENTS** | | P |
| | The instructions for use shall contain a summary of the USE SPECIFICATION as specified in IEC 62366-1:2015, AMD1:2020, Clause 5.1 | Refer to “POWER SUPPLY INFORMATION” and “ELECTRICAL SPECIFICATIONS” of SPEC | P |
| | The same information is also included in the technical description, if this is provided as a separate document from instructions for use | Not separately provided | N/A |

| ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **4** | **PRINCIPLES** | | P |
| 4.1.1 | The MANUFACTURER has established, documented and maintains a USABILITY ENGINEERING PROCESS addressing USER interactions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT | QF-GT-DJD-7.3.2-4 Usability Engineering File | P |
| 4.1.2 | The USABILITY ENGINEERING PROCESS complies with this standard and the acceptance criteria in the USABILITY VALIDATION plan have been met | QF-GT-DJD-7.3.2-4Usability Engineering File | P |
| 4.1.3 | Information for SAFETY used as a RISK CONTROL measure has been evaluated according to the USABILITY ENGINEERING PROCESS | QF-GT-DJD-7.3.2-4Usability Engineering File Page 5 section1.15 | P |
| 4.2 | The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE .....: | QF-GT-DJD-7.3.2-4Usability Engineering File | P |
| 4.3 | The USABILITY ENGINEERING PROCESS is scaled-up or scaled-down based on the significance of the modification as determined by the results of the RISK ANALYSIS .....: | Document Reference No. in usability engineering file:<br>QF-GT-DJD-7.3.2-4Usability Engineering File Page 8, section 6 | P |
| **5** | **USABILITY ENGINEERING PROCESS** | | P |
| 5.1 | The MANUFACTURER shall prepare a USE SPECIFCATION. The USE SPECIFICATION shall include the following.....: | Document Reference No. in usability engineering file:<br>QF-GT-DJD-7.3.2-4Usability Engineering File | P |
| | – intended medical indication | QF-GT-DJD-7.3.2-4Usability Engineering File Page 4, section 1.4 | P |
| | – intended PATIENT population | QF-GT-DJD-7.3.2-4Usability Engineering File Page 4, section 1.4 | P |
| | – intended part of the body or type of tissue applied to or interacted with | QF-GT-DJD-7.3.2-4Usability Engineering File Page 4, section 1.4 | P |
| | – intended USER PROFILE | QF-GT-DJD-7.3.2-4Usability Engineering File Page 4, section 1.5 | P |
| | – intended USE ENVIRONMENT | QF-GT-DJD-7.3.2-4Usability Engineering File Page 4, section 1.6 | P |
| | – operating principle | Document Reference No. in usability engineering file:<br>QF-GT-DJD-7.3.2-4Usability Engineering File | P |

| ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 5.2 | The MANUFACTURER shall identify USER INTERFACE characteristics that could be related to SAFETY as part of a RISK ANALYSIS performed according to ISO 14971:2019, Clause 5.3 | QF-GT-DJD-7.3.2-4Usability Engineering File Page 6, section 2 | P |
| 5.3 | As part of this RISK ANALYSIS, the MANUFACTURER shall identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS which could affect PATIENTS, USERS or others, related to the use of the MEDICAL DEVICE. | QF-GT-DJD-7.3.2-4Usability Engineering File Page 6, section 2 | P |
| 5.4 | The RISK ANALYSIS includes a description of all the reasonably foreseeable HAZARD-RELATED USE SCENARIOS associated with the identified HAZARD and HAZARDOUS SITUATIONS. | Document Reference No. in usability engineering file:<br>QF-GT-DJD-7.3.2-4Usability Engineering File Page 4, section 1.7 | P |
| | The description of each identified HAZARD-RELATED USE SCENARIO includes all TASKS and their sequences | QF-GT-DJD-7.3.2-4Usability Engineering File Page 4, section 1.7 | P |
| | The SEVERITY of the possible resulting associated HARM was determined | QF-GT-DJD-7.3.2-4Usability Engineering File Page 4, section 1.7 | P |
| 5.5 | The MANUFACTURER shall select the HAZARD-RELATED USE SENARIOS to be included in a SUMMATIVE EVALUATION as part of the USABILITY FILE.<br>This SUMMATIVE EVALUATION shall include: | Document Reference No. in usability engineering file:<br>QF-GT-DJD-7.3.2-4 Usability Engineering File P6 section 1.18 | P |
| | - all HAZARD-RELATED USE SCENARIOS; | | P |
| | - a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM that could be caused by USE ERROR (e.g. for which medical intervention would be needed); or | | P |
| | - a subset of the HAZARD-RELATED USE SCENARIOS based on the SEVERITY of the potential HARM and based on other circumstances specific to the MEDICAL DEVICE and the MANUFACTURER | | N/A |
| | A summary of any selection scheme, the rationale for its use and the results of applying it shall be stored in the USABILITY ENGINEERING FILE | : | N/A |
| 5.6 | The MANUFACTURER shall establish and maintain a USER INTERFACE SPECIFICATION | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | P |
| 5.7 | The MANUFACTURER shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | P |

| ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 5.8 | The MANUFACTURER shall design and implement the USER INTERFACE, including the ACCOMPANYING DOCUMENTATION if needed, and training capability, if needed, as described in the USER INTERFACE SPECIFICATION .....: | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | P |
| | Where new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered during this step the MANUFACTURER shall repeat the steps of Clause 5 as appropriate | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 6 | P |
| | If training on the specific MEDICAL DEVICE is required for the safe us of the MEDICAL DEVICE by the intended USER, the MANUFACTURER shall design and implement a training capability for the EXPECTED SERVICE LIFE of the MEDICAL DEVICE by doing at least one of the following: | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 9, section 7.2 | P |
| | - provide the materials necessary for training; | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 9, section 7.2 | P |
| | - ensure the materials necessary for training are available; | QF-GT-DJD-7.3.2-12Usability Engineering File Page 9, section 7.2 | P |
| | - make the training available; or | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 9, section 7.2 | P |
| | - make training available to the RESPONSIBLE ORGANIZATION that enables it to train its USERS | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 9, section 7.2 | P |
| 5.9 | The MANUFACTURER shall perform a SUMMATIVE EVALUATION of each HAZARD-RELATED USE SCENARIO selected in Clause 5.5 | Document Reference No. in usability engineering file:<br>QF -GT-DJD-7.3.2-4 Usability Engineering File Page89, section 6 | P |
| | All USE ERRORS and use difficulties that occurred shall be identified | QF -GT-DJD-7.3.2-4 Usability Engineering File Page89, section 6 | P |
| | Where USE ERROR or use difficulty can lead to a HAZARDOUS SITUATION the root causes should be determined | QF -GT-DJD-7.3.2-4 Usability Engineering File Page89, section 6 | P |
| | If new USE ERRORS, HAZARDS, HAZARDOUS SITUATIONS or HAZARD-RELATED USE SCENARIOS are discovered during this data analysis: | | – |
| | - if yes, then the MANUFACTURER shall repeat the activities of Clause 5 as appropriate; | | P |
| | - if not, then the MANUFACTURER determine whether further improvement of the USER INTERFACE design as it relates to SAFETY is necessary and practicable | | N/A |

| ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 1) If yes, then the MANUFACTURER shall re-enter the USABILITY ENGINEERING PROCESS at Clause 5.6 | | N/A |
| | 2) If not then the MANUFACTURER shall: | | N/A |
| | i) Document why improvement is not necessary or not practicable; | | N/A |
| | ii) Identify the data from the USABILITY ENGINEERING PROCESS needed to determine the RESIDUAL RISK related to use; and | | N/A |
| | iii) Evaluate the RESIDUAL RISK according to ISO 14971:2019, Clause 7.3 | | N/A |
| 5.10 | USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) was evaluated according to Annex C rather than the requirements of 5.1 through 5.9. | | N/A |

| **Annex C** | **Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)** | | P |
|---|---|---|---|
| C.2.1 | The MANUFACTURER shall establish a USE SPECIFICATION as required in 5.1. | Document Reference No. in usability engineering file:<br>QF -GT-DJD-7.3.2-4 Usability Engineering File | P |
| C.2.2 | The MANUFACTURER of a device with UOUP shall review POST-PRODUCTION information including complaints and field reports for incidents and near incidents. All identified cases of USE ERROR shall be stored in the USABILITY ENGINEERING FILE and addressed in C.2.3 and C.2.4 | Document Reference No. in usability engineering file:<br>QF -GT-DJD-7.3.2-4 Usability Engineering File Page 4, section 1.8 | P |
| C.2.3 | The MANUFACTURER shall review the RISK ANALYSIS of the MEDICAL DEVICE with UOUP and ensure that all HAZARDS and HAZARDOUS SITUATIONS associated with USABILITY have been identified and documented | Document Reference No. in usability engineering file:<br>QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 6 | P |
| C.2.4 | The MANUFACTURER shall verify and document that adequate RISK CONTROL measures have been implemented for all identified HAZARDS and HAZARDOUS SITUATIONS identified in C.2.3 and that all RISKS are reduced to an acceptable level as indicated by the RISK ASSESSMENT | Document Reference No. in usability engineering file:<br>QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 6 | P |
| C.2.5 | Based on any new information identified in performing steps C.2.3 and C.2.4 the MANUFACTURER re-evaluated the overall RESIDUAL RISK according to ISO 14971:2019, Clause 7.3 and documented the results in either the USABILITY ENGINEERING FILE or RISK MANAGEMENT FILE | Document Reference No. in usability engineering file or Risk Management File:<br>GT-RM2015-001 | P |

| ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| **Table 5.3** | **USABILITY ENGINEERING FILE RESULTS TABLE: RISK ANALYSIS** | | **P** |
|---|---|---|---|
| | **Document Ref. in USABILITY ENGINEERING FILE** | **Result - Remarks** | **Verdict** |
| An identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS which could affect PATIENTS, USERS or others, related to the use of the MEDICAL DEVICE. was performed according to ISO 14971:2019, Clause 5.3 | QF -GT-DJD-7.3.2-4 Usability Engineering File | Acceptable according to IEC 62366-1 | P |
| During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered: | | | — |
| – USE SPECIFICATION, including USER PROFILE(S) (See 5.1) | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 4, section 1.5 | Acceptable according to IEC 62366-1 | P |
| – information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; and | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 4, section 1.5 | Acceptable according to IEC 62366-1 | P |
| – identified USE ERRORS (see 5.2). | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 4, section 1.5 | Acceptable according to IEC 62366-1 | P |

| **Table 5.6** | **USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE SPECIFICATION** | | **P** |
|---|---|---|---|
| | **Document Ref. in USABILITY ENGINEERING FILE** | **Result - Remarks** | **Verdict** |
| USER INTERFACE SPECIFICATION | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | Acceptable according to IEC 62366-1 | P |
| The USER INTERFACE SPECIFICATION shall consider: | | | — |
| – the USE SPECIFICATION (See 5.1) | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | Acceptable according to IEC 62366-1 | P |
| – the known or foreseeable USE ERRORS associated with the medical device (See 5.2); and | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | Acceptable according to IEC 62366-1 | P |
| – the HAZARD-RELATED USE SCENARIOS (See 5.4) | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | Acceptable according to IEC 62366-1 | P |
| Inputs to the USER INTERFACE SPECIFICATION shall include the following: | | | — |

| ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| **Table 5.6** | **USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE SPECIFICATION** | | **P** |
|---|---|---|---|
| | **Document Ref. in USABILITY ENGINEERING FILE** | **Result - Remarks** | **Verdict** |
| – testable technical requirements relevant to the USER INTERFACE, including the requirements for those parts of the USER INTERFACE associated with the selected RISK CONTROL measures; | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | Acceptable according to IEC 62366-1 | P |
| – an indication as to whether ACCOMPANYING DOCUMENTATION is required; and | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | Acceptable according to IEC 62366-1 | P |
| – an indication as to whether MEDICAL DEVICE specific training is required | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 7, section 3 | Acceptable according to IEC 62366-1 | P |

| **Table 5.7** | **USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan** | | **P** |
|---|---|---|---|
| | **Document Ref. in USABILITY ENGINEERING FILE** | **Result - Remarks** | **Verdict** |
| The manufacturer shall establish and maintain a USER INTERFACE EVALUATION plan for the USER INTERFACE | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| The USER INTERFACE EVALUATION plan shall document: | | | — |
| a) the objective and identify the method of any planned FORMATIVE EVALUATIONS and SUMMATIVE EVALUATIONS | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| b) if USABILITY TESTS are employed,<br>– document which USER GROUPS are intended to be included in the test; | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| – document the test environment and other conditions of use, based on the USE SPECIFICATION; | QF-GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| – specify whether ACCOMPANYING DOCUMENTATION is provided during the test; and | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| – specify whether MEDICAL DEVICE-specific training is provided prior to the test and the minimum elapsed time between the training and the beginning of the test. | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |

| ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| **Table 5.7** | **USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan** | | **P** |
|---|---|---|---|
| | **Document Ref. in USABILITY ENGINEERING FILE** | **Result - Remarks** | **Verdict** |
| The USER INTERFACE evaluation plan for FORMATIVE EVALUATION shall address: | | | — |
| a) the evaluation methods being used; | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| b) which part of the USER INTERFACE is being evaluated; and | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| c) when in the USABILITY ENGINEERING PROCESS to perform each of the USER INTERFACE EVALUATIONS. | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| For each selected HAZARD-RELATED USE SCENARIO (see 5.5), the USER INTERFACE EVALUATION plan for SUMMATIVE EVALUATION shall specify: | | | — |
| a) the evaluation method being used and a rationale that the method produces OBJECTIVE EVIDENCE; | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | |
| b) which part of the USER INTERFACE is being evaluated; | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| c) where applicable, the criteria for determining whether the information for SAFETY is perceivable, understandable and supports CORRECT USE of the MEDICAL DEVICE (4.1.3); | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| d) the availability of the ACCOMPANYING DOCUMENTATION and provision of training during the SUMMATIVE EVALUATION; and | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| e) for a USABILITY TEST,<br>– how the characteristics of the test participants are representative of the intended USER PROFILES; | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| – justifying how the test participants are grouped into distinct USER GROUPS for the purpose of determining the number of test participants; | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |

| ANNEX I - IEC 62366-1:2015, AMD1:2020 – Usability engineering process checklist | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| **Table 5.7** | **USABILITY ENGINEERING FILE RESULTS TABLE: USER INTERFACE EVALUATION plan** | | **P** |
|---|---|---|---|
| | **Document Ref. in USABILITY ENGINEERING FILE** | **Result - Remarks** | **Verdict** |
| – the test environment and conditions of use and a rationale for how they are adequately representative of the intended USE ENVIRONMENT; | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| – the definition of CORRECT USE for each HAZARD-RELATED USE SCENARIO; and | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |
| – the method of collecting data during the USABILITY TEST for the subsequent analysis of observed USE ERRORS and use difficulties. | QF -GT-DJD-7.3.2-4 Usability Engineering File Page 8, section 4 | Acceptable according to IEC 62366-1 | P |