

Electronics & Telematics Laboratory

#### Test Certificate No. <u>9552373168</u> In accordance with Clause 12 of the Standards Law – 1953

#### **Details of Order**

Name of customer : GlobTek, Inc

Address : 186 Veterans Drive Northvale, NJ 07647, USA

Date of order : 15/11/26

**Description of sample** 

Medical Power Supply

Model tested : GTM41078-0605-USB Description: Medical Power Supply

Manufacturer : GlobTek, Inc.

Country of origin : China

The sample was taken on the following date: 15/11/26

Sample size: 1

#### Nature of test

To test compliance with the requirements of clauses: of Israeli Standard SI 60601 Part 1.2-" Medical electrical equipment: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests of April 2008.

This document contains 4 pages and may be used only in full.

The test results in this document refer only to the tested item

This document is not a permit to mark the product with SII Mark

### **Test Conclusions**

The sample doesn't comply with the requirements of the standard in the following clauses:

8.11 – MAINS PARTS, components and layout

The sample complies with the other clauses of the Standard, according to the above tests. The sample doesn't tested by the other clause of the standard.

#### Remarks:

The test sample tested by Intertek Semko AB, Sweden, as per the CB test Certificate No.SE-73537, dated 16.07.2013, IEC 60601-1:2005 and C1+C2.

The CB Test Certificate was validated.

Details are given on the following pages of this document.

The original Test Certificate was signed by:

Name: Kamal Ayadeh Position: Inspector

On:<u>2015/12/24</u>

Date:2015/12/27

I confirm that this a true translation of the Hebrew original. Only the original test certificate is authentic.

Signature:

Name: Igal Zusman Position: Manager, Follow-Up Services

42 Chaim Levanon St. Tel-Aviv 69977 Israel. Management: Tel: 972-3-6467800 Fax: 972-3-6467779 www.sii.org.il Electronics: Tel: 972-3-6465050 Fax: 972-3-7454026 - Alarms Systems Section: Tel: 972-3-6465370 Fax: 972-3-6467262



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#### **Details of nonconformances**

The product tested does not comply with the requirements of the following clause.

8.11 – MAINS PARTS, components and layout

The product tested complies with the remaining requirements of the clauses to which it was tested.

#### Broadened description of the product

The instrument bears the following markings:





(Electronics & Telematics Laboratory)

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## Photo of the samples tested













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#### **Test Results:**

Clause No. in Standard	Property tested	Remarks	Defects found	Compliance with Standard
4.11	Power input	measured: 200mA		Complies
7	ME EQUIPMENT identification, marking and documents			Complies
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	measured: EnLC=26μA (ON)		Complies
8.8.3	Dielectric strength	tested at: 3KVAC(2MOOP)		Complies
8.11	MAINS PARTS, components and layout		The sample doesn't contain feeding plug which complies to the demands of Israeli standard number 32.	Does not comply
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS			Complies



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#### Test Certificate No. <u>9652301337</u> In accordance with Clause 12 of the Standards Law – 1953

#### **Details of Order**

Name of customer : GlobTek, Inc

Address : 186 Veterans Drive Northvale, NJ 07647, USA

Date of order : 16/01/10

**Description of sample** 

Medical Power Supply

Model tested : GTM41078-0605-USB Description: Medical Power Supply

Manufacturer : GlobTek, Inc.

Country of origin : China

**Sampling details:** 

The sample was taken on the following date: 16/01/14

Sample size: 1

#### Test of removal of the deficiencies detailed in SII Test Certificate No.9552373168

To test with the requirements of clause:

8.11 – MAINS PARTS compliance, components and layout

Of Israeli Standard SI 60601 Part 1.2-" Medical electrical equipment: General requirements, November 2015.

This document contains 3 pages and may be used only in full.

The test results in this document refer only to the tested item

This document is not a permit to mark the product with SII Mark

#### **Test Conclusions**

The sample complies with the requirements of the standard, according to the above tests. The sample doesn't tested by the other clause of the standard.

#### Remarks:

Test of removal of the deficiencies detailed in SII Test Certificate No. 9552373168

Dated 24.12.2015.

The test sample tested by Intertek Semko AB, Sweden, as per the CB test Certificate

No.SE-73537, dated 16.07.2013, IEC 60601-1:2005 and C1+C2.

The CB Test Certificate was validated.

Details are given on the following pages of this document.

The original Test Certificate was signed by:

Name: Amihai Kahalani

Position: Inspector On:2016/01/26

I confirm that this a true translation of the Hebrew original. Only the original test certificate is authentic.

Signature:

Name: Igal Zusman Position: Manager, Follow-Up Services Date:2016/01/27

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#### **Broadened description of the product**

The instrument bears the following markings:



#### Photo of the samples tested





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#### **Test Results:**

Clause No. in Standard	Property tested	Remarks	Defects found	Compliance with Standard
8.11	MAINS PARTS, components and layout			Complies