Testing Site Acceptance

RTL

The following organization has been assessed and found to comply with the relevant requirements of ISO/IEC 17025 and the Intertek Global Recognized Test Laboratory Policy Manual

Recognized Test Laboratory

under the Test Data Acceptance for the ETL Mark and is authorized to perform test work for the product types identified on the endorsement to this Testing Site Acceptance.

Intertek RTL Program

Our data acceptance testing program allows a qualified laboratory to perform product testing at their site, with the same validity as if it were conducted in an Intertek laboratory.

Organization:

Hermon Laboratories Ltd.

Hatachana St. POB 23 Rakevet Industrial Zone, Binyamina 30500 Israel

Acceptance Number 2013-RTL-L4-71

Issue Number00005Issue Date09 July 2017Expiry Date09 July 2018

This Testing Site Acceptance is valid until the expiry date shown above, subject to continuing compliance with the conditions specified in the endorsement of this site acceptance.

The Testing Site Acceptance is comprised of this front sheet and 1 endorsement.

Signature: Jim F Pierce, PE

Name: Jim Pierce, PE

Title: RTL Program Technical Director

Date: July 26, 2017

The acceptance is for the exclusive use of the testing site and is provided pursuant to the agreement between Intertek and the testing site. Intertek assumes no liability to any party for any loss, expense or damage occasioned by the use of this acceptance. Only the testing site is authorized to copy or distribute this acceptance. Any use of the Intertek name or one of its marks for the sale or advertisement of any tested material, product or service must first be approved in writing by Intertek.

Testing Site Acceptance

RTL

Endorsement to Acceptance No: 2013-RTL-L4-71

The details below define the conditions applicable to the Testing Site Acceptance granted to the Laboratory, and are valid only for the period stated below. The acceptance is subject to the laboratory's continuing compliance with the applicable rules according to Intertek's Recognized Test Laboratory Program.

Scope of Acceptance:

Standard	Description
UL 60950-1: 2nd edition CAN/CSA-C22.2 No. 60950- 1:07+Amend 1:2011	Information Technology Equipment - Safety - Part 1: General Requirements
UL 60950-21: 1st edition	Information Technology Equipment - Safety – Part 21: Remote Power Feeding
UL 60950-22: 1st edition	Information Technology Equipment - Safety – Part 22: Equipment to be Installed Outdoors
UL 60065: 7th edition	Audio, Video and Similar Electronic Apparatus - Safety Requirements
UL 50 12th edition	Enclosures for Electrical Equipment, Non-Environmental Considerations
IEC 62368-1:14	Audio/video, information and communication technology equipment – Part 1: Safety requirements
UL 1012 7th edition	Power units other than Class 2
UL 1081 6th edition	Swimming Pool Pumps, Filters, and Chlorinators
UL 61010-1: 3rd edition	
UL 61010-1: 2nd edition	Safety Requirements for Electrical Equipment for Electrical
CAN/CSA-C22.2 No. 61010- 1:04	Equipment Measurement, Control, and Laboratory Use - Part 1: General Requirements
CSA C22.2 No. 61010-1-12	
IEC 61010-2-010:03;	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-030:10	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-030: Particular requirements for testing and measuring circuits
UL 61010-031: 1st edition	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part031: Safety Requirements for Hand-Held Probe Assemblies for Electrical Measurement and Test

Testing Site Acceptance

RTL

Scope of Acceptance:

IEC 61010-2-040:05;	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washerdisinfectors used to treat medical materials
UL 61010A-2-041: 1st edition	Standard for Electric Equipment for Laboratory Use: Part 2 - Particular Requirements for Autoclaves Using Steam
IEC 61010-2-101:02	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
UL 60601-1: 1st edition	Medical Electrical Equipment - Part 1: General
CAN/CSA C22.2 NO. 601.1- M90	Requirements for Safety
ANSI/AAMI ES60601-1:05 +C1:09 + A2:10 ANSI/AAMI ES60601-	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance (IEC601-1:2005, Mod)
1:05+A1:12+C1:09 +A2:10	
CAN/CSA C22.2 NO. 60601-1- 08	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, third edition, 2005-12), Includes Corrigendum 1:2011
IEC 60601-1-4:96+A1:99;	Medical electrical Part 1.General requirements for safety 4. Collateral std.: Programmable electrical medical systems
IEC 60601-1-6:10+A1:13;	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8:06+A1:12;	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
IEC 60601-1-11:10; IEC 60601-1-11:15;	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-12:14	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

Testing Site Acceptance

RTL

Scope of Acceptance:

IEC 60601-2-2:06;	Medical electrical equipment - Part 2-2: Particular
IEC 60601-2-2:09	requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-2-3:12;	Medical electrical equipment - Part 2-3: Particular
IEC 00001-2-3.12,	requirements for the basic safety and essential performance of short-wave therapy equipment
IEC 60601-2-5:00;	Medical electrical equipment - Part 2-5: Particular
IEC 60601-2-5:09;	requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment
IEC 60601-2-10:87+A1:01;	Medical electrical equipment - Part 2-10: Particular
IEC 60601-2-10:12;	requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 60601-2-12:01;	Medical electrical equipment- Part 2-12: Particular
	requirements for the safety of lung ventilators - Critical care ventilators
IEC 60601-2-18:96+A1:00;	Medical electrical equipment - Part 2-18: Particular
	requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-22:95;	Medical electrical equipment - Part 2-22: Particular
IEC 60601-2-22:07+A1:12;	requirements for basic safety and essential performance of
120 00001 2 22.07 17(1.12)	surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-2-24:98;	Medical electrical equipment - Part 2-24: Particular
,	requirements for the basic safety and essential performance
	of infusion pumps and controllers
IEC 60601-2-25:93+A1:99;	Medical electrical equipment - Part 2-25: Particular
IEC 60601-2-25:11;	requirements for the basic safety and essential performance
	of electrocardiographs
IEC 60601-2-26:12;	Medical electrical equipment - Part 2-26: Particular
	requirements for the basic safety and essential performance
	of electroencephalographs
IEC 60601-2-27:94;	Medical electrical equipment - Part 2-27: Particular
IEC 60601-2-27:05;	requirements for the safety, including essential performance,
	of electrocardiographic monitoring equipment
IEC 60601-2-30:99;	Medical electrical equipment -Part 2-30: Particular
	requirements for the safety, including essential performance
	of automatic cycling non-invasive blood pressure monitoring equipment
IEC 60601-2-32:94;	Medical electrical equipment. Part 2: Particular requirements
	for the safety of associated equipment of X-ray equipment
IEC 60601-2-34:00;	Medical electrical equipment - Part 2-34: Particular
IEC 60601-2-34:11;	requirements for the basic safety and essential performance
	of invasive blood pressure monitoring equipment

Testing Site Acceptance

Scope of Acceptance:

RTL

IEC 60601-2-35:96;	Medical Electrical equipment. Part 2. Section:35 Particular
	requirements for the safety of blankets, pads, and
	mattresses, intended for heating in medical use
EN 60601-2-	Medical electrical equipment - Part 2-37: Particular
37:01+A1:05+A2:05	requirements for the basic safety and essential performance
IEC 60601-2-37:07+A1:15;	of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-38:96+A1:99;	Medical electrical equipment. Part 2. Section:38 Particular
	requirements for the safety of electrically operated hospital beds
IEC 60601-2-40:98;	Medical electrical equipment - Part 2-40: Particular
	requirements for the safety of electromyographs and
	evoked response equipment
IEC 60601-2-49:11;	Medical electrical equipment - Part 2-49: Particular
	requirements for the basic safety and essential performance
	of multifunction patient monitoring equipment
IEC 60601-2-57:11;	Medical electrical equipment - Part 2-57: Particular
	requirements for the basic safety and essential performance
	of non-laser light source equipment intended for
	therapeutic, diagnostic, monitoring and cosmetic/aesthetic
	use
IEC 62366:07+A1:14	Medical devices – Application of usability engineering to
	medical devices
UL 60335-1: 4th edition	Safety Of Household And Similar Electrical UL 60335-1: 5th
	edition Appliances - Part 1: General Requirements
UL 60335-1: 5th edition	Part 1: General Requirements
CAN/CSA-C22.2 NO. 60335-1-	Safety of household and similar appliances - Part 1: General
11	requirements (Tri-national standard, with NMX-J-521/1-
	ANCE and UL 60335-1)
IEC 60335-2-	Household and similar electrical appliances - Safety - Part 2-
2:2002+A1:04+A2:06;	2: Particular requirements for vacuum cleaners and water-
	suction cleaning appliances
IEC 60335-2-6:2002+A1:04;	Household and similar electrical appliances - Safety - Part 2-
	6: Particular requirements for stationary cooking ranges,
	hobs, ovens and similar appliances
IEC 60335-2-14:2006+A1:08;	Household and similar electrical appliances - Safety - Part 2-
	14: Particular requirements for kitchen machines
IEC 60335-2-17:2002+A1:06;	Household and similar electrical appliances - Safety - Part 2-
	17:Particular requirements for blankets, pads, clothing and
	similar flexible heating appliances
CAN/CSA-E60335-2-23-05	Household and Similar Electrical Appliances – Safety - Part
IEC 60335-2-	2-23: Particular Requirements for Appliances for Skin or Hair
23:2003+A1:08+A2:12;	Care (Adopted IEC 60335-2-23:2003, fifth edition, 2003-01)



Testing Site Acceptance

RTL

Scope of Acceptance:

IEC 60335-2- 24:2002+A1:05+A2:07;	Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances,
·	ice-cream appliances and ice makers
IEC 60335-2-	Household and similar electrical appliances - Safety - Part
36:2002+A1:04+A2:08;	2-36: Particular requirements for commercial electric
	cooking ranges, ovens, hobs and hob elements
IEC 60335-2-	Household and similar electrical appliances - Safety - Part
41:2002+A1:04+A2:09;	2-41: Particular requirements for pumps
IEC 60335-2-60:2002+A1:04;	Household and similar electrical appliances - Safety - Part
	2-60: Particular requirements for whirlpool baths and
	whirlpool spas
IEC 60335-2-	Household and similar electrical appliances - Safety - Part
75:02+A1:04+A2:08;	2-75:Particular requirements for commercial dispensing
	appliances and vending machines
IEC 60335-2-96:2002+A1:03;	Household and similar electrical appliances - Safety - Part
	2-96: Particular requirements for flexible sheet heating
	elements for room heating
IEC 60335-2-109:2010	Household and similar electrical appliances - Safety - Part
	2-109: Particular requirements for UV radiation water
	treatment appliances
IEC 62301:05	Household electrical appliances - Measurement of standby
J=0.50=0.0 1.0 1.0 5	power
IEC 60598-1:03+A1:06	Luminaires - Part 1: General requirements and tests
IEC 60598-2-1:79+A1:87	Luminaires - Part 2: Fixed general purpose luminaires

Conditions applicable to the Acceptance:

Refer to Audit Report for outline of Level 4 test limitations

The Testing Site Acceptance is comprised of the front sheet and 1 endorsement.

Signature: Jim F Pierce, PE

Name: Jim Pierce, PE

Title: RTL Program Technical Director

Date: July 26, 2017

The acceptance is for the exclusive use of the testing site and is provided pursuant to the agreement between Intertek and the testing site. Intertek assumes no liability to any party for any loss, expense or damage occasioned by the use of this acceptance. Only the testing site is authorized to copy or distribute this acceptance. Any use of the Intertek name or one of its marks for the sale or advertisement of any tested material, product or service must first be approved in writing by Intertek.