SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

MEDICAL EQUIPMENT COMPLIANCE ASSOCIATES, LLC.
5060 West Ashland Way
Franklin, WI 53132
Ms. Cathi Koch Phone: 262 672 6901
Email: ck@60601-1.com

ELECTRICAL

Valid to: January 31, 2019 Certificate Number: 3392.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following Product Safety tests:

Test Technology:	**Test Method(s) [1, 2]:**
Medical Electrical Equipment– Part 1: General Requirements for Safety	IEC 60601-1 (Ed. 2) + A1 + A2; EN 60601-1:1990 + A1 + A2; UL 60601-1 (Ed. 1); CAN/CSA C22 No. 601.1-M90 (*excluding:* *Clause 29 [X-Radiation],* *Clause 39 [Category AP and APG Testing]*)
Medical Electrical Equipment– Part 1: General Requirements for Basic Safety and Essential Performance	IEC 60601-1 (Ed. 3) + A1; EN 60601-1:2006 + A11 + A1; ANSI/AAMI ES 60601-1 (2005) + 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; CAN/CSA C22 No. 60601-1:08; CAN/CSA C22.2 No. 60601-1:14 (*excluding:* *Clause 8.8.4.2 [Oxygen Aging for Rubber Insulation Parts], Clause 9.6.3 [Hand Transmitted Vibration], Clause 10.1 [X-Radiation], Annex G [Protection against hazards of ignition of flammable anesthetic mixtures], Annex L [Insulated winding wires for use without interleaved insulation]*)
Safety Requirements for Medical Electrical Systems	IEC 60601-1-1 (Ed. 1) + A1; IEC 60601-1-1 (Ed. 2); EN 60601-1-1:2001; CAN/CSA C22.2 No. 60601-1-1:02

5202 Presidents Court, Suite 220 | Frederick, MD 21703-8515 | Phone: 301 644 3248 | Fax: 240 454 9449 | www.A2LA.org

Test Technology:	**Test Method(s) [1, 2]:**
Programmable Electrical Medical Systems	IEC 60601-1-4 (Ed. 1) + A1; EN 60601-1-4:96 + A1:99; CAN/CSA C22.2 No. 60601-1-4:02
Usability	IEC 60601-1-6 (Ed. 2); EN 60601-1-6:07; IEC 60601-1-6 (Ed. 3) + A1;2013 (Ed. 3.1); EN 60601-1-6:10; CAN/CSA C22.2 No. 60601-1-6:08; CAN/CSA C22.2 No. 60601-1-6:11; IEC 62366:2007 + A1; EN 62366:2008; ANSI/AAMI/IEC 62366:2007 + A1; CAN/CSA IEC 62366:14
Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment	IEC 60601-1-11:2010 (Ed. 1); IEC 60601-1-11:2015 (Ed. 2); EN 60601-1-11:10; ANSI/AAMI HA 60601-1-11:11; CAN/CSA C22.2 No. 60601-1-11:11
Requirements/Guidelines for Alarms in Medical Electrical Equipment	IEC 60601-1-8 (Ed. 1 + A1), (Ed. 2), (Ed. 2.1); EN 60601-1-8:07 + A1:13, 04 + A1:06; CAN/CSA C22 No. 60601-1-8:05; CAN/CSA C22 No. 60601-1-8:08; ANSI/AAMI/IEC 60601-1-8:2006 + A1:2012
Requirements for Physiological Closed-Loop Controllers	IEC 60601-1-10 (Ed. 1) + A1; EN 60601-1-10 (Ed. 1); CAN/CSA C22.2 No. 60601-1-10:09
High Frequency Surgical Equipment	IEC 60601-2-2 (Ed. 2), (Ed. 3), (Ed. 4), (Ed. 5); ANSI/AAMI/IEC 60601-2-2:2009; EN 60601-2-2:2007; EN 60601-2-2:09 + A11; CAN/CSA C22.2 No. 60601-2-2:08; CAN/CSA C22.2 No. 60601-2-2:09 (*excluding:* *Ed. 2, 3, 4 Clause 59.104.7,* *Ed. 5 Clause 201.15.101.7* *[Neutral Electrode Adhesion]*)
Cardiac Defibrillators, Defibrillator-Monitors	IEC 60601-2-4 (Ed. 3), (Ed. 2); ANSI/AAMI/IEC 60601-2-4:2010; EN 60601-2-4:11, 03; CAN/CSA C22.2 No. 60601-2-4:04; CAN/CSA C22.2 No. 60601-2-4:12

Test Technology:	**Test Method(s) [1, 2]:**
Nerve and Muscle Stimulators	IEC 60601-2-10 (Ed. 1), (Am.1), (Ed. 2), (Ed. 2.1); CSA-C22.2 No. 601.2.10 (Ed.1), (Am.1); CAN/CSA C22.2 No. 60601-2-10:14; EN 60601-2-10:00 + A1
Hemodialysis Equipment	IEC 60601-2-16 (Ed. 2), (Ed. 3), (Ed. 4); ANSI/AAMI/IEC 60601-2-16:2012; EN 60601-2-16:98; CAN/CSA C22.2 No. 60601-2-16:01; CAN/CSA C22.2 No. 60601-2-16:09; CAN/CSA C22.2 No. 60601-2-16:14
Endoscopic Equipment	IEC 60601-2-18 (Ed. 2) + A1, (Ed. 3); EN 60601-2-18:96 + A1; CAN/CSA C22.2 No. 60601-2-18:01; CAN/CSA C22.2 No. 60601-2-18:11
Infusion Pumps and Controllers	IEC 60601-2-24 (Ed. 1), (Ed. 2); EN 60601-2-24:98; CAN/CSA C22.2 No. 60601-2-24:01(R09)
Electrocardiographs	IEC 60601-2-25 (Ed. 2), (Ed. 1.1); EN 60601-2-25:95 + A1; CAN/CSA C22.2 No. 601.2.25-94; CAN/CSA C22.2 No. 60601-2-25:12; ANSI/AAMI/IEC 60601-2-25:2011
Electroencephalographs	IEC 60601-2-26 (Ed.1), (Ed. 2), (Ed. 3); EN 60601-2-26:03; CAN/CSA C22.2 No. 60601-2-26:04(R09); CAN/CSA C22.2 No. 60601-2-26:14
Electrocardiographic Monitoring Equipment	IEC 60601-2-27 (Ed. 1), (Ed. 2), (Ed. 3); ANSI/AAMI/IEC 60601-2-27:2011; EN 60601-2-27:06, 94; 14; CAN/CSA C22.2 No. 60601-2-27:06; CAN/CSA C22.2 No. 60601-2-27:11
Automated Non-Invasive Sphygmomanometers	IEC 60601-2-30 (Ed. 1), (Ed. 2); CAN/CSA C22.2 No. 60601-2-30:02(R11); EN 60601-2-30:00; ISO 80601-2-30 (Ed. 1) + A1; ANSI/AAMI/IEC 80601-2-30:2009; EN ISO 80601-2-30 :10 + A1:13; CAN/CSA C22.2 No. 80601-2-30:10

Test Technology:	**Test Method(s) [1, 2]:**
Magnetic Resonance Equipment for Medical Diagnosis	IEC 60601-2-33 (Ed. 1) *(excluding 51.105.2, 51.105.2.3, 51.105.3.2, & 51.105.3.3)*, (Ed. 2.2), (Ed. 3), (Ed. 3.1) *(excluding 201.12.4.105.2.2, 201.12.4.105.2.3, & 201.12.4.105.3.3)*; EN 60601-2-33:02, A2:2008; EN 60601-2-33:2010 + A11; CAN/CSA C22.2 No. 60601-2-33:04; CAN/CSA C22.2 No. 60601-2-33:12
Invasive Blood Pressure Monitoring Equipment	IEC 60601-2-34 (Ed. 3), (Ed. 2), (Ed. 1); EN 60601-2-34:00; CAN/CSA C22.2 No. 60601-2-34:02; CAN/CSA C22.2 No. 60601-2-34:12
Heating Devices Using Blankets, Pads, and Mattresses	IEC 60601-2-35 (Ed. 1); EN 60601-2-35:96; EN 80601-2-35:09 + A11; ISO 80601-2-35 (Ed. 2), (Ed. 2.1); CAN/CSA C22.2 No. 80601-2-35:12 (*excluding: Ed.1 Clause 59.2.101 [Spark Ignition Test]*)
Extracorporeally Induced Lithotripsy	IEC 60601-2-36 (Ed. 1), (Ed. 2); EN 60601-2-36:97; CAN/CSA C22.2 No. 60601.2.36:98(R12)
Electrically Operated Hospital Beds	IEC 60601-2-38 (Ed. 1.1); EN 60601-2-38:96 + A1:2000; CAN/CSA C22.2 No. 60601-2-38:03(R07)
Peritoneal Dialysis Equipment	IEC 60601-2-39 (Ed. 1), (Ed. 2); EN 60601-2-39:99; EN 60601-2-39:08 + A11:11; CAN/CSA C22.2 No. 60601-2-39:02(R07); CAN/CSA C22.2 No. 60601-2-39:09(R14)
Electromyographs and Evoked Response Equipment	IEC 60601-2-40 (Ed. 1), (Ed. 2.0); EN 60601-2-40:98; CAN/CSA C22.2 No. 60601-2-40:01(R14)
Operating Tables	IEC 60601-2-46 (Ed. 1), (Ed. 2), (Ed. 3.0); EN 60601-2-46:11, 98; CAN/CSA C22.2 No. 60601-2-46:01(R09); CAN/CSA C22.2 No. 60601-2-46:12
Ambulatory Electrocardiographic Monitors	IEC 60601-2-47 (Ed. 1), (Ed. 2); ANSI/AAMI/IEC 60601-2-47:2012; EN 60601-2-47:01; CAN/CSA C22.2 No. 60601-2-47:03(R2012); CAN/CSA C22.2 No. 60601-2-47:14

Test Technology:	**Test Method(s) [1, 2]:**
Multiparameter Patient Monitoring Equipment	IEC 60601-2-49 (Ed.1), (Ed. 2); EN 60601-2-49:01; CAN/CSA C22.2 No. 60601-2-49:11; CAN/CSA C22.2 No. 60601-2-49:04(R09)
Recording and Analyzing Single and Multichannel Electrocardiographs	IEC 60601-2-51 (Ed. 1); EN 60601-2-51:03; CAN/CSA C22.2 No. 60601-2-51:04(R09) (*excluding:* *Clause 50.102 [Automated ECG interpretation for analyzing electrocardiographs]*)
Safety of Medical Beds	IEC 60601-2-52 (Ed. 1), (Ed. 1.1); EN 60601-2-52:10 + AC:2011; CAN/CSA C22.2 No. 60601-2-52:11
Respiratory Gas Monitors	ISO 80601-2-55 (Ed. 1); EN ISO 80601-2-55:11; CAN/CSA C22.2 No. 80601-2-55:14
Clinical Thermometers for Body Temperature Measurement	ISO 80601-2-56 (Ed. 1); CAN/CSA C22.2 No. 80601-2-56:12; EN ISO 80601-2-56:2012
Dental Equipment	ISO 80601-2-60 (Ed. 1); (*excluding:* *201.10 Protection against excessive radiation hazards* *201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS*)
Pulse Oximeter Equipment	ISO 80601-2-61 (Ed. 1); EN ISO 80601-2-61:11; CAN/CSA C22.2 No. 80601-2-61:14
Pulse Oximeter Equipment for Medical Use	ISO 9919 (Ed. 2); CAN/CSA Z9919-07(R2012) (*excluding:* *Clause 50.101.2 [Clinical Determination of SpO2 Accuracy]*)
Medical Vehicles and Their Equipment	EN 1789:2007 + A1:2010 Only Clause 6 (Medical Devices) (*excluding:* *Clause 6.1 [Provision of medical devices]* *Clause 6.2 [Medical device storage]* *Clause 6.3.5 [Fixation of medical devices]* *Clause 6.3.8 [Gas supply]* *Clause 6.5 [List of equipment]*)

Test Technology:	**Test Method(s) [1, 2]:**
Degrees of Protection Provided by Enclosures	IEC 60529; EN 60529; CAN/CSA C22.2 No. 60529:2005(R2010)
Software Life-Cycle Processes	IEC 62304 (Ed. 1), (Ed. 1.1); EN 62304 (Ed. 1); ANSI/AAMI/IEC 62304:2006; CAN/CSA CEI/IEC 62304:14
Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory use – Part 1: General Requirements	IEC 61010-1 (Ed. 2), (Ed. 3) (*excluding subclause 16.2 category III & IV*); EN 61010-1 (Ed. 2), (Ed. 3) (*excluding subclause 16.2 category III & IV*)
Equipment for Heating of Materials	CAN/CSA C22.2 No. 61010-1 (Ed. 2), (Ed. 3); UL 61010-1 (Ed. 2), (Ed. 3); IEC 61010-2-010 (Ed. 1); EN 61010-2-010 (Ed. 1); CAN/CSA C22.2 No. 61010-2-010 (Ed. 1)
Laboratory Centrifuges	IEC 61010-2-020 (Ed. 2), (Ed. 3.0) (*excluding 7.3.101, 7.6*); EN 61010-2-020 (Ed. 2) (*excluding 7.3.101 & 7.6*); CAN/CSA C22.2 No. 61010-2-020 (Ed. 2) (*excluding 7.3.101 & 7.6*)
Equipment for Mixing & Stirring	IEC 61010-2-051 (Ed. 1), (Ed. 2.0), (Ed. 3.0); EN 61010-2-051 (Ed. 1); CAN/CSA C22.2 No. 60601-2-051 (Ed. 1)
Automatic & Semi-Automatic Laboratory Equipment for Analysis	IEC 61010-2-081 (Ed. 1.1), (Ed. 2.0); CAN/CSA C22.2 No. 61010-2-081:04(R2014); EN 61010-2-081:2002 + A1:2003
IVD Medical Equipment	IEC 61010-2-101 (Ed. 1), (Ed. 2.0); EN 61010-2-101 (Ed. 1); CAN/CSA C22.2 No. 61010-2-101 (Ed. 1)

[1] All standard references to IEC 60601-1-2 (EMC) testing are not within the scope (Ed. 2 Clause 36, Ed. 3 Clause 17); Broadband random vibration, Mechanical shock, and Clinical are not included within the testing listed on the scope of accreditation

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

On the following products or types of products: Medical Equipment, Laboratory Equipment

Accredited Laboratory

A2LA has accredited

MEDICAL EQUIPMENT COMPLIANCE ASSOCIATES, LLC.

Franklin, WI

for technical competence in the field of

Electrical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*. 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 8 January 2009*).

Presented this 30th day of May 2017.

President and CEO
For the Accreditation Council
Certificate Number 3392.01
Valid to January 31, 2019

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