



CERTIFICATE OF ACCREDITATION

The ANSI National Accreditation Board

Hereby attests that

CertifiGroup, Inc.
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.

A handwritten signature in black ink, appearing to read 'R. Douglas Leonard Jr.', is positioned above a horizontal line.

R. Douglas Leonard Jr., VP, PILR SBU

Expiry Date: 12 May 2023
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

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

CertifiGroup, Inc.

901 Sheldon Dr.

Cary, NC 27513

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CALIBRATION

Valid to: **May 12, 2023**

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 | IEC 61010-1 Edition 3.1 2017-01 | Entire Standard |
| Medical Electrical Equipment | Electrical, Physical, & Mechanical Tests | ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) | Entire Standard |
| Medical Electrical Equipment | Usability Review | IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION IEC 60601-1-6 Edition 3.1 2013-10 | Entire Standard |
| Medical Electrical Equipment and Systems for used in the Home Healthcare Environment | Electrical, Physical, & Mechanical Tests | ANSI AAMI HA60601-1-11:2015 | Entire Standard |
| Medical Electrical Equipment and Systems for use in Emergency Medical Services Environment | Electrical, Physical, & Mechanical Tests | IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION | 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 ¹

| Product Type | Specific Tests or Properties Measured | Specification, Standard, Method, or Technique Used | Comments |
|--|--|---|-----------------|
| Electrosurgical Generators | Electrical, Physical, & Mechanical Tests | IEC 60601-2-2 Edition 6.0 2017-03 | Entire Standard |
| Nerve and Muscle Stimulators | Electrical, Physical, & Mechanical Tests | IEC 60601-2-10 Edition 2.1 2016-04 | Entire Standard |
| Endoscopic Equipment | Electrical, Physical, & Mechanical Tests | IEC 60601-2-18 Edition 3.0 2009-08 | Entire Standard |
| Electrocardiographs | Electrical, Physical, & Mechanical Tests | IEC 60601-2-25 Edition 2.0 2011-10 | Entire Standard |
| Electrocardiographic Monitoring Equipment | Electrical, Physical, & Mechanical Tests | IEC 60601-2-27 Edition 3.0 2011-03 | Entire Standard |
| Invasive Blood Pressure Monitoring Equipment | Electrical, Physical, & Mechanical Tests | IEC 60601-2-34 Edition 3.0 2011-05 | Entire Standard |
| Ultrasonic Medical Diagnostic and Monitoring Equipment | Electrical, Physical, & Mechanical Tests | IEC 60601-2-37 Edition 2.1 2015 | Entire Standard |
| Medical Beds | Electrical, Physical, & Mechanical Tests | IEC 60601-2-52 Edition 1.0 2009-12 | Entire Standard |
| Dental Oral X-Ray Equipment | Electrical, Physical, & Mechanical Tests | IEC 60601-2-65 Edition 1.1 2017-05 CONSOLIDATED VERSION | Entire 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 |

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) 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 |
| 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 |

Mechanical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|--|--|------------------------------------|--|
| 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 |
| 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) | NEMA 250 | Enclosures, Electrical Equipment | Mechanical Probes, Drip Box, Rain Test Apparatus, Immersion Tank, Jet Nozzle, Atomized Water Nozzle, Salt Fog Chamber, Tensile Strength Tester, Thermocouple Reader |

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, 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) | UL 50E | Enclosures, Electrical Equipment | 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 |
| 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 |



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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 |
|---|--|--|---|
| 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 |
| 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 |

Mechanical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|---|---|---|---|
| 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 |
| 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 |

Mechanical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|---|---|---|---|
| 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 |
| 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 |

Mechanical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|---|--|------------------------------------|--|
| 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 |
| 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 |

Mechanical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|--|--|---|--|
| 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 |
| 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 |

Mechanical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|--|--|---|---|
| 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 |
| 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 |

Mechanical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|---|--|---|--|
| 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 |
| 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 |



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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 |
|---|---|------------------------------------|---------------------------------|
| 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 |
| 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 |

Mechanical

| Specific Tests and/or Properties Measured | Specification, Standard, Method, or Test Technique | Items, Materials or Product Tested | Key Equipment or Technology |
|--|---|------------------------------------|--|
| 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 |
| 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 |

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 / 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 |


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 | 0-12500 VAC | Insulation materials, Electrical products, Circuit Boards | Hi-Pot (Dielectric) Tester, Stopwatch |
| Dielectric Voltage Withstand | 0-15000 VDC | Insulation materials, Electrical products, Circuit Boards | Hi-Pot (Dielectric) Tester, Stopwatch |
| Grounding Continuity Test | 1-500 Amps | Electrical Products | GC Tester, DMM, Clamp-on Meter |
| Voltage Measurements | AC & DC 0-600V | Electrical Products | DMM |
| Current Measurements | 0-400A | Electrical Products | Ammeter |
| Insulation Resistance Test | 0->2KMΩ | Insulation and Electrical Products | IR Meter |
| Capacitor Discharge Test | Mains Voltage 0-300VAC Decay Voltage 0-425VDC | 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 CSA C22.2 No. 213, 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 |
|--|--|-------------------------------------|--|
| 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.
 2. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-1545



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