



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

Standards Institution of Israel Electrical and Electronics Laboratory

Corporate Location
42 Chaim Levanon St.
Tel Aviv, 6997701 Israel

Fulfills the requirements of
ISO/IEC 17025:2017

In the field of

TESTING

and

**U.S. Federal Communication Commission (FCC) EMC and Telecommunications (EC&T)
Testing Designation Program**

**Recognition of Telecommunications Testing - Innovation, Science, and Economic Development
(ISED) Canada**

**FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Basic Safety
and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and
Laboratory Medical Equipment**

This certificate is valid only when accompanied by a current scope of accreditation document.

The current scope of accreditation can be verified at www.anab.org.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 14 May 2024
Certificate Number: AT-1359



This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017.
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).

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

Standards Institution of Israel Electrical and Electronics Laboratory

Corporate Location

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Tel Aviv, 6997701 Israel

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TESTING

Valid to: **May 14, 2024**

Certificate Number: **AT-1359**

Testing performed in support of FCC approval procedures for certification ⁵

Type of Device Examples	Scope of Accreditation	Supporting FCC Guidance	Comments/Maximum Frequency Tested
Unintentional Radiators (FCC Part 15, Subpart B)	ANSI C63.4-2014	-	40 GHz
Industrial, Scientific, and Medical Equipment (FCC Part 18) Consumer ISM equipment	FCC MP-5, (February 1986)	-	40 GHz
Intentional Radiators (FCC Part 15, Subpart C)	ANSI C63.10-2013	-	40 GHz
UPCS (FCC Part 15, Subpart D) Unlicensed Personal Communication Systems devices	ANSI C63.17-2013	-	40 GHz
U-NII without DFS Intentional Radiators (FCC Part 15, Subpart E) Unlicensed National Information Infrastructure Devices (U-NII without DFS)	ANSI C63.10-2013	KDB Publication 789033	40 GHz



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Testing performed in support of FCC approval procedures for certification ⁵

Type of Device Examples	Scope of Accreditation	Supporting FCC Guidance	Comments/Maximum Frequency Tested
U-NII with DFS Intentional Radiators (FCC Part 15, Subpart E) Unlicensed National Information Infrastructure U-NII) Devices with Dynamic Frequency Selection (DFS)	FCC KDB Publication 905462 D02 UNII DFS Compliance Procedures New Rules v02 (April 8, 2016)	-	40 GHz
UWB Intentional Radiators (FCC Part 15, Subpart F) Ultra-wideband Operation	ANSI C63.10-2013	-	40 GHz
BPL Intentional Radiators (FCC Part 15, Subpart G) Access Broadband Over Power Line (Access BPL)	ANSI C63.10-2013	-	40 GHz
White Space Device Intentional Radiators (FCC Part 15, Subpart H) White Space Devices	ANSI C63.10-2013	-	40 GHz
Commercial Mobile Services (FCC Licensed Radio Service Equipment) Part 22 (cellular) Part 24 Part 25 (below 3 GHz) Part 27	ANSI/TIA-603-E or TIA-102.CAAA-E-2016 or ANSI C63.26-2015	KDB Publication 971168	40 GHz
General Mobile Radio Services (FCC Licensed Radio Service Equipment) [1] Part 22 (non-cellular) Part 90 (below 3 GHz) Part 95 (below 3 GHz) Part 97 (below 3 GHz) Part 101 (below 3 GHz)	ANSI/TIA-603-E or TIA-102.CAAA-E-2016 or ANSI C63.26-2015	-	40 GHz
Citizens Broadband Radio Services (FCC Licensed Radio Service Equipment) Part 96	ANSI/TIA-603-E or TIA-102.CAAA-E-2016 or ANSI C63.26-2015	KDB Publication 971168 KDB Publication 940660	40 GHz
Maritime and Aviation Radio Services (FCC Licensed Radio Service Equipment) Part 80 Part 87	ANSI/TIA-603-E or ANSI C63-26-2015	-	40 GHz



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Testing performed in support of FCC approval procedures for certification ⁵

Type of Device Examples	Scope of Accreditation	Supporting FCC Guidance	Comments/Maximum Frequency Tested
Microwave and Millimeter Bands Radio Services (FCC Licensed Radio Service Equipment) Part 25 Part 30 Part 74 Part 90 (above 3 GHz) Part 95 (above 3 GHz) Part 97 (above 3 GHz) Part 101	ANSI/TIA-603-E or TIA-102.CAAA-E-2016 or ANSI C63.26-2015	KDB Publication 653005	40 GHz
Broadcast Radio Services (FCC Licensed Radio Service Equipment) Part 73 Part 74 (below 3 GHz)	ANSI/TIA-603-E or TIA-102.CAAA-E-2016 or ANSI C63.26-2015	-	40 GHz
Signal Boosters (Part 20) Wideband Consumer signal boosters Provider-specific signal boosters Industrial signal boosters Signal Boosters (Section 90.219)	ANSI C63.26-2015	KDB Publication 935210 D03, D04, and D05 [A]	40 GHz

Notes:

- A. For Signal Boosters (Part 20) accreditation is required for Commercial Mobile Services (FCC Licensed Radio Services Equipment) and for Signal Booster (Section 90.219) accreditation is required for General Mobile Radio Services (FCC Licensed Radio Service Equipment).

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Current Harmonics	IEC, EN and BS EN 61000-3-2; IEC/EN and BS EN 61000-3-12; EN and BS EN 61000-4-7; EN and BS EN 61000-4-13	Up to 40th Harmonics	Power Analyzer
Voltage Fluctuations and Flicker	IEC, EN and BS EN 61000-3-3; SI 61000-3.3; EN and BS EN 61000-3-11; EN and BS EN 61000-4-15	Below 75 A/250 V _{AC}	Power Analyzer



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Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Conducted Emissions	47 CFR, FCC Parts 15.A, 15.B, 15.C using ANSI C63.4-2014; 47 CFR, FCC Part 18, using MP-5; AS/NZS 2064; AS/NZS 3548; IEC/CISPR 11, EN and BS EN 55011; AS/NZS CISPR 11; AS/NSZ CISPR 22; IEC/CISPR 14-1; EN and BS EN 55014-1; AS/NZS CISPR 14-1; IEC/CISPR 22; EN and BS EN 55032; CISPR 32; AS/NZS CISPR32; VCCI-CISPR32; SI 961-32; ICES-003; EN 55022; SI 961-6.1; EN 50083-2; SI 961-11; SI 961-14.1; EN 61204	Up to 40 GHz	EMI Receiver, LISN, T- ISN, Voltage Probe
Radiated Emissions	47 CFR, FCC Parts 15.A, 15.B, 15.C using ANSI C63.4-2014; 47 CFR, FCC Part 18; AS/NZS 2064; AS/NZS 3548; IEC/CISPR 11; EN 55011; AS/NZS CISPR 11; AS/NSZ CISPR 22; IEC/CISPR 14-1; EN 55014-1; AS/NZS CISPR 14-1; IEC/CISPR 22; EN 55022; CISPR 32; EN and BS EN 55032; AS/NZS CISPR32; VCCI-CISPR32; ICES-003; CISPR 25; SI 961-32; SI 961-6.1; EN 50083-2; ECE Regulation No. 10; SI 961-11; SI 961-14.1; EN 61204	Up to 40 GHz	EMI Receiver, EMI Analyzer, Antenna



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Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Radiated and Conducted Emissions	FCC 47 CFR Part 15, Unintentional Radiators CB Receiver / Super regenerative Receiver / All other Receivers subject to Part 15 / TV Interface Device / Cable System Terminal Device / Class B Personal Computers and Peripherals / CPU Boards and Internal Power Supplies used with Class B Personal Computers / Class B Personal Computers assembled using Authorized CPU Boards or Power Supplies ANSI C63.4, American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz	Up to 40 GHz	Unintentional Radiators
Radiated and Conducted Emissions	ICES-001 Industrial, Scientific and Medical (ISM) Radio Frequency Generators	Up to 40 GHz	Unlicensed Devices
Radiated and Conducted Emissions	FCC 47 CFR Part 18-Industrial, Scientific, and Medical Equipment; Consumer ISM Equipment FCC MP-5 (February 1986); FCC Methods of Measurements of Radio Noise Emissions from Industrial, Scientific, and Medical Equipment	Up to 40 GHz	Industrial, Scientific and Medical Devices
Radiated and Conducted Emissions	EN and BS EN 55032 / CISPR 32: Electromagnetic Compatibility of Multimedia Equipment- Emission Requirements	Up to 40 GHz	Multimedia Equipment
Insertion Loss, Radiated and Conducted Disturbances	ICES-005; CISPR 15; AS/NZS CISPR 15; EN and BS EN 55015; SI 961 Part 15 Radio Frequency Lighting Devices	Up to 6 GHz	Power Analyzer EMI Receiver
Electrostatic Discharge (ESD)	IEC, EN, and BS EN 61000-4-2; ECE Regulation No. 10	Up to ±16.5 kV	ESD Simulator



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Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Radiated and Conducted Disturbances	IEC/EN and BS EN 61547 Radio Frequency Lighting Devices	ESD: Up to ± 16.5 kV; Surge: Up to 6.6 kV	Immunity Test Set
Radiated Immunity	ENV 50204; IEC, EN and BS EN 61000-4-3; ECE Regulation No. 10	Up to 100 V/m	Signal Generator, Antenna, RF Power Amplifier
Electrical Fast Transients/Burst	IEC, EN and BS EN 61000-4-4; ECE Regulation No. 10	Up to 6 kV	EFT Test Set
Surge Immunity	IEC, EN and BS EN 61000-4-5; EN and BS EN 61000-4-12; IS 961-6.2; ITU-T K.17; ITU-T K.20; ITU-T K.21; ECE Regulation No. 10	Up to 6.6 kV	Surge Test Set
Conducted Immunity	IEC, EN and BS EN 61000-4-6; ECE Regulation No. 10; IEC, EN and BS EN 61000-4-13; IEC, EN and BS EN 61000-4-17; EN and BS EN 61000-4-16	Up to 20 V _{rms}	Signal Generator, RF Power Amplifier, CDN
Power Frequency Magnetic Field	IEC, EN and BS EN 61000-4-8; IEC, EN and BS EN 61000-4-9; EN and BS EN 61000-4-10	Up to 300 A/m	Field Generator
Voltage Dips and Interruptions	IEC, EN and BS EN 61000-4-11; IEC, EN and BS EN 61000-4-29; IEC, EN and BS EN 61000-4-14; IEC, EN and BS EN 61000-4-28; EN and BS EN 61000-4-34	Single-Phase 15 kVA/ Three-Phase 5 kVA per phase	PQF Test Set
Damped Oscillatory Wave	IEC, EN and BS EN 61000-4-18	Up to 6.6 kV	Immunity Test Set
Emission & Immunity	CISPR 32; EN and BS EN 55032; KS C 9832 ; IEC/CISPR 24; EN 55024; EN 300 386; CISPR 35; EN and BS EN 55035; KS C 9835; EN 301 489-XX; SI 31489-XX; ITU-T K.17; ITU-T K.20; ITU-T K.21; ITU-T K.44; ITU-T Rec. K.41; ITU-T Rec. K.45; EN 300 132-X ; SI 961-32; SI 961-35	Per Emission Range and Per Immunity Range	ITE / Telecom, Multimedia

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
	IEC/CISPR 14-2; EN and BS EN 55014-2; SI 961-14-2; IEC, EN and BS EN 60730-X; IEC, EN and BS EN 60669-2-1; IEC/CISPR 14-1; EN 55014-1; IEC, EN and BS EN 60669-1		Household Appliances
	IEC 61326; EN and BS EN 61326; IEC 62052-11; EN and BS EN 61000-6-5		Measurement Control & Laboratory
Emission & Immunity	IEC, EN and BS EN 60601-1-2; IEC, EN and BS EN 60601-2-XX IEC, EN and BS EN 80601-2-XX ANSI/AAMI/IEC 60601-1-2 ANSI/AAMI/IEC 80601-2-XX CSA C22.2 NO 60601-1-2 SI 60601 Part 1.2	Per Emission Range and Per Immunity Range	Medical Devices
	EN 12015; EN 12016		Lifts, Escalators and Moving Walks
	EN 50130; EN 50131-2-2		Alarm systems
	EN 55103-1 and -2		Audio, Video, Audio-visual and Entertainment; Lighting Control Apparatus for Professional Use
	SEMI E33; SEMI S3; SEMI F47; SEMI F42; SEMI S23		Equipment for Semiconductor Industry
	IEC, EN and BS EN 61000-6-3, 61000-6-4, 60439-X, 61439-X; IEC, EN and BS EN 61000-6-1, 61000-6-2		Residential, Commercial and Light Industrial
	EN 50065		Signaling on Low-voltage Electrical Installation
	EN 50121-1, 2, 3, 4, 5; IEC and EN 62236; IEC, EN and BS EN 50155; ISO 7637; ECE Regulation No. 10; EN and BS EN 50498; EN and BS EN 12184; ISO 7176-21		Railway/Automotive Applications

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
	IEC, EN and BS EN 61800-3; IEC, EN and BS EN 62040-2; EN 61204, IEC, EN and BS EN 61800-5-2; IEC, EN and BS EN 60255-26		UPS and Power Units
Human Exposure to Radiation Emitted by Equipment	EN12198-1; EN12198-2; EN12198-3; EN50366, EN 50364; EN 50371; EN 62311; IEC 62233	Up to 40 GHz	EM Field Probe Spectrophotometer

Testing to Meet the Requirements for Recognition of Telecommunications Testing – Innovation, Science, and Economic Development (ISED) Canada ⁶

Test Method (Standard)	Issue, Date, Amendment	Test Specification(s)	Comments
RSS-GEN	Issue #5 Amendment 2, February 2021	General Requirements for Compliance of Radio Apparatus	-
RSS-102	Issue #5 March 2015, Amendment 1, February - 2021	Radio Frequency (RF) Exposure compliance of Radiocommunications Apparatus (All Frequency Bands)	RF Exposure (RF Exp) - Measurement
RSS-119	Issue #12, May 2015	Land Mobile and Fixed Equipment Operating in the Frequency Range (27.41 to 960) MHz	-
RSS-192	Issue #4, May 2020	Flexible Use Broadband Equipment Operating in the Band (3 450 to 3 650) MHz	-
RSS-194	Issue #1, October 2007	Fixed Wireless Access Equipment Operating in the Band (953 to 960) MHz	-
RSS-195	Issue #2, April 2014	Wireless Communication Service (WCS) Equipment Operating in the Bands (2 305 to 2 320) MHz and (2 345 to 2 360) MHz	-
RSS-197	Issue #1 February 2010	Wireless Broadband Access Equipment Operating in the Band (3 650 to 3 700) MHz	-
RSS-210	Issue #10 December 2019, Amendment April 2020	License-Exempt Radio Apparatus: Category I Equipment	-
RSS-247	Issue #2 February 2017, Note Mar 2017	Digital Transmission Systems (DTS), Frequency Hopping Systems (FHSs) and License-Exempt Local Area Networks (LE-LAN) Devices	Without DFS
RSS-248	Issue #1 Nov 2021	Radio Local Area Network (RLAN) Devices Operating in the (5 925 to 7 125) MHz Band	Per ISED notice 2021-DRS0011



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Radio

Test Method	Test Specification(s)	Range	Comments
Radio & EMC	EN 300 220; EN 300 328; EN 300 330; EN 300 440; EN 303 406; EN 300 086; EN 300 113; EN 300 390; EN 301 390; EN 302 326-2; EN 301 893; EN 302 502; EN 301 598; FCC Part 15 (except for Sections 15.253, 15.255, 15.257) Subpart D (Sections 15.301-323), and Subpart F (Sections 15.501-15.523); CFR 47 Part 90 using, TIA/EIA 603- C:04; TIA/EIA 603-D:10; AS/NZS 4268; AS/NZS 4295; AS/NZS 4771; AS/NZS 4768.1; AS/NZS 4768.2; EN 301 126-XX; EN 301 511; EN 301 908-XX EN 303 413; EN 303 417; EN 303 447; EN 302 065-1; EN 302 065-2; EN 302 065-3; EN 302 065-4; EN 302 065-5; EN 302 208; EN 301 839; EN 302 195; EN 302 537; EN 303 609; EN 50385; EN 302 544-1; EN 302 544-2	Up to 40 GHz	Wireless Communication

Product Safety

Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Comments
Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-1, EN 60601-1, BS EN 60601-1; UL 60601-1; ANSI/AAMI ES 60601-1, CAN/CSA-C22.2 No.601.1; SI 1011; SI 60601 Part 1; IEC, EN and BS EN 60601-1-X, -XX, IEC, EN, EN IEC, BS EN and BS EN IEC 60601-2-X, -XX; IEC, EN, EN IEC, BS EN and BS EN IEC 80601-2-X, -XX; SI 60601-1-X, -XX, SI 60601-2-X, -XX; ISO, EN ISO and BS EN ISO 80601-2-X, -XX, CAN/CSA C22.2 No. 60601-2-X, -XX, ANSI/AAMI/IEC 60601-1-X, -XX ANSI AAMI IEC 80601-2-X, -XX IEC/TR 62354; ISO 14971, ANSI/AAMI EC53, ANSI/AAMI EC12; IEC, EN and BS EN 62304	Medical Electrical Equipment	-
Physical/Performance Tests:	IEC, EN, BS EN and BS EN IEC 60825-X, -XX ; SI 60825 Part 1; IEC60601-2-22, IEC60601-2-57 ; AS/NZS 2211.1; ANSI Z136.1 21 CFR §1040.10 , 21 CFR §1040.11	Laser Equipment	-
Physical/Performance Tests:	EN and BS EN 12198-1; EN and BS EN 12198-2; EN and BS EN 12198-3; EN and BS EN 50366, EN and BS EN 50364, EN and BS EN 50371, EN and BS EN 62311, IEC and BS EN 62233; IEC, EN and BS EN 62471; IEC60601-2-57	Human exposure to radiation emitted by equipment	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC and EN 60950; IEC, EN and BS EN 60950-1; UL 60950-1; CSA/C22.2-225; CAN/CSA-C22.2 No. 60950-1-03; AS/NZS 60950.1; AS/NZS 4117; AS/NZS 3100; IS 60950 Part 1; IEC 60950-21; IEC 60950-22; IEC 60950-23; EN and BS EN 60950-21; EN and BS EN 60950-22; EN and BS EN 60950-23; UL 60950-21; UL 60950-22; UL 60950-23; EN and BS EN 41003 IEC and EN 62368-1; UL 62368-1; CAN/CSA C22.2 No. 62368-1-14; EN IEC 62368-1, BS EN IEC 62368-1, CAN/CSA C22.2 NO. 62368-1:19; IEC 62368-3, EN IEC 62368-3:2020, BS EN IEC 62368-3	ITE / Telecom	-

Product Safety

Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Comments
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC, EN, EN IEC, BS EN and BS EN IEC 61010-1, 61010-2-X, 61010-031; UL 61010-1; SI 61010 Part 1; AS 61010.1; AS 61010.2.XXX, IEC 61557-1, -8, IEC62053-22/23, IEC62052-11	Measuring, Control and Laboratory Equipment	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC, EN and BS EN 60335-1, 60335-2-X; SI 900; AS/NZS 60335.1; AS/NZS 60335.X.XXX; UL 60335-1; UL 60335-2-X; UL867; UL 1081; AS/NZS 3136; UL499; UL399; UL916; UL923; UL197; UL541, IEC, EN and BS EN 60669-2-1; IEC, EN and BS EN 60669-1	Household Equipment	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC 60065; EN and BS EN 60065; UL 60065; UL 6500; SI 250; AS/NZS 60065	Audio, Video Equipment	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC, EN and BS EN 60439-1; IEC, EN and BS EN 60439-X; EN and BS EN 50178; IEC, EN and BS EN 61439-X	Low-voltage switchgear and controlgear	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC, EN and BS EN 60204-1; IEC and EN 60204-33, EN ISO 12100-1; EN ISO 12100-2; EN and BS EN 349; EN 547-1; EN 547-2; EN 547-3; EN 574; EN 614-1; EN 614-2; EN 842; EN 894-1; EN 894-2; EN 894-3; EN 953; EN 981; EN 982; EN 983; EN 999; EN 1010-1; EN 1010-2; EN 1010-3; EN 1010-4; EN 1010-5; EN 1037; EN 1088; EN 1837; EN ISO and BS EN ISO 7250; EN ISO 7731; EN ISO 10218-1; EN ISO 10218-2; EN ISO 13732-1; EN ISO 13849-1; EN ISO 13857; EN ISO 14121-1; EN and BS EN 61310-1; EN 61310-2; EN61310-3; IEC 61508-SER; IEC 61508-0; IEC 61508-1; IEC 61508-2; IEC 61508-3; IEC 61508-4; IEC 61508-5; IEC 61508-6; IEC 61508-7; UL 775, EN ISO and BS EN ISO 12100; AS/NZS 4024.1204, NFPA 79, UL2011	Machinery	-

Product Safety

Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Comments
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC, EN and BS EN 60034-X	Motors	-
Environmental Tests	IEC, EN and BS EN 60529	IP tests for electrical/electronic equipment	IPX0, IPX1, IPX2, IPX3, IPX4, IPX5, IPX6, IPX7, IPX8, IP1X, IP2X, IP3X, IP4X, IP5X, IP6X
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	SEMI S2; SEMI S8; SEMI S9; SEMI S10; SEMI S14; SEMI S22; SEMI F47; SEMI F42; SEMI S17; SEMI E10; SEMI S3; SEMI S23	Equipment for semiconductor industry	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	UL 508; UL 508A; UL 508C; CSA CSA-C22.2 No. 14; CSA C22.2 No. 274; UL 61800-5-1; IEC, EN and BS EN 61800-5-1; IEC, EN and BS EN 61800-5-2; IEC and EN 61800-2	Industrial control equipment	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC, EN and BS EN 60730-1; IEC, EN and BS EN 60730-2-X; UL 60730-1A; UL 60730-2-X; UL 244A	Automatic electrical controls for household and similar use	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	IEC, EN and BS EN 60598-1; 60598-2-X; 61347-1; 61347-2-X; IEC, EN, EN IEC, BS EN and BS EN IEC 62031 AS/NZS 61347.1; AS/NZS 61347.2.X; UL 1472; UL 935; UL 1029; UL 2108; UL 1598; UL 8750; UL 1598C; ANSI/CAN/UL8800; CSA-C22.2 No. 250.0; CSA-C22.2 No. 9.0; CSA-C22.2 No. 250.13	Luminaires and lighting controls	-

Product Safety

Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Comments
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	UL 1778; EN 50091-1; IEC, EN, EN IEC, BS EN and BS EN IEC 62040-1-1; 62040-1-2; 62040-1; UL 963; UL 1012; UL 1310; CSA-C22.2 No. 107.1; CAN/CSA-C22.2 No. 223; IEC, EN, EN IEC, BS EN and BS EN IEC 61558-1; IEC, EN and BS EN 61558-2-X; IEC, EN and BS EN 61800-5-1; IEC, EN and BS EN 61851-1, -22	UPS and power units	-
Overvoltage	ITU-T K.17; ITU-T K.20; ITU-T K.21 ; UL60950-1, UL62368-1	Telecom	-
Electrical Tests A Thermal Tests Mechanical Tests Environmental Tests	EN 50131-1; EN 50131-X-X; EN 50130-5; UL 365; UL603; UL609; UL 1023; UL 1076; UL 1610; UL 636; UL 1635; UL 639; UL 1037	Alarm systems	-
Physical/Performance Tests	IEC, EN and BS EN 62471	Lamps/luminaries	-
Photometric measurements	LM-79	Lamps/luminaries	-



ANSI National Accreditation Board

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ⁷

Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
Medical Electrical Equipment and Systems	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:200/(R)2012 and A2:2010/(R)2012 (Consolidated Text) ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [incl. AMD2:2021]	Entire Standard except spark test
Electrical Equipment for Measurement Control & Laboratory Use	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 61010-1 Edition 3.1 2017-07	Entire Standard
Medical Electrical Equipment and Systems	Electromagnetic Compatibility Emissions & Immunity	IEC 60601-1-2 Edition 4.0 2014-02 ANSI AAMI IEC 60601-1-2:2014 [including AMD 1:2021]	Excluding Figure 3 and Sub Clause 8.9, Table 8 per partial FDA recognition
Medical Electrical diagnostic X-ray Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-1-3 Edition 2.1 2013-04 IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Entire Standard
Medical Electrical Equipment	Usability Review	IEC 60601-1-6 Edition 3.1 2013-10 IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Entire Standard
Alarm systems in Medical Electrical Equipment and medical electrical systems	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-1-8 Edition 2.1 2012-11 ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	Entire Standard



ANSI National Accreditation Board

Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ⁷

Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
Development of physiologic closed-loop controllers in Medical Electrical Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-1-10 Edition 1.1 2013-11 IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION	Entire Standard
Medical Electrical Equipment and Systems for use in the Home Healthcare Environment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-1-11 Edition 2.0 2015-01 IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	Excluding Note 2 to entry in Sub-clause 3.1 per partial FDA recognition
Medical Electrical Equipment and Systems for use in the Home Healthcare Environment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ANSI AAMI HA60601-1-11:2015	Entire Standard
Medical Electrical Equipment and Systems for use in Emergency Medical Services Environment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-1-12 Edition 1.0 2014-06 ANSI AAMI HA 60601-1-12:2016 [Including AMD 1:2021]	Entire Standard
Electrosurgical Generators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-2 Edition 6.0 2017-03	Excluding Subclauses 202.7 and 202.8 per partial FDA recognition



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Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ⁷

Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
Ultrasonic physiotherapy equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-5 Edition 3.0 2009-07	Entire Standard
Nerve and Muscle Stimulators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-10 Edition 2.1 2016-04	Entire Standard
Endoscopic Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-18 Edition 3.0 2009-08	Entire Standard
Infant incubators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-19 Edition 2.1 2016-04 CONSOLIDATED VERSION	Entire Standard
Infant transport incubators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-20 Edition 2.1 2016-04 CONSOLIDATED VERSION	Entire Standard



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Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
Infant radiant warmers	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-21 Edition 2.1 2016-04 CONSOLIDATED VERSION	Entire Standard
Surgical, cosmetic, therapeutic and diagnostic laser equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-22 Edition 3.1 2012-10	Entire Standard
Electrocardiographs	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-25 Edition 2.0 2011-10	Excluding Clauses 201.12.1.101.2, 201.12.1.103.3.1, 201.12.1.103.3.2 per partial FDA recognition
Electrocardiographic Monitoring Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-27 Edition 3.0 2011-03	Entire Standard
Magnetic resonance equipment for medical diagnosis	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-33 Edition 3.2b:2015	Excluding Clause 201.12.4.101.3 per partial FDA recognition



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Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
Invasive Blood Pressure Monitoring Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-34 Edition 3.0 2011-05	Entire Standard
Ultrasonic Medical Diagnostic and Monitoring Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-37 Edition 2.1 2015	Entire Standard
X-ray equipment for interventional procedures	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-43 Edition 2.1 2017-05 CONSOLIDATED VERSION	Entire Standard
X-ray equipment for computed tomography	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-44 Edition 3.2:2016	Excluding Sub-clause 203.108 per partial FDA recognition
Mammographic X-ray equipment and mammographic stereotactic devices	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-45 Edition 3.1 2015	Entire Standard



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Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
Ambulatory electrocardiographic systems	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-47 Edition 2.0 2012-02	Entire Standard
Infant phototherapy equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-50 Edition 2.1 2016-04 CONSOLIDATED VERSION	Entire Standard
Medical Beds	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-52 Edition 1.0 2009-12	Entire Standard
X-ray equipment for radiography and radioscopy	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION	Entire Standard
Non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-57 Edition 1.0 2011-01	Entire Standard



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Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
High intensity therapeutic ultrasound equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-62 Edition 1.0 2013-07	Entire Standard
Dental Oral X-Ray Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-63 Edition 1.1 2017-07 CONSOLIDATED VERSION	Entire Standard
Dental Oral X-Ray Equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-65 Edition 1.1 2017-05 CONSOLIDATED VERSION	Entire Standard
X-ray-based image-guided radiotherapy equipment	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 60601-2-68 Edition 1.0 2014-09	Entire Standard
Critical care ventilators	Electrical Tests A Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-12 First Edition 2011-04-15	Entire Standard
Anesthetic workstation	Electrical Tests A	ISO 80601-2-13	Entire Standard



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Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	First edition 2011-08-11	
Automated non-invasive sphygmomanometers	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 80601-2-30 Edition 2.0 2018-03	Excluding Clause 211.8.3.1 per partial FDA recognition
Heating devices using blankets pads or mattresses and intended for heating in medical use	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 80601-2-35 Edition 2.1 2016-04	Entire Standard
Respiratory gas monitors	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-55 Second edition 2018-02	Entire Standard
Thermometers for body temperature measurement	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-56 Second edition 2017-03	Entire Standard
Dental equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 80601-2-60 Edition 2.0 2019-06	Entire Standard



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Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
Pulse oximeter equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)	Excluding Clause 201.12.1.101.1 per partial FDA recognition
Oxygen concentrator equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-69 First Edition 2014-07-15	Entire Standard
Sleep apnoea breathing therapy equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-70 First Edition 2015-01-15	Entire Standard
Home healthcare environment ventilators for ventilator-dependent patients	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-72 First edition 2015-04-11	Entire Standard
Respiratory humidifying equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-74 First edition 2017-05	Entire Standard
Robotically assisted surgical equipment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	IEC 80601-2-77 Edition 1.0 2019-07	Entire Standard



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Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment ⁷

Product Type	Specific Tests or Properties Measured (See ANNEX A for Detailed Descriptions)	Specification, Standard, Method, or Technique Used	Comments
Ventilatory support equipment for ventilatory impairment	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-79 First edition 2018-07	Entire Standard
Ventilatory support equipment for ventilatory insufficiency	Electrical Tests B Thermal Tests Mechanical Tests Environmental Tests Physical/Performance Tests	ISO 80601-2-80 First edition 2018-07	Entire Standard

ANNEX A – List of Safety Tests

Types	Specific Tests
Electrical Tests - A	Input Voltage mismatch Battery testing Working voltage measurement Capacitance discharge Residual voltage measurement Impedance of PE connection Grounding continuity Earth leakage current Touch current Dielectric strength Insulation resistance Abnormal operation Single fault condition (short-circuits, overloads) Limited voltage/current Impulse Motor overload protection CTI EMO operation testing Others

ANNEX A – List of Safety Tests

Types	Specific Tests
Electrical Tests - B	Defibrillation-proof applied part protection: Common and differential mode, energy reduction, response time Patient leakage current Patient auxiliary current RF output accuracy Monotonicity Output amplitude, pulse parameters Frequency response Signal to noise Input impedance Common mode rejection Multichannel crosstalk Gain accuracy Accuracy of signal reproduction Sweep speed Others
Mechanical tests	Durability of marking Ball pressure Glow wire Creepage clearance distances Strain relief test / cord anchorage Cord guard flexing / cord bending Over-travel end stop test Stability/instability Handle loading Overflow, spillage, leakage Mechanical strength Stress relief / mold stress Support/suspension system/ loading Accessibility
Thermal Tests	Temperature rise, Others
Environmental Tests	Resistance to environmental stress Humidity preconditioning Thermal / humidity cycling Others

ANNEX A – List of Safety Tests

Types	Specific Tests
Physical/Performance Tests:	Accuracy of radiation output: X-Radiation, Alpha, beta, gamma, neutron and other particle radiation, Microwave radiation, Lasers, Other visible electromagnetic radiation, Infrared radiation, Ultraviolet radiation, Ultrasound radiation, Electromagnetic radiation Linearity of radiation output Wavelength Power / Energy Pulse duration Spectral Irradiance Measurement accuracy System response time and rise time Alarms Volume-control inflation-type testing Pressure-control Others

Notes:

1. X = any number denoting a particular product standard of the same standard series.
2. For standards or methods listed on the scope of accreditation without a revision date, laboratories are expected to be competent in the use of the current version within one year of standard or method publication update (or by the authorized use date of a recognition body or regulatory agency). When an older standard or method is required for an accredited test, the scope will include the superseded date/version if lab demonstrated to be enveloped by and within the limits of the listed tests and the general controls enveloped in ISO/IEC 17025 Accreditation.
3. For the CISPR and/or IEC standards, the test laboratory is using the regional test requirement documents when applicable as opposed to the base reference documents as defined by the regional regulatory agencies (e.g. AS/NZ representing Australia and New Zealand or any others). For EN standards, the test laboratory is using the requirements of the Official Journal of the European Union (when applicable). Regulatory Bodies, such as the USA based FCC, are listed when the issued regulatory requirement establishes, enhances or modifies the base standard (e.g. ANSI C63.4-2014) and defined regulatory body requirements FCC OET website that incorporates FCC KDB Publication 853844 D01 Accredited Lab Checklist v02, FCC KDB Publication 974614 Accredited Test Lab Roles and Resp v03 and FCC KDB Publication 704992.
4. Open-air 10-meter test site: David Pinkas 45, Rupin Academic Center, Israel.
5. Testing performed in support of FCC approval procedures for certification per ANAB SR 2412 Supplemental Requirements: FCC Recognition of Accredited Testing Laboratories.
6. Testing performed per ANAB SR 2435 Supplemental Requirements: ISED Recognition of Accredited Testing Laboratories to meet the Requirements for Recognition of Telecommunications Testing – Innovation, Science, and Economic Development (ISED) Canada.
7. Testing to meet the requirements of ANAB Supplemental Requirements SR 2437 - FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment.
8. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1359.



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