



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

MTIC InterCert S.r.l.
Via Moscova, 11
20017, Rho, Milano
Italy

Fulfills the requirements of

ISO/IEC 17025:2017

and

**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**

In the field of

TESTING

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

Jason Stine, Vice President

Expiry Date: 3 February 2027
Certificate Number: AT-3175



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

and

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 ¹

MTIC InterCert S.r.l.

Via Moscova, 11

20017, Rho, Milano, Italy

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TESTING

Valid to: **February 3, 2027**

Certificate Number: **AT-3175**

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 ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Medical Electrical Equipment	Electrical Safety and Essential Performance	19-46, ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Excluding Sections 11.2.2, 11.4, Annex G
Medical Electrical Equipment	Usability	5-132, IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION IEC 60601-1-6 Edition 3.1 2013-10	Complete Standard
Medical Electrical Equipment	Alarm Systems	5-131, IEC 60601-1-8 Edition 2.2 2020-07 Consolidated Version	Complete Standard
Medical Electrical Equipment	Alarm Systems	5-76, IEC 60601-1-8 Edition 2.1 2012-11	Complete Standard
Medical Electrical Equipment	Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment	19-38, IEC 60601-1-11 Edition 2.1 2020-07 Consolidated Version	Complete standard

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 ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Medical Electrical Equipment	Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment	19-14, IEC 60601-1-11 Edition 2.0 2015-01	Complete standard
Medical Electrical Equipment	Medical Electrical Equipment and Medical Electrical Systems Intended for use in the Emergency Medical Services Environment	19-39, IEC 60601-1-12 Edition 1.1 2020-07 Consolidated Version	Complete standard
Medical Electrical Equipment	Medical Electrical Equipment and Medical Electrical Systems Intended for use in the Emergency Medical Services Environment	19-15, IEC 60601-1-12 Edition 1.0 2014-06	Complete standard
Electrical Equipment for Measurement Control & Laboratory Use	Electrical Safety and Essential Performance	19-34, IEC 61010-1 Edition 3.1 2017-01 Consolidated Version	Complete standard
Surgical Equipment and High Frequency Surgical Accessories	Electrical Safety and Essential Performance	6-389, IEC 60601-2-2 Edition 6.0 2017-03	Excluding Section 12
Ultrasonic Physiotherapy Equipment	Electrical Safety and Essential Performance	12-205, IEC 60601-2-5 Edition 3.0 2009-07	Excluding Section 12
Microwave Therapy Equipment	Electrical Safety and Essential Performance	6-423, IEC 60601-2-6 Edition 2.1 2016-04	Complete standard
Nerve and Muscle Stimulators	Electrical Safety and Essential Performance	17-16, IEC 60601-2-10 Edition 2.1 2016-04	Complete standard
Surgical Cosmetic Therapeutic and Diagnostic Laser Equipment:	Electrical Safety and Essential Performance	12-268, IEC 60601-2-22 Edition 3.1 2012-10	Excluding Section 12
Electrocardiographs	Electrical Safety and Essential Performance	3-105, IEC 60601-2-25 Edition 2.0 2011-10	Excluding Section 12
Electrocardiographs	Electrical Safety and Essential Performance	3-126, IEC 60601-2-27 Edition 3.0 2011-03	Excluding Section 12

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 ¹

Product Type	Specific Tests or Properties Measured	Specification, Standard, Method, or Technique Used	Comments
Ultrasonic Medical Diagnostic and Monitoring Equipment	Electrical Safety and Essential Performance	12-293, 12-293, IEC 60601-2-37 Edition 2.1 2015	Excluding Section 12
Electrocardiographs	Electrical Safety and Essential Performance	3-155, IEC 60601-2-47 Edition 2.0 2012-02	Excluding Section 12
Medical Beds	Electrical Safety and Essential Performance	6-321, IEC 60601-2-52 Edition 1.0 2009-12	Complete standard
Pulse Oximeters	Electrical Safety and Essential Performance	1-139, IEC 80601-2-61 Second Edition 2017-12 (Corrected Version 2018-02)	Complete standard
Medical electrical equipment-Emissions tests, Immunity tests	Basic Safety and Essential Performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36, IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	To the extent of the FDA ASCA partial recognition
	Basic Safety and Essential Performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]	19-36, ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Electrical, Mechanical, Temperature, Environmental Tests	IEC 61010-1 IEC 61010-2-040 IEC 61010-2-081 IEC 61010-2-101 Exclusions: 12.2, 12.4, 12.5.2, 12.6, 13.2.3, 14.8	Equipment for measurement, control and laboratory use	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Pressure and vacuum gauge, Data logger, Climatic chamber, Oven, Creepage and clearance tools

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Electrical, Mechanical, Temperature, Environmental Tests	IEC/EN 60601-1, AAMI ES60601-1 IEC / EN 60601-1-6, IEC / EN 60601-1-8, IEC / EN 60601-1-11 IEC / EN 60601-1-12, IEC / EN 62304, IEC / EN 62366-1, ISO / IEC 14971, IEC/EN 60601-2-2, IEC/EN 60601-2-5, IEC/EN 60601-2-6, IEC/EN 60601-2-10, IEC/EN 60601-2-22, IEC/EN 60601-2-25, IEC/EN 60601-2-27, IEC/EN 60601-2-37, IEC/EN 60601-2-47, IEC/EN 60601-2-52, ISO 80601-2-61 Exclusions: 11.2.2, 11.4, 12 (for IEC/EN 60601-2-2, IEC/EN 60601-2-5, IEC/EN 60601-2-22, IEC/EN 60601-2-25, IEC/EN 60601-2-27, IEC/EN 60601-2-37, IEC/EN 60601-2-47, ISO 80601-2-61 Annex G, IEC/EN 60601-2-52 201.9.1.101 and Section BB.2	Medical Electrical Equipment and Medical Electrical Systems	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Pressure and vacuum gauge, Data logger, Climatic chamber, Oven, Creepage and clearance tools
Electrical, Mechanical, Temperature, Environmental Tests	IEC / EN 60335-1 IEC / EN 60335-2-102 Exclusions: 14, 30.2	Household and similar electrical appliance	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Pressure and vacuum gauge, Data logger, Climatic chamber, Oven, Creepage and clearance tools

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Electrical, Mechanical, Temperature, Environmental Tests	IEC / EN 60598-1 Exclusions: 13.3.1, 13.3.2, 13.4.1	Luminaries	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Pressure and vacuum gauge, Data logger, Climatic chamber, Oven, Creepage and clearance tools
Electrical, Mechanical, Temperature, Environmental Tests	IEC / EN 62368-1 Exclusions: 5.4.1.10.2 (Vicat test), 5.4.2.3.2, 5.4.3.3 (CTI test), 5.4.4.6.5, 5.4.10, 5.6.6.2 b), 6.4.8.3.3, 6.4.8.3.4, 6.5.1, 8.5.5.2	Audio/video, Information and Communication technology equipment	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Pressure and vacuum gauge, Data logger, Climatic chamber, Oven, Creepage and clearance tools
Electrical, Mechanical, Temperature, Environmental Tests	IEC / EN 62115	Electric toys	Digital Multimeter, Dielectric Tester, Force gauge, Oscilloscope, Sound meter, Data logger, Climatic chamber, Oven, Creepage and clearance tools
Electrical, Mechanical	IEC / EN 60204-1	Machines	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Electrical, Mechanical, Environmental Tests	EN 54-2 ISO / AS 7240-2	Control and indicating equipment	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-3 ISO / AS 7240-3	Sounders	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-4 ISO / AS 7420-4	Power supply equipment	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-5 (§§ 4.6, 5.6)	Point heat detectors	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-7 (only §§ 4.7, 5.7)	Point smoke detectors	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-10 (only §§ 5.7, 5.8, 5.9, 5.10, 5.11, 5.12, 5.13, 5.14, 5.15, 5.16, 5.17)	Point detectors	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Electrical, Mechanical, Environmental Tests	EN 54-11 (only §§ 5.6, 5.7, 5.8, 5.9, 5.10, 5.11, 5.12, 5.13, 5.14, 5.15, 5.16, 5.17, 5.18)	Manual call points	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-12 (only §§ 4.6, 5.6)	Line detectors	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-16 ISO / AS 7420-16	Voice alarm control and indicating equipment	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-17	Short-circuit isolators	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-18:	Input/output devices	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-20 (only §§ 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 6.10, 6.11, 6.12, 6.13, 6.14)	Input/output devices	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Electrical, Mechanical, Environmental Tests	EN 54-21	Routing equipment	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 54-24 ISO / AU 77420-24	Loudspeakers	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 12094-1	Electrical automatic control and delay devices	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber
Electrical, Mechanical, Environmental Tests	EN 12101-10	Power supplies	Digital Multimeter, Force gauge, Power meter, Oscilloscope, Ammeter, Sound meter, Data logger, Climatic chamber

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Power frequency magnetic field - only to 100A/m CW and 100A/m Pulse	EN 61000-4-8 IEC 61000-4-8	Electric and electronic equipment	Magnetic field generator with antenna
Emissions tests (9 kHz to 6 GHz)	EN 61000-6-3 EN IEC 61000-6-3 IEC 61000-6-3	Electrical and electronic equipment for residential, commercial and light industrial environments	FAR chamber EMI Receiver Loop antenna Log antenna

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Emissions tests, Immunity tests	EN 61326-2-6 EN IEC 61326-2-6 IEC 61326-2-6	Electrical equipment for measurement, control and laboratory use: In vitro diagnostic (IVD) medical equipment	FAR chamber EMI Receiver Log Antenna Line Impedance Stabilization Network Absorbing clamp RF generator RF amplifier with control system RF power meters RF field sensor
Basic Safety and Essential Performance - Collateral Standard: Electromagnetic disturbances	IEC 60601-1-2 EN 60601-1-2	Medical electrical equipment- Emissions tests, Immunity tests	FAR chamber EMI Receiver Log Antenna Line Impedance Stabilization Network Absorbing clamp RF generator RF amplifier with control system RF power meters RF field sensor Coupling/decoupling Network Injection clamp ESD generator Burst generator Surge generator Dips generator
Harmonic currents emission (Up to 2 kHz)	EN 61000-3-2 EN IEC 61000-3-2 IEC 61000-3-2	Electric and electronic equipment	Stabilized generator Harmonic currents measurement equipment
Conducted disturbance measurements (9 kHz to 30 MHz)	EN 55016-2-1 CISPR 16-2-1	Electric and electronic equipment	Line Impedance Stabilization Network EMI Receiver Absorbing clamp
Radiated disturbance measurements (9 kHz to 18 GHz)	EN 55016-2-3 CISPR 16-2-3	Electric and electronic equipment	FAR chamber EMI Receiver Loop antenna Log/horn antenna
Surge immunity test (Up to ± 4 kV)	EN 61000-4-5 IEC 61000-4-5	Electric and electronic equipment	Surge generator

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Radiated radio frequency electromagnetic field immunity test (80 MHz to 6 GHz; Up to 30 V/m)	EN 61000-4-3 EN IEC 61000-4-3 IEC 61000-4-3	Electric and electronic equipment	FAR chamber Log Antenna RF generator RF amplifier RF power meters RF field sensor
Emission tests (9 kHz to 18 GHz)	EN 55016-1-4 EN IEC 55016-1-4 CISPR 16-1-4	Electric and electronic equipment	FAR chamber EMI Receiver Loop antenna Log antenna Horn antenna
Emissions tests (9 kHz to 1 GHz)	EN 55016-1-2 CISPR 16-1-2	Electric and electronic equipment	FAR chamber EMI Receiver Loop antenna Log antenna
Voltage dips, short interruptions, and voltage variations immunity tests for equipment with input current up to 16 A per phase	EN 61000-4-11 EN IEC 61000-4-11 IEC 61000-4-11	Electric and electronic equipment	Dips generator
Electrostatic discharge immunity test (Up to ± 8 kV with contact and ± 15 kV in air)	EN 61000-4-2 IEC 61000-4-2	Electric and electronic equipment	Electrostatic discharge generator
Conducted disturbances induced by radio-frequency field immunity test (0.15 MHz to 230 MHz)	EN 61000-4-6 IEC 61000-4-6	Electric and electronic equipment	RF generator RF amplifier Coupling/decoupling network Injection clamp
Electrical fast transient - burst immunity test (Up to ± 4 kV)	EN 61000-4-4 IEC 61000-4-4	Electric and electronic equipment	Fast transient-burst generator Injection clamp
Voltage changes, voltage fluctuations and flicker	EN 61000-3-3 IEC 61000-3-3	Electric and electronic equipment	Voltage changes, fluctuations, and flicker measurement equipment

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Emissions tests, Immunity tests	EN 61326-1 EN IEC 61326-1 IEC 61326-1	Electrical equipment for measurement, control and laboratory use	FAR chamber EMI Receiver Log Antenna Line Impedance Stabilization Network Absorbing clamp RF generator RF amplifier RF power meters RF field sensor Coupling/decoupling Network Injection clamp ESD generator Burst generator Surge generator Dips generator
Emissions tests (9 kHz to 18 GHz)	EN 55011 CISPR 11	Industrial, scientific, and medical equipment	FAR chamber EMI Receiver Loop Antenna Log Antenna Horn antenna
Emissions tests (9 kHz to 6 GHz)	EN 55032 CISPR 32	Multimedia equipment	FAR chamber EMI Receiver Loop Antenna Log Antenna
Immunity tests - except 4.2.7	EN 55035 CISPR 35 KN 35	Multimedia equipment	RF generator RF amplifier RF power meters RF field sensor Coupling/decoupling Network Injection clamp ESD generator Burst generator Surge generator Dips generator

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Immunity tests	EN 50130-4	Components of fire, intruder, hold up, CCTV, access control and social alarm systems	RF generator RF amplifier RF power meters RF field sensor Coupling/decoupling Network Injection clamp ESD generator Burst generator Surge generator Dips generator
Emissions tests (150 kHz to 6 GHz)	EN 55014-1 CISPR 14-1 EN IEC 55014-1	Household appliances, electric tools and similar apparatus	FAR chamber EMI Receiver Loop Antenna Log Antenna Line Impedance Stabilization Network Absorbing clamp
Immunity tests	EN 55014-2 CISPR 14-2 EN IEC 55014-2	Household appliances, electric tools, and similar apparatus	RF generator RF amplifier RF power meters RF field sensor Coupling/decoupling Network Injection clamp ESD generator Burst generator Surge generator Dips generator
Emissions tests, Immunity tests	ETSI EN 301 489-19	Radio equipment and services: receive Only Mobile Earth Stations (ROMES) operating in the 1, 5 GHz band providing data communications and GNSS receivers operating in the RNSS band (ROGNSS) providing positioning, navigation, and timing data	GPS repeater

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Emissions tests, Immunity tests	ETSI EN 301 489-1 ETSI EN 301 489-3 ETSI EN 301 489-17	Radio equipment and services: short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Radio equipment and services; broadband Data Transmission Systems	FAR chamber EMI receiver Log Antenna Horn Antenna RF generator RF amplifier RF power meters RF field sensor Coupling/decoupling Network Injection clamp ESD generator Burst generator Surge generator Dips generator
Emissions tests, Immunity tests	ETSI EN 303 446-2	Combined and/or integrated radio and non-radio equipment: equipment intended to be used in industrial locations	FAR chamber EMI receiver Log Antenna Horn Antenna RF generator RF amplifier RF power meters RF field sensor Coupling/decoupling Network Injection clamp ESD generator Burst generator Surge generator Dips generator

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Emissions tests, Immunity tests	ETSI EN 303 446-1	Combined and/or integrated radio and non-radio equipment: equipment intended to be used in residential, commercial, and light industry location	FAR chamber EMI receiver Log Antenna Horn Antenna RF generator RF amplifier RF power meters RF field sensor Coupling/decoupling Network Injection clamp ESD generator Burst generator Surge generator Dips generator
Radio test (9 kHz to 6 GHz)	ETSI EN 300 330	Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz	FAR chamber Climatic chamber RF Spectrum analyzer Log Antenna Horn antenna RF Generator
Radio test (9 kHz to 6 GHz)	ETSI EN 300 220-2	Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz	FAR chamber Climatic chamber RF Spectrum analyzer Log Antenna Horn antenna RF Generator
Radio test (9 kHz to 6 GHz)	ETSI EN 300 220-3-2	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz: wireless alarms operating in designated LDC/HR frequency bands 868,60 MHz to 868,70 MHz, 869,25 MHz to 869,40 MHz, 869,65 MHz to 869,70 MHz	FAR chamber Climatic chamber RF Spectrum analyzer Log Antenna Horn antenna RF Generator

Electromagnetic Compatibility

Test Method	Test Specification(s)	Range	Comments
Radio test (9 kHz to 6 GHz)	ETSI EN 300 220-3-1	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz: low duty cycle high reliability equipment, social alarms equipment operating on designated frequencies (869,200 MHz to 869,250 MHz)	FAR chamber Climatic chamber RF Spectrum analyzer Log Antenna Horn antenna RF Generator
Radio test (9 kHz to 6 GHz)	ETSI EN 300 220-4	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz: metering devices operating in designated band 169,400 MHz to 169,475 MHz	FAR chamber Climatic chamber RF Spectrum analyzer Log Antenna Horn antenna RF Generator
Radio test (9 kHz to 6 GHz)	ETSI EN 300 220-1	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz	FAR chamber Climatic chamber RF Spectrum analyzer Log Antenna Horn antenna RF Generator
Radio test (30 MHz to 18 GHz)	ETSI EN 300 440	Short Range Devices (SRD) - Radio equipment to be used in the 1 GHz to 40 GHz frequency range	FAR chamber RF Spectrum analyzer Log Antenna Horn antenna
Radio test (30 MHz to 12.75 GHz)	ETSI EN 300 328 only §§5.4.2 (RF output power) §§5.4.9, §§5.4.10	Wideband transmission systems - Data transmission equipment operating in the 2, 4 GHz band	FAR chamber RF Spectrum analyzer Log Antenna Horn antenna
Radio test only 4.2.2 (30 MHz to 8.3 GHz)	ETSI EN 303 413	Satellite Earth Stations and Systems (SES); Global Navigation Satellite System (GNSS) receivers; Radio equipment operating in the 1 164 MHz to 1 300 MHz and 1 559 MHz to 1 610 MHz frequency bands	FAR chamber RF Spectrum analyzer Log Antenna Horn antenna

Environmental Testing

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
High / Low Temperature	EN ISO 60068-2-2	-	Climatic chamber
High / Low Temperature	EN ISO 60068-2-14 (sub-clause 8)	-	Climatic chamber
Humidity / Moisture Resistance	EN ISO 60068-2-30	-	Climatic chamber
Sulphur dioxide	EN 60068-2-42	-	Sulphur dioxide chamber
Salt mist	EN IEC 60068-2-52 EN IEC 60068-2-11 EN ISO 9227	-	Salt mist chamber
Hammer tests	IEC 60068-2-75 (Test Ehb)	-	Spring Hammer
Ball pressure test	EN 60695-10-2	-	Climatic chamber
Water/Dust	EN ISO 60529 ISO 20653 Exclusions: IPX8, IPX9	Degrees of protection provided by enclosure	IP Test Apparatus

Vibration

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Vibration (Sine & Random)	EN ISO 60068-2-1	-	Vibration Test Bench Max 2 kHz
Vibration – Random and Sinusoidal	EN ISO 60068-2-6	-	Vibration Test Bench Max 2 kHz
Vibration – Random and Sinusoidal	EN 60068-2-64	-	Vibration Test Bench Max 2 kHz
Mechanical Shock	EN 60068-2-27	-	Vibration Test Bench Max 2 kHz

Notes:

1. Testing to meet the requirements of ANAB Supplemental Requirements SR 2437, FDA Accreditation Scheme for Conformity Assessment (ASCA) Program – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment. Recognition by the FDA can be confirmed by visiting their website <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories>.
2. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-3175.



Jason Stine, Vice President