DRAFT SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

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MECHANICAL

Valid To: September 30, 2025 Certificate Number: 1152.03

In recognition of the successful completion of the A2LA evaluation process, (including an assessment of the organization's compliance with A2LA's FDA ASCA Accreditation Program[1] requirements), accreditation is granted to this laboratory at the location listed above, ***as well as the satellite laboratory locations listed below***, to perform the following product safety, electromagnetic compatibility, and telecommunications testing:

Test Technology:	**Test Method(s)[1]:**
Environmental Exposure	
Temperature	MIL-STD-810, Method 501, 502, 503; UN-DO-160 Section 5; MIL-PRF-28800F; ETSI/EN_300019-1-0, -1, -2, -3, -5, -6, -7, -8; IEC/EN 60068-2-1, -2, -14, -30; ISO 16750-4
Temperature (-40 to 177) ºC, Transition up to 15 ºC / min	MIL-STD-202, Method 108A; EN/IEC 60068-2-14
Humidity (10 to 90) ºC, (20 to 95) %RH	MIL-STD-810, Method 507; MIL-STD-202, Methods 103B and 106G; UN-DO-160 Section 6.0; MIL-PRF-28800F; ETSI/EN_300019-1-0, -1, -2, -3, -5, -6, -7, -8, -30; ISO 9022-14-1994
Dust Test	MIL-STD-810, Method 510; UN-DO-160 Section 12.0; MIL-PRF-28800F; ETSI/EN 300019-1-1, -2, -3, -5, -6, -8
Ingress, Impact Protection	EN/IEC/AS/NZS/SI 60529; IEC/EN 62262; IEC/EN 60068-2-18, 75; MIL STD 810, Test Method 512, 506; RTCA DO-160, Section 11; MIL-STD-108E

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Test Technology:	**Test Method(s)[1]:**
Drop Tests (Free Fall)	MIL-STD-810, Method 516; UN-DO-160 Section 7.0 and 8.0; MIL-PRF-28800F; IEC/EN 60068-2-31, -32; IEC/EN 60601-1-11[1]; ETSI/EN_300019-1-2, -5, -6; ASTM C635 SI 5103 part1, 4
Vibration	MIL-STD-810, Method 514; UN-DO-160 Section 7.0, 8.0; MIL-PRF-28800F; ETSI/EN_300019-1-2, -3, -4, -5, -6, -8; IEC/EN 60068-2-6, -27, 64; IEC 60601-1-11[1]; ISO 16750-3
Salt Fog	MIL-STD-810, Method 509; UN-DO-160 Section 14.0; MIL-PRF-28800F; ETSI/EN_300019-1-3; IEC/EN 60068-2-11, 52; ISO 16750-5
Freeze / Thaw / Icing	MIL-STD-810, Method 524, 521 UN-DO-160 Section 24; ETSI/EN_300019-1-3, -6, -7
National Standards (comprising test methods above)	JSS 55555, STANAG 4370
Pressure	IEC 60601-2-11[1] (Clause 4.2.2), EN/IEC 60068-2-13;
UV	IEC 60068-2-5, MIL STD 810. Method 505
Contamination By Fluids	MIL-STD-810, Method 504
Aging	ASTM F1980; ISO 11607-1
PV	IEC/EN/UL/SI 61730-1, -2; IEC/EN/UL/SI 61215-1, -2
Packaged-products	ISTA 2A
Flammability	EN 13501-1

[1] The laboratory is only accredited for testing activities outlined within the test methods listed above. Reference to any other activity within these standards, such as risk management or risk assessment, does not fall within the laboratory's accredited capabilities.

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* published on September 25th, 2020, and in accordance with all requirements of A2LA *R256 Specific Requirements- FDA ASCA Program* [1]

Standards	**ASCA Doc Number**
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION;	19-38
IEC 60601-2-11 Edition 3.0 2013-01	12-255

[4] These methods have been assessed by A2LA according to A2LA's FDA ASCA Program requirements. Accreditation by A2LA does not imply FDA ASCA-Accreditation. All ASCA-accreditation decisions for testing laboratory applications are made solely by the FDA, a list of approved laboratories can be found at FDA.gov.

Accredited Laboratory

A2LA has accredited

I.T.L. PRODUCT TESTING LTD

Modiin, Israel

for technical competence in the field of

Mechanical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets A2LA R256 - Specific Requirements - FDA ASCA Program. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (*refer to joint ISO-ILAC-IAF Communiqué dated April 2017*).

Presented this 28th day of March 2024.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 1152.01
Valid to September 30, 2025

For the types of tests to which this accreditation applies, please refer to the laboratory's Mechanical Scope of Accreditation.