



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

**Eurofins Electrical & Electronic Testing NA, Inc.
(Eurofins E&E) dba Eurofins CertifiGroup
901 Sheldon Drive
Cary, NC 27513**

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: 12 May 2025

Certificate Number: AT-1545



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

**Eurofins Electrical & Electronic Testing NA, Inc. (Eurofins E&E) dba
Eurofins CertifiGroup**

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Cary, NC 27513

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TESTING

Valid to: May 12, 2025

Certificate Number: AT-1545

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
Electrical Equipment for Measurement Control & Laboratory Use	Electrical, Physical, & Mechanical Tests	19-34, IEC 61010-1 Edition 3.1 2017-01 Consolidated Version	Complete Standard
Medical Electrical Equipment	Electrical, Physical, & Mechanical Tests	19-4, ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Complete Standard
Radiation Protection in Diagnostic X-ray Equipment	Electrical, Physical, & Mechanical Tests	12-336, IEC 60601-1-3 Edition 2.2 2021-01 Consolidated Version 12-269, IEC 60601-1-3 Edition 2.1 2013-04	Complete Standard
Medical Electrical Equipment	Usability Review	5-132, IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION 5-89, IEC 60601-1-6 Edition 3.1 2013-10	Complete Standard
Medical Electrical Equipment	Development of Closed-Loop Controllers	19-37, IEC 60601-1-10 Edition 1.2 2020-07 Consolidated Version 19-9, IEC 60601-1-10 Edition 1.1 2013-11	Complete Standard



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Medical Electrical Equipment and Systems for used in the Home Healthcare Environment	Electrical, Physical, & Mechanical Tests	19-16, ANSI AAMI HA60601-1-11:2015	Complete Standard
Medical Electrical Equipment and Systems for used in the Home Healthcare Environment	Electrical, Physical, & Mechanical Tests	19-38, IEC 60601-1-11 Edition 2.1 2020-07 Consolidated Version 19-14, IEC 60601-1-11 Edition 2.0 2015-01	To the extent of the FDA ASCA partial recognitions
Medical Electrical Equipment and Systems for use in Emergency Medical Services Environment	Electrical, Physical, & Mechanical Tests	19-39, IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	Complete Standard
Electrosurgical Generators	Electrical, Physical, & Mechanical Tests	6-389, IEC 60601-2-2 Edition 6.0 2017-03, ANSI AAMI IEC 60601-2-2:2017	To the extent of the FDA ASCA partial recognition
Nerve and Muscle Stimulators	Electrical, Physical, & Mechanical Tests	17-16, IEC 60601-2-10 Edition 2.1 2016-04	Complete Standard
Endoscopic Equipment	Electrical, Physical, & Mechanical Tests	9-114, IEC 60601-2-18 Edition 3.0 2009-08	Complete Standard
Surgical Cosmetic Therapeutic and Diagnostic Laser Equipment:	Electrical, Physical, & Mechanical Tests	12-268, IEC 60601-2-22 Edition 3.1 2012-10	Complete Standard
Electrocardiographs	Electrical, Physical, & Mechanical Tests	3-105, IEC 60601-2-25 Edition 2.0 2011-10, ANSI AAMI IEC 60601-2-25:2011/(R) 2016	To the extent of the FDA ASCA partial recognition
Electrocardiographic Monitoring Equipment	Electrical, Physical, & Mechanical Tests	3-126, IEC 60601-2-27 Edition 3.0 2011-03, ANSI AAMI IEC 60601-2-27:2011/(R) 2016	Complete Standard
Invasive Blood Pressure Monitoring Equipment	Electrical, Physical, & Mechanical Tests	3-115, IEC 60601-2-34 Edition 3.0 2011-05	Complete Standard
Ultrasonic Medical Diagnostic and Monitoring Equipment	Electrical, Physical, & Mechanical Tests	12-293, IEC 60601-2-37 Edition 2.1 2015	Complete Standard
Medical Beds	Electrical, Physical, & Mechanical Tests	6-321, IEC 60601-2-52 Edition 1.0 2009-12	Complete Standard
Dental Oral X-Ray Equipment	Electrical, Physical, & Mechanical Tests	12-311, IEC 60601-2-65 Edition 1.1 2017-05 Consolidated Version 12-340, IEC 60601-2-65 Edition 1.2 2021-05 Consolidated Version	Complete Standard

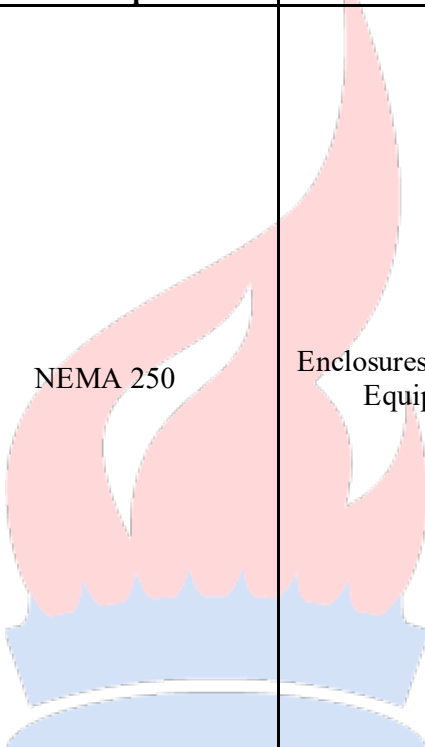
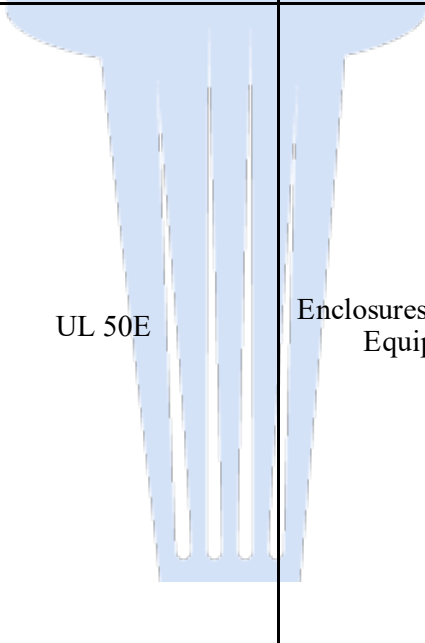
Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Ingress Protection Tests (IP1X-6X) (IPX1-X9)	IEC 60529	Enclosures, Electrical Equipment	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank
Ingress Protection Tests (IP2X-6X) (IPX1-X9)	IEC 60598-1	Luminaries	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank
Ingress Protection Tests (IP1X-6X) (IPX1-X9) Sec. 33.6 Rain Test	IEC 60034-5 UL 1004-1	Rotating Electrical Machine	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank, Rain Test Apparatus
Ingress Protection Tests (IP1X-6X) (IPX1-X9)	EN / IEC 60204-1	Electrical Equipment of Machines	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank
Ingress Protection Tests (IP1X-6X) (IPX1-X9)	UL / CSA / EN / IEC 60079	Explosive Atmospheres	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank
Ingress Protection Tests (IP1X-6X) (IPX1-X9)	UL / CSA / EN / 60335-1	Household and similar Electrical Appliances	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank
Ingress Protection Tests (IP1X-6X) (IPX1-X9)	UL / CSA / EN / IEC 60601-1 AAMI ES60601-1	Medical Equipment	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank
Ingress Protection Tests (IP1X-6X) (IPX1-X9)	UL / CSA / EN / IEC 61010-1	Laboratory Equipment	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank

Mechanical

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Ingress Protection Tests (IP1X-6X) (IPX1-X9)	UL / CSA / EN / IEC 60065	Audio, video, and similar electronic apparatus	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank, 50mm sphere, Oven, Impact Hammer
IP1X-4X, IPX1-X4, IPX4K, IPX5-6, IPX6K, IPX7-X9, IPX6K, IPX9K	DIN 40050-9	Enclosures, Road Vehicle Equipment	Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Immersion Tank, Dust Chamber
IP5X, IPX4 - Section 9.1 IP5X, IP6X - Section 9.3(Dust) Sec. 10.2 (Impact Test) Sec. 8.5, Annex D (Gasket Tests)	UL / CSA / EN / IEC 60950-22	Outdoor Use Equipment	Dust Chamber, Spray Tester, Oscillating Spray Tester, Thermocouple Reader, Tensile Strength Tester, Temperature and Humidity Recorder, 50 mm sphere, 18kg Weight, 1.35kg Impact Weight, Calipers
Outdoor Use Equipment Sec. 1.1.2, Annex T Ingress Protection Tests (IP1X-6X) (IPX1-X9)	UL / CSA / EN / IEC 60950-1	Information Technology Equipment	50 mm sphere, Oven, Mechanical Probes, Drip Box, Oscillating Spray Tester, Spray Tester, Jet Nozzle, Dust Chamber, Immersion Tank

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Type 1, 2, 3, 3R, 3X, 3RX, 3S, 3SX, 4, 4X, 5, 6, 6P, 12, 12K, 13 Sec 5.2 (Protection against Hazardous Parts) Sec. 5.3 (Dripping and Light Splashing) Sec 5.4 (Rain) Sec. 5.5.2.1.3 (Atomized Water-Method A) Sec. 5.5.2.2.3 (Atomized Water-Method B) Sec. 5.5.1.3 (Hose Method) Sec. 5.6 (External Icing) Sec. 5.7 (Hosedown) Sec. 5.8 (Indoor Corrosion Protection) Sec. 5.9 (Outdoor Corrosion Protection) Sec. 5.10 (Corrosion Protection) Sec. 5.11 (Temporary Submersion) Sec. 5.12 (Prolonged Submersion) Sec. 5.14 (Gasket Tests)	 <p>NEMA 250</p>	<p>Enclosures, Electrical Equipment</p>	<p>Mechanical Probes, Drip Box, Rain Test Apparatus, Immersion Tank, Jet Nozzle, Atomized Water Nozzle, Salt Fog Chamber, Tensile Strength Tester, Thermocouple Reader</p>
Type 1, 2, 3, 3R, 3S, 4, 4X, 5, 6, 6P, 12, 12K, 13 Sec 8.2 (Drip Test) Sec. 8.3 (Rain Test) Sec. 8.4.2.1.2 (Atomized Water-Method A) Sec 8.4.2.2.2 (Atomized Water-Method B) Sec. 8.4.1.2(Hose Method) Sec. 8.5 (External Icing) Sec. 8.6 (Hosedown) Sec. 8.7 (Indoor Corrosion) Sec. 8.8(Outdoor Corrosion) Sec. 8.9 (Additional Corrosion) Sec.8.10 (Submersion Test) 8.11.2 (External Pressurization Method) Sec. 8.13 (Gasket Tests) Sec. 8.14 (Rod Entry)	 <p>UL 50E</p>	<p>Enclosures, Electrical Equipment</p>	<p>Drip Box, Rain Test Apparatus, Immersion Tank, Jet Nozzle, Atomized Water Nozzle, Salt Fog Chamber, Immersion Tank, Tensile Strength Tester, Thermocouple Reader, 18kg Weight, 1.35kg Impact Weight, Calipers</p>

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sec 26.4.3 Drop Test	UL/CSA/EN/IEC 60079-0	Enclosures, Electrical Equipment	Tape Measure, Concrete
Wet Locations Sec. 16.5.2 Rain Sec. 16.5.4 Immersion	UL 1598	Luminaries	Rain Test Apparatus, Immersion Tank
Outdoor Use	UL 73	Motor Operated Appliances	Rain Test Apparatus
Sec. 49 Water Spray Test	UL 1278	Movable and Wall or Ceiling Hung Electric Room Heaters	Rain Test Apparatus
Sec. 38 Water Spray Test	UL 507	Electric Fans	Rain Test Apparatus
Temperature Humidity Test (-100 to 200) °C (0 to 99) % RH	Multiple Standards or Customer Request	Temperature and Humidity	Temperature and Humidity Recorder, Environmental Chambers
Salt Spray (Fog) Immersion Test Sec. 509.4, 512.4 (F) Sec. 509.5, 512.5 (G)	MIL-STD-810 F MIL-STD-810 G	Department of Defense Test Standard for Environmental Engineering Considerations and Laboratory Test	Salt Fog Chamber, Immersion Tank
Salt Spray (Fog)	ASTM B117	Standard Practice for Operating Salt Spray (Fog) Apparatus	Salt Fog Chamber
Sec. 5.1.1.2 High Humidity Sec. 5.1.1.13 High Temp/Thermal Shock	GR-63-CORE	NEBS Requirements: Physical Protection	Environmental Chambers, Oven, Thermocouple Reader
Sec. 3.31.2 Rain Intrusion Sec. 3.31.3 & 3.31.4 Water Intrusion Sec. 3.31.5 Lawn Sprinklers	GR-487-CORE	Generic Requirements for Electronic Equipment Cabinets	Rain Test Apparatus, Immersion Tank,
Sec. 4.3 Salt Spray Atmosphere	SAE J1455	Surface Vehicle Recommended Practice	Salt Fog Chamber,
Sec. 26.4.2 Explosive Atmospheres	UL/CSA/EN/IEC 60079-0	Resistance to Impact Test	25mm/1kg sphere Hardened steel base
Small Parts (Choke Hazard)	ASTM F963-17; 4.6 16 CFR 1501 SOR/2011-17; 7, 30, S1 M00.1(4) ISO 8124-1; 4.4,5.2 EN71-1; 8.2	Toys	Choke Hazard Tester

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Sharp Edges	ASTM F963-17; 4.7 16 CFR 1500.49 M00.2(4) ISO 8124-1; 4.6,5.8 EN71-1; 4.7,8.11	Toys	Sharp Edge Tester, Caliper
Sharp Points	ASTM F963-17; 4.9 16 CFR 1500.49 M00.3(4) ISO 8124-1; 4.7,5.9 EN71-1; 8.12	Toys	Sharp Point Tester SPT-1000, Caliper
Accessibility	ASTM F963-17; 3.1.2 ISO 8124-1; 5.7 EN71-1; 8.10	Toys	Child Finger Probes, Caliper
Drop Test (Impact Test)	ASTM F963-17; 8.7.1 16 CFR 100.51(b) M01.1(5.4) ISO 8124-1; 5.24.2 EN71-1; 4.5,8.5	Toys	Scale, Tape Measure, Impact Medium
Flexure Test	ASTM F963-17; 8.12 16 CFR 1500.51(d) ISO 8124-1; 4.9,5.24.8 EN71-1; 8.13	Toys	Flexure Tester, Force Gauge
Torque test for removal of components	ASTM F963-17; 8.8 16 CFR 1500.51(e) ISO 8124-1; 5.24.5 EN71-1; 8.3	Toys	Torque Wrench
Tension test for removal of components	ASTM F963-17; 8.9 16 CFR 1500.51(f) M01.1(5.5) ISO 8124-1; 5.24.6 EN71-1; 8.4	Toys	Force Gauge, Seam Clamp, Feeler Gauge Attachment
Tension test for seams	ASTM F963-17; 4.27,8.9.1 ISO 8124-1; 5.24.6.2 EN71-1; 8.4.2.2	Toys	Force Gauge, Seam Clamp, Feeler Gauge Attachment
Compression test	ASTM F963-17; 8.10 16 CFR 1500.51(g) ISO 8124-1; 5.24.7 EN71-1; 8.8	Toys	Force Gauge, Rigid metal disc attachment
Bite Test	16 CFR 1500.51(c)	Toys	Tape Measure, Force Gauge, Bite Test Clamp

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Leakage of liquid-filled toys	ISO 8124-1; 4.24,5.19 EN71-1; 5.5,8.15	Toys	Force Gauge, Puncture Tester, Stopwatch, Cobalt Chloride Paper, Temp/Humidity Chamber
Tire Removal and snap in axle tension/compression Test	ASTM F963-17; 8.11	Toys	Wire Hook, Rigid Plate, Weights, Sharp Point Tester, Sharp Edge Tester
Toys with Locking Mechanisms and Hinges	ASTM F963-17; 4.13, 8.25 SOR/2011/17; 14	Toys	Force Gauge
Security of attached eyes and noses to Dolls, Plush Toys, and Soft Toys	SOR/2011/17; 31, S4 M01.2	Toys	Weights, Claw Hook, Discs, Stopwatch, Caliper, Test Stand
Simulated Protective Devices (Masks, Helmets, etc.)	ASTM F963-17; 4.19.1, 8.7.4 ISO 8124-1; 4.14,5.14, 5.24.6.4 EN71-1; 8.4.2.3	Toys	Force Gauge, Steel Ball, Tape Measure, Multiple Equipment Items
Pacifiers, Rattles, Teethers, Squeeze Toys (Geometric Shape of Certain Toys)	ASTM F963-17; 4.20,4.22,4.23,4.24 16 CFR 1510,1511 SOR/2011-17; 40, S8 ISO 8124-1; 4.5,5.3 EN71-1; 5.8,8.16	Toys	Rattle Test Fixture, Supplemental Test Fixture, Caliper
Preschool Play Figures	ASTM F963-17; 4.32.3 ISO 8124-1; 4.5.4,5.6 EN71-1; 5.11,8.33	Toys	Rattle Test Fixture, Supplemental Test Fixture, Caliper
Small Balls and Suction Cups	ASTM F963-17; 4.34 16 CFR1500.18(a)(17) ISO 8124-1; 4.5.2,5.4 EN71-1; 5.10,5.13,8.32	Toys	Small Ball Test Fixture
PomPoms	ASTM F963-17; 4.35, 8.16 ISO 8124-1; 4.5.3,5.5	Toys	Torque Wrench, Seam Clamp, Small Ball Test Fixture, Force Gauge
Hemispheric-Shaped toys	ASTM F963-17; 4.36 ISO 8124-1; 4.5.5 EN71-1; 5.12	Toys	Caliper, Optical Comparator
Toys with nearly Spherical Ends	ASTM F963-17; 4.32	Toys	Supplemental Fixture, Scale, Tape Measure/ Caliper
Jaw Entrapment in handles and steering wheels	ASTM F963-17; 4.39	Toys	Jaw Entrapment Fixtures

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Tests for toys with shaft-like handles	SOR/2011/17; 37	Toys	Tape Measure, Force Gauge
Springs	ASTM F963-17; 4.18.6 ISO 8124-1; 4.14 EN71-1; 4.10.4	Toys	Calipers, Force Gauge
Spring Wound Driving Mechanisms	SOR/2011/17; 15(d)	Toys	Ruler/Caliper, Child Test Finger
Perimeter of Cords and Chains	EN71-1; 8.36	Toys	Test Blocks, Force Gauge, Head Probe
Tests for Loops, Cords, and Elastics	ASTM F963-17; 4.14, 8.22 SOR/2011/17; 41 ISO 8124-1; 4.11,5.11 EN71-1; 4.13,5.4,8.19,8.20	Toys	Force Gauge, Caliper, Weights, Tape Measure, Head Probe, Hook Test Fixture
Breakaway feature separation test	EN71-1; 8.38	Toys	Force Gauge
Self-retracting cords	EN71-1; 8.39	Toys	1 kg weight, Tape Measure
Length of cords, chains, and electrical cables	EN71-1; 8.40	Toys	Tape Measure
Toys comprising monofilament fibers	EN71-1; 5.9	Toys	Tape Measure
Plastic Film/Sheet Thickness	ASTM F963-17; 4.12, 8.21 SOR/2011/17; 4 M03(4) ISO 8124-1; 4.10,5.10 EN71-1; 4.3,5.3,8.25	Toys	Tape Measure, Micrometer
Toys with Accessible Wires or Rods	ASTM F963-17; 4.10	Toys	Angle Meter, Tape Measure, Caliper, Force Gauge
Toys Containing Nails and Fasteners	ASTM F963-17; 4.11 SOR/2011/17; 28	Toys	Multiple Equipment Items
Toy Closures and Ventilation	ASTM F963-17; 4.16	Toys	Caliper, Force Gauge
Toy Clearance	ASTM F963-17; 4.18	Toys	Accessibility Probes, Calipers, Force Gauge
Tip Over Test	ASTM F963-17; 8.7.2 16 CFR 1500.51(b)(4) ISO 8124-1; 5.24.3	Toys	Scale, Impact Medium

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Stability of Stationary Floor Toys	ASTM F963-17: 4.15.4	Toys	Angle Meter, Scale, Tape Measure
Tumble Test for Wheeled Toys	ASTM F963-17; 8.7.3	Toys	Scale, Wooden Steps
Ride on Stability Test	ASTM F963-17; 8.15	Toys	Angle Meter, Weights, Tape Measure
Overload of ride on toy seats	ASTM F963-17; 8.26	Toys	Weights, Tape Measure
Dynamic Strength Test for wheeled ride on toys	ASTM F963-17; 8.20	Toys	Weights, Stopwatch, Tape Measure
Wheels, Tires, and Axles	ASTM F963-17; 4.17	Toys	Sharp Edge Tester, Sharp Point Tester, Choke Hazard Tester
Toys Intended to be Attached to a Crib or Playpen	ASTM F963-17; 4.26	Toys	Inspection
Projections	ASTM F963-17; 4.8	Toys	Inspection
Use and Abuse Testing	ASTM F963-17; 8.5,8.6	Toys	Washer/Dryer, Multiple Equipment Items
Creepage & Clearance Distances	US and International Standards	Electrical Products	Calipers, Tape Measure
Strain Relief Test	US and International Standards	Electrical Products	Force Gauge, Tape Measure, Stopwatch
Stability Test	US and International Standards	Electrical and Mechanical Products	Angle Meter, Tape Measure
Impact Test	US and International Standards	Electrical and Mechanical Products	Mechanical Probes, Impact Ball, Impact Hammer, 50 mm sphere, Tape Measure, Force Gauge
Enclosure Push Test	US and International Standards	Electrical and Mechanical Products	Mechanical Probes, Force Gauge
Pull Test	US and International Standards	Electrical and Mechanical Products	Force Gauge
Permanence of Marking	US and International Standards	Electrical and Mechanical Products	Stopwatch
Weight Loading Test	US and International Standards	Electrical and Mechanical Products	Force Gauge, Stopwatch, Tape Measure



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Drop Test	US and International Standards	Electrical and Mechanical Products	Tape Measure, Concrete Surface, Tile Surface, Wood Surface
Thermal Shock Test	IEC/UL/CSA/EN 60079-0, Clause 26.5.2	Equipment for Explosive Atmospheres	Digital Thermometer
Torque Test for Bushings	IEC/UL/CSA/EN 60079-0, Clause 26.6	Equipment for Explosive Atmospheres	Torque Wrenches
Thermal Endurance to Heat	IEC/UL/CSA/EN 60079-0, Clause 26.8 IEC/UL/CSA/EN 60079-18, Clause 8.2.3.1	Equipment for Explosive Atmospheres	Environmental Chambers
Thermal Endurance to Cold	IEC/UL/CSA/EN 60079-0, Clause 26.9 IEC/UL/CSA/EN 60079-18, Clause 8.2.3.2	Equipment for Explosive Atmospheres	Environmental Chambers
Alternative Qualification of Elastomeric Sealing O-Rings	IEC/UL/CSA/EN 60079-0, Clause 26.16	Equipment for Explosive Atmospheres	Calipers, Environmental Chambers
Maximum Overpressure Test	IEC/UL/CSA/EN 60079-2, Clause 16.2	Equipment for Explosive Atmospheres	Pressure Gage, Stopwatch
Leakage Test	IEC/UL/CSA/EN 60079-2, Clause 16.3	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch
Purging Test – Air	IEC/UL/CSA/EN 60079-2, Clause 16.4.2 and 16.4.4 NFPA 496, Clauses 5.4.1 and 5.5.1	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch, O ₂ Analyzer
Purging Test – Inert Gas	IEC/UL/CSA/EN 60079-2, Clause 16.4.3 NFPA 496, Clauses 5.4.1 and 5.5.1	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch, O ₂ Analyzer
Filling Procedure Test – Static Pressurization	IEC/UL/CSA/EN 60079-2, Clause 16.4.5	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch, O ₂ Analyzer
Purging Test – Internal Source of Release <2% Oxygen	IEC/UL/CSA/EN 60079-2, Clause 16.5.2	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch, O ₂ Analyzer
Purging Test – Internal Source of Release <21% Oxygen	IEC/UL/CSA/EN 60079-2, Clause 16.5.3.1	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch, O ₂ Analyzer
Dilution Test – Internal Source of Release < 21 %Oxygen	IEC/UL/CSA/EN 60079-2, Clause 16.5.3.2	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch, O ₂ Analyzer

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Purging Test – Continuous Flow	IEC/UL/CSA/EN 60079-2, Clause 16.5.4.1	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch, O ₂ Analyzer
Dilution Test – Continuous Flow	IEC/UL/CSA/EN 60079-2, Clause 16.5.4.2	Equipment for Explosive Atmospheres	Pressure Gage, Flow Meter, Stopwatch, O ₂ Analyzer
Verification of Minimum Overpressure	IEC/UL/CSA/EN 60079-2, Clause 16.6	Equipment for Explosive Atmospheres	Pressure Gage
Overpressure Test – Limited Release	IEC/UL/CSA/EN 60079-2, Clause 16.8	Equipment for Explosive Atmospheres	Pressure Gage, Stopwatch
Mechanical Tests – Encapsulated Fuses	IEC/UL/CSA/EN 60079-11, Clause 10.6.2	Equipment for Explosive Atmospheres	Digital Thermometer, Tape Measure, Stopwatch
Mechanical Tests - Partitions	IEC/UL/CSA/EN 60079-11, Clause 10.6.3	Equipment for Explosive Atmospheres	Force Gauge, Test Rod, Stopwatch
Cable Pull Test	IEC/UL/CSA/EN 60079-11, Clause 10.9	Equipment for Explosive Atmospheres	Force Gage, Stopwatch
Type test requirements for restricted-breathing enclosures	IEC/UL/CSA/EN 60079-15, Clause 22.6	Equipment for Explosive Atmospheres	Pressure Gage, Stopwatch
Rotor cage aging process	IEC/UL/CSA/EN 60079-15, Clause 22.13.1.2	Equipment for Explosive Atmospheres	Digital Thermometer, DMM
Water absorption test	IEC/UL/CSA/EN 60079-18, Clause 8.1.1	Equipment for Explosive Atmospheres	Caliper, Digital Thermometer, Stopwatch, Digital Scale
Cable pull test	IEC/UL/CSA/EN 60079-18, Clause 8.2.5	Equipment for Explosive Atmospheres	Force Gage, Calipers
Pressure test for Group I and Group II electrical equipment	IEC/UL/CSA/EN 60079-18, Clause 8.2.6	Equipment for Explosive Atmospheres	Pressure Gage, Stopwatch
Sealing test for build-in protective devices	IEC/UL/CSA/EN 60079-18, Clause 8.2.8	Equipment for Explosive Atmospheres	Digital Thermometer, Tape Measure
Pressure Test	IEC/UL/CSA/EN 60079-31, Clause 6.1.1.3	Equipment for Explosive Atmospheres	Pressure Gage, Stopwatch
Entrapment	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.1.101	Medical Beds	Entrapment Cone, Cylinder Probe
Entrapment – Alternative Method	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.1.101	Medical Beds	Wedge Tool
Lateral Stability	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.4.2.2	Medical Beds	eights



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Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Longitudinal Stability	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.4.2.2	Medical Beds	Weights
Instability from Horizontal & Vertical Forces	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.4.2.3	Medical Beds	Weights
Force for Propulsion	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.4.2.4.2	Medical Beds	Force Gauge
Movement over Threshold	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.4.2.4.3	Medical Beds	Threshold
Instability in Transport	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.4.3.1	Medical Beds	Weights, Angle Meter
Audible Acoustic Energy	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.6.2.1	Medical Beds	A-weighted sound pressure meter
Static Forces Due to Loading from Persons on Bed and Bed Lift	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.8.3.2	Medical Beds	Weights
Static Forces Due to Loading from Persons on Lifting Poles - Downward Force	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.8.3.2	Medical Beds	Weights
Dynamic Forces Due to Loading from Persons	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.8.3.3.1	Medical Beds	Loading Pad, Cycling Machine
Dynamic Testing of Height Adjustment Mechanism	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.8.3.3.2	Medical Beds	Weights, Cycling Machine
Side Rail Strength & Latch Reliability	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.8.3.3a	Medical Beds	Cycling Machine Force Gauge
Side Rail Force Test	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.9.8.3.3b, c, d	Medical Beds	Force Gauge Cycling Machine
Cleaning & Disinfection	UL/CSA/EN/IEC 60601-2-52, Clause 201.11.6.6	Medical Beds	Cleaning Materials
Machine Washable Medical Bed	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.11.6.6.101	Medical Beds	Test Oven, Washing Machine

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Interruption of Power	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.11.8	Medical Beds	Electrical Switch
Mechanical Strength – Handheld Equipment	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.15.3.4.1	Medical Beds	Tumbling Barrel
Rough Handling	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.15.3.4	Medical Beds	Wood board
Mechanical Strength – Foot Operated Controls	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause 201.15.4.7.1	Medical Beds	Weights
Impact to Mattress Support	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause BB.2.2	Medical Beds	Drop Impactor
Loading on Edge of Support	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause BB.2.3	Medical Beds	Loading Pads with Weights
Durability of Mattress Support Moveable Sections	UL/CSA/EN/IEC 60601-2-52, Clause BB.2.4	Medical Beds	Weights
Operating Forces for Handles & Pedals	UL/CSA/EN/IEC 60601-2-52, AAMI ES60601-2-52 Clause BB.3.4	Medical Beds	Force Gauge
Mold Stress Test	US and International Standards	Plastics	Lab Oven
Ball Pressure Test	US and International Standards	Plastics	Lab Oven, Ball Pressure Tester, Ball Pressure Test Stand, Thermocouple, Thermocouple Meter
<u>Flame Tests</u> 3/4 Inch, 20 mm, 5 Inch, 127 mm, Horizontal Burn: HB Vertical Burn: V-0, V-1, V-2, 5VA, 5VB, 50W, 500W, Needle Flame	US and International Standards	Plastics	Flame Hood, Gas Supplies, Gas Flow Meter, Manometer/Pressure Gauge, Bunsen Burners, Needle Flame Burner, Flame Calibration Blocks, Flame Calibration Gauges, Burner Test Stand, Burner Wing Tips, Burner Angle Blocks, Wire Gauze & Screens, Stopwatch

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Glow Wire Test	US and International Standards	Plastics	Glow Wire Tester
Hot Wire Ignition Test	US and International Standards	Plastics	Hot Wire Ignition Tester, Hot Wire Ignition Tester Power Supply
Electrical, Mechanical, Chemical and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test.	UL / CSA / EN / IEC 60950-1 UL / CSA / EN / IEC 62368-1	ITE	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, force gauge, power meter, Oscilloscope, ammeter, temperature / humidity meter, pressure and vacuum gauge, scale, data logger, oven, creepage and clearance tools, stopwatch, measuring tape
Electrical, Mechanical, Chemical and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test	UL / CSA / EN / IEC 61010-1	Measurement Control and Lab Use	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, force gauge, power meter, Oscilloscope, ammeter, temperature / humidity meter, pressure and vacuum gauge, scale, data logger, oven, creepage and clearance tools, stopwatch, measuring tape
Electrical, Mechanical, Chemical and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test	UL / CSA / EN / IEC 60601-1 AAMI ES60601-1	Medical Equipment	Digital Multimeter, Dielectric Tester, Leakage Current Meter, Ground Continuity Tester, force gauge, power meter, Oscilloscope, ammeter, temperature / humidity meter, pressure and vacuum gauge, scale, data logger, oven, creepage and clearance tools, stopwatch, measuring tape

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Electrical, Mechanical, Chemical, and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test	UL/CSA/EN/IEC60601-2-52 AAMI ES60601-2-52	Medical Beds	Entrapment Cone, Cylinder Probe, Wedge Tool, Weights, Threshold, Angle Meter, Sound Pressure Meter, Force Gauge, Loading Pad, Cycling Machine, Test Oven, Washing Machine, Tumbling Barrel, Wood Board, Drop Impactor
Electrical, Mechanical, Chemical and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test	EN / IEC 60204-1	Machinery	Digital Multimeter, Dielectric Tester, Insulation Resistance Tester, Ground Continuity Tester, Oscilloscope, Ammeter, Protractor, Force Gauge, Measuring Tape
Electrical, Mechanical, Chemical and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test Permanence of Marking, Weight Loading Test, Mold Stress Test, Ball Pressure Test, Humidity Conditioning Test	UL/CSA/EN/IEC60335-1	Household & Similar Electronics	Digital Multimeter, Dielectric Tester Leakage Current Meter, force gauge, power meter, Oscilloscope, ammeter, temperature / humidity meter, pressure and vacuum gauge, scale, data logger, oven, creepage and clearance tools, stop-watch, measuring tape
Electrical, Mechanical, Chemical and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test	UL / CSA / EN / IEC 60065-1 UL / CSA / EN / IEC 62368-1	Audio, Video and Similar Electronic App.	Digital Multimeter, Dielectric Tester, Leakage Current Meter, force gauge, power meter, Oscilloscope, ammeter, temperature / humidity meter, pressure and vacuum gauge, scale, data logger, oven, creepage and clearance tools, stopwatch, measuring tape

Mechanical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Electrical, Mechanical, Chemical, and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test	UL/CSA/EN/IEC60079-0 UL/CSA/EN/IEC60079-2 UL/CSA/EN/IEC60079-7 UL/CSA/EN/IEC60079-11 UL/CSA/EN/IEC60079-15 UL/CSA/EN/IEC60079-18 UL/CSA/EN/IEC60079-31 ISA/UL12.12.01 NFPA 496	Equipment for Explosive Atmospheres	Environmental Chambers, Digital Thermometers, Torque Wrenches, Calipers, Pressure Gage, Stopwatch, Flow Meter, O ₂ Analyzer, Spark Test Apparatus, Tape Measure, Stopwatch, Force Gauge, Test Rod, Digital Scale, Digital Multimeter, LCR Meter, Oscilloscope, Power Analyzer, Dielectric Tester, IR Tester
Electrical, Mechanical, Chemical and Environmental Tests per the selected Standard and in accordance with the Test Plan for the Equipment Under Test	IEC 529, EN60529 Amendment 1: 1999-11 Section 13.2 & Section 14.2	General (Enclosures)	Accessibility Probes, Dust Test Chamber, Drip Box System, Oscillating Spray Test System, Handheld Spray Tester, Jet Nozzle Kit, High Flow Rate Water Delivery System with Water Tanks, Immersion Tanks, High Pressure, High Temperature Spray Test System
Thermal Shock	Low Temperature Thermal Shock High Temperature Thermal Shock Cyclic Temperature Thermal Shock	Products	HALT Chamber, Thermocouple, Thermal Shock Chamber
Temperature and Vibration	HALT-HASS Processes and Implementation	Products	HALT Chamber, Thermocouple, Accelerometer

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Input	(Standards)	Electrical Products	Oscilloscope, DMM, Power Analyzer
Leakage Current	(General, North America)	Electrical Products	Digital Multimeter, Leakage Current Meter



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Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
Leakage Current	Harmonized Standards, 60950, 61010, 60335	ITE, Laboratory, Household	Digital Multimeter, Leakage Current Meter
Leakage Current	Medical 60601-1	Medical Equipment	Digital Multimeter, Leakage Current Meter
Temperature Rise	Thermocouple Method	Electrical Products	Data Logger, Measuring Tape, Digital Multimeter
Temperature Rise	Change of Resistance Method	Products	Data Logger, Measuring Tape, Digital Multimeter. COR Tester
Dielectric Voltage Withstand	(0 to 12 500) VAC	Insulation materials, Electrical products, Circuit Boards	Hi-Pot (Dielectric) Tester, Stopwatch
Dielectric Voltage Withstand	(0 to 15 000) VDC	Insulation materials, Electrical products, Circuit Boards	Hi-Pot (Dielectric) Tester, Stopwatch
Grounding Continuity Test	(1 to 500) Amps	Electrical Products	GC Tester, DMM, Clamp-on Meter
Voltage Measurements	AC & DC (0 to 600) V	Electrical Products	DMM
Current Measurements	(0 to 400) A	Electrical Products	Ammeter
Insulation Resistance Test	(0 to >2) MΩ	Insulation and Electrical Products	IR Meter
Capacitor Discharge Test	Mains Voltage (0 to 300) VAC Decay Voltage (0 to 425) VDC	Electrical Products	Oscilloscope
Abnormal Operation	Component Fault, Locked Rotor, Short Circuit, Blocked Vents, Overload Current	Electrical Products	Data Logger, Measuring Tape, DMM, Power Analyzer, Hi-Pot (Dielectric) Tester, Tissue Paper, Cheese Cloth
Transformer Fault Testing	Short Circuit Test Overload Test	Transformers and Electrical Products	DMM
Surface Resistance	IEC/UL/CSA/EN 60079-0, Clause 26.13	Equipment for Explosive Atmospheres	Environmental Chamber, Digital Multimeter
Measurement of Capacitance	IEC/UL/CSA/EN 60079-0, Clause 26.14	Equipment for Explosive Atmospheres	LCR Meter
Spark Ignition Test	IEC/UL/CSA/EN 60079-11, Clause 10.1 ISA/UL12.12.01, Clause 11.2	Equipment for Explosive Atmospheres	Spark Test Apparatus, O ₂ Analyzer, DMM

Electrical

Specific Tests and/or Properties Measured	Specification, Standard, Method, or Test Technique	Items, Materials or Product Tested	Key Equipment or Technology
	CSA C22.2 No. 213, Clause 11.2		
Determination of Parameters	IEC/UL/CSA/EN 60079-11, Clause 10.4	Equipment for Explosive Atmospheres	DMM, LCR Meter
Electrolyte Leakage Test	IEC/UL/CSA/EN 60079-11, Clause 10.5.2	Equipment for Explosive Atmospheres	DMM
Test for Intrinsically Safe Apparatus Containing Piezoelectric Devices	IEC/UL/CSA/EN 60079-11, Clause 10.7	Equipment for Explosive Atmospheres	DMM, Oscilloscope
Transformer Tests	IEC/UL/CSA/EN 60079-11, Clause 10.10	Equipment for Explosive Atmospheres	DMM, Power Analyzer, Dielectric Tester
Optical Isolator Tests	IEC/UL/CSA/EN 60079-11, Clause 10.11	Equipment for Explosive Atmospheres	DMM, Power Analyzer, Digital Thermometer, Dielectric Tester, IR Tester
Infallible Printed Circuit Board Connections	IEC/UL/CSA/EN 60079-11, Clause 10.12	Equipment for Explosive Atmospheres	DMM, Stopwatch
Tests for sealed devices	IEC/UL/CSA/EN 60079-15, Clause 22.5 ISA 12.12.01, Clause 13 CSA C22.2 No. 213, Clause 13	Equipment for Explosive Atmospheres	Environmental Chambers, Dielectric Tester, Stopwatch
Test for resettable thermal protective device with switching contacts	IEC/UL/CSA/EN 60079-18, Clause 8.2.7.1	Equipment for explosive Atmospheres	DMM, Digital Thermometer
Test for resettable thermal protective device without switching contacts	IEC/UL/CSA/EN 60079-18, Clause 8.2.7.2	Equipment for Explosive Atmospheres	DMM, Digital Thermometer

Notes:

1. 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. 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-1545



Jason Stine, Vice President