SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

MEDICAL EQUIPMENT COMPLIANCE ASSOCIATES, LLC.
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ELECTRICAL

Valid to: January 31, 2023 Certificate Number: 3392.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the organization's compliance with A2LA's FDA ASCA Accreditation Program [1] requirements), accreditation is granted to this laboratory to perform the following Product Safety tests:

Test Technology:	**Test Method(s) [2,3]:**
Medical Electrical Equipment– Part 1: General Requirements for Safety	IEC 60601-1:1988 + A1:1991 + A2:1995; EN 60601-1:1990 + A11:1993 + A12:1993 + A1:1993 + A13:1996 + A2:1995; UL 60601-1:2003 (updates through 2006); CAN/CSA C22 No. 601.1-M90 (*excluding clauses:* *29 X-Radiation;* *39 Category AP and APG Testing*)
Medical Electrical Equipment– Part 1: General Requirements for Basic Safety and Essential Performance	IEC 60601-1:2005 + A1:2012 + A2:2020; EN 60601-1:2006 + A11:2011 + A12:2014 + AC:2014 + A1:2013; ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) [1]; ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 + A2:2010; CAN/CSA C22.2 No. 60601-1:2008; CAN/CSA C22.2 No. 60601-1:2014 (*excluding clauses:* *8.8.4.2 Oxygen Aging for Rubber Insulation Parts;* *9.6.3 Hand Transmitted Vibration;* *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 60601-1-1:2000; EN 60601-1-1:2001; CAN/CSA C22.2 No. 60601-1-1:2002

Test Technology:	**Test Method(s) [2,3]:**
Medical electrical equipment – Electromagnetic disturbances	General Requirements: IEC 60601-1-2:2014 + A1:2020[1] (aka IEC 60601-1-2:2020) ANSI/AAMI ES 60601-1-2:2014[1] CAN/CSA C22.2 No. 60601-1-2:2016 Test Methods required by IEC 60601-1-2: CISPR 11:2015 + A1:2016* IEC 61000-3-2:2005 + A1:2008 + A2:2009* IEC 61000-3-2:2014* IEC 61000-3-3:2013* IEC 61000-4-2:2008 IEC 61000-4-3:2006 + A1:2007 + A2:2010* IEC 61000-4-3:2020* IEC 61000-4-4:2012 IEC 61000-4-5:2005 IEC 61000-4-5:2014 + A1:2017 IEC 61000-4-6:2013 + C1:2020* IEC 61000-4-8:2009 IEC 61000-4-11:2004 IEC 61000-4-11:2020 + C1:2020 IEC 61000-4-39:2017* IEC 7637-2:2011 *Excluded from the laboratory scope of accreditation
Programmable Electrical Medical Systems	IEC 60601-1-4:1996 + A1:1999 (IEC 60601-1-4:2000); EN 60601-1-4:1996 + A1:1999; CAN/CSA C22.2 No. 60601-1-4:2002
Usability	IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION [1]; IEC 60601-1-6 Edition 3.1 2013-10 [1]; IEC 60601-1-6:2010 + A1:2013 + A2:2020; EN 60601-1-6:2010 + A1:2015; CAN/CSA C22.2 No. 60601-1-6:2008; CAN/CSA C22.2 No. 60601-1-6:2011; IEC 62366:2007 + A1:2014; EN 62366:2008 + A1:2015; ANSI/AAMI/IEC 62366:2007 + A12013; CAN/CSA IEC 62366:2014; IEC 62366-1:2015 + A1:2020; ANSI/AAMI/IEC 62366-1:2015; ANSI/AAMI/IEC 62366-1:2015 + AMD1:2020; CAN/CSA-IEC 62366-1:2015; EN 62366-1:2015

Test Technology:	**Test Method(s) [2,3]:**
Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment	IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION [1]; IEC 60601-1-11 Edition 2.0 2015-01 [1]; ANSI AAMI HA60601-1-11:2015 [1]; IEC 60601-1-11:2010; IEC 60601-1-11:2015 + A1:2020; EN 60601-1-11:2010; EN 60601-1-11:2015; ANSI AAMI HA60601-1-11:2011; CAN/CSA C22.2 No. 60601-1-11:2011; CAN/CSA C22.2 No. 60601-1-11:2015
Medical Electrical Equipment and Medical Electrical Systems used in the Emergency Medical Services Environment	IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION [1]; IEC 60601-1-12 Edition 1.0 2014-06 [1]; IEC 60601-1-12:2014 + A1:2020; ANSI/AAMI 60601-1-12:2016; IEC 60601-1-12:2016; CAN/CSA C22.2 No. 60601-1-12:2015; EN 60601-1-12:2015
Requirements/Guidelines for Alarms in Medical Electrical Equipment	IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION [1]; IEC 60601-1-8 Edition 2.1 2012-11 [1]; IEC 60601-1-8:2003 + A1:2006; IEC 60601-1-8:2006 + A1:2012 + A2:2020; EN 60601-1-8:2007 + A1:2013; EN 60601-1-8:2004 + A1:2006; CAN/CSA C22 No. 60601-1-8:2005; CAN/CSA C22 No. 60601-1-8:2008; ANSI/AAMI 60601-1-8:2006 + A1:2012; ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [1]
Requirements for Physiological Closed-Loop Controllers	IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION [1]; IEC 60601-1-10 Edition 1.1 2013-11 [1]; IEC 60601-1-10:2007 + A1:2013 + A2:2020; EN 60601-1-10:2008 + A1:2015; CAN/CSA C22.2 No. 60601-1-10:2009; CAN/CSA C22.2 No. 60601-1-10A-09

Test Technology:	**Test Method(s) [2,3]:**
High Frequency Surgical Equipment	IEC 60601-2-2 Edition 6.0 2017-03 [1]; ANSI AAMI IEC 60601-2-2:2017 [1]; IEC 60601-2-2:1998; IEC 60601-2-2:2006; IEC 60601-2-2:2009; IEC 60601-2-2:2017; ANSI/AAMI/IEC 60601-2-2:2009; ANSI/AAMI/IEC 60601-2-2:2017; EN 60601-2-2:2007; EN 60601-2-2:2009 + A11:2011; EN 60601-2-2:2018; CAN/CSA C22.2 No. 60601-2-2:2008; CAN/CSA C22.2 No. 60601-2-2:2009 (*excluding:* *Ed. 2, 3, 4 Clause 59.104.7;* *Ed. 5 Clause 201.15.101.7* *[Neutral Electrode Adhesion]*)
Cardiac Defibrillators, Defibrillator-Monitors	IEC 60601-2-4:2002; IEC 60601-2-4:2010 + A1:2018; ANSI/AAMI/IEC 60601-2-4:2010; EN 60601-2-4:2011; EN 60601-2-4:2003; CAN/CSA C22.2 No. 60601-2-4:2004; CAN/CSA C22.2 No. 60601-2-4:2012
Nerve and Muscle Stimulators	IEC 60601-2-10 Edition 2.1 2016-04 [1]; IEC 60601-2-10:1987 + A1:2001; IEC 60601-2-10:2012 [1]; IEC 60601-2-10:2016; CSA C22.2 No. 601.2.10:1992; CAN/CSA C22.2 No. 60601-2-10:2014; EN 60601-2-10:2000 + A1:2001; EN 60601-2-10:2015 + A1:2016
Hemodialysis Equipment	IEC 60601-2-16 Edition 5.0 2018-4 [1]; ANSI AAMI IEC 60601-2-16:2018 [1]; IEC 60601-2-16:1998; IEC 60601-2-16:2008; IEC 60601-2-16:2012; IEC 60601-2-16:2018; ANSI/AAMI/IEC 60601-2-16:2012; EN 60601-2-16:1998; EN 60601-2-16:2015; EN 60601-2-16:2019; CAN/CSA C22.2 No. 60601-2-16:2001; CAN/CSA C22.2 No. 60601-2-16:2009; CAN/CSA C22.2 No. 60601-2-16:2014
Endoscopic Equipment	IEC 60601-2-18: Edition 3.0 2009-08 [1]; IEC 60601-2-18:1996 + A1:2000; IEC 60601-2-18:2009; EN 60601-2-18:1996 + A1:2000; EN 60601-2-18:2015; CAN/CSA C22.2 No. 60601-2-18:2001; CAN/CSA C22.2 No. 60601-2-18:2011

Test Technology:	Test Method(s) [2,3]:
Infusion Pumps and Controllers	IEC 60601-2-24:1998; IEC 60601-2-24:2012; EN 60601-2-24:1998; EN 60601-2-24:2015; CAN/CSA C22.2 No. 60601-2-24:2001(R09); CAN/CSA C22.2 No. 60601-2-24:2015
Electrocardiographs	IEC 60601-2-25 Edition 2.0 2011-10 [1]; ANSI AAMI IEC 60601-2-25:2011/(R)2016 [1]; IEC 60601-2-25:1993 + A1:1999; IEC 60601-2-25:2011; EN 60601-2-25:1995 + A1:1999; EN 60601-2-25:2015; CAN/CSA C22.2 No. 601.2.25:1994; CAN/CSA C22.2 No. 60601-2-25:2012; ANSI/AAMI/IEC 60601-2-25:2011
Electroencephalographs	IEC 60601-2-26:2002; IEC 60601-2-26:2012; IEC 80601-2-26:2019; EN 60601-2-26:2003; EN 60601-2-26:2015; 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 Edition 3.0 2011-03 [1]; ANSI AAMI IEC 60601-2-27:2011(R)2016 [1]; IEC 60601-2-27:1994; IEC 60601-2-27:2005; IEC 60601-2-27:2011 + COR1:2012; ANSI/AAMI/IEC 60601-2-27:2011; EN 60601-2-27:1994; EN 60601-2-27:2006; EN 60601-2-27:2014; CAN/CSA C22.2 No. 60601-2-27:2006; CAN/CSA C22.2 No. 60601-2-27:2011
Automated Non-Invasive Sphygmomanometers	IEC 60601-2-30:1999; CAN/CSA C22.2 No. 60601-2-30:2002(R11); EN 60601-2-30:2000; ANSI AAMI IEC 80601-2-30:2009 & A1:2013 (R2016) [1]; IEC 80601-2-30 Edition 1.1 2013-07 [1]; IEC 80601-2-30 Edition 2.0 2018-03 [1]; ANSI AAMI IEC 80601-2-30:2018 [1]; EN ISO 80601-2-30:10 + A1:2015; CAN/CSA C22.2 No. 80601-2-30:2010; CAN/CSA C22.2 No. 80601-2-30:2019
Invasive Blood Pressure Monitoring Equipment	IEC 60601-2-34:2000; IEC 60602-3-34:2011; EN 60601-2-34:2000; EN 60601-2-34:2014; CAN/CSA C22.2 No. 60601-2-34:2002; CAN/CSA C22.2 No. 60601-2-34:2012

Test Technology:	Test Method(s) [2,3]:
Heating Devices Using Blankets, Pads, and Mattresses	IEC 60601-2-35:1996; EN 60601-2-35:1996; IEC 80601-2-35 Edition 2.1 2016-04 [1]; ANSI AAMI IEC 80601-2-35:2009/A1:2016; EN 80601-2-35:2009 + A11:2011 + A1:2016; EN 80601-2-35:2009 + A11:2011 + AC:2015 + A1:2016; CAN/CSA C22.2 No. 80601-2-35:2012; IEC 60601-2-35:2020 (*excluding: Ed.1 Clause 59.2.101 [Spark Ignition Test]*)
Extracorporeally Induced Lithotripsy	IEC 60601-2-36 Edition 2.0 2014-04 [1]; IEC 60601-2-36:1997; EN 60601-2-36:1997; IEC 60601-2-36:2014; EN 60601-2-36:2015; CAN/CSA C22.2 No. 60601-2-36:1998; CAN/CSA C22.2 No. 60601-2-36:2016
Ultrasonic Monitoring and Diagnostic Equipment	IEC 60601-2-37:2008 + A1:2015; CSA C22.2 No. 60601-2-37:08 + A1:2019; EN 60601-2-37:2008 + A1:2015
Electrically Operated Hospital Beds	IEC 60601-2-38:1996 + A1:1999; EN 60601-2-38:1996 + A1:2000; CAN/CSA C22.2 No. 60601-2-38:2003
Peritoneal Dialysis Equipment	IEC 60601-2-39:1999; IEC 60601-2-39:2007; IEC 60601-2-39:2018; EN 60601-2-39:1999; EN 60601-2-39:2008 + A11:2011; CAN/CSA C22.2 No. 60601-2-39:2002; CAN/CSA C22.2 No. 60601-2-39:2009
Electromyographs and Evoked Response Equipment	IEC 60601-2-40:1998; IEC 60601-2-40:2016; EN 60601-2-40:1998; CAN/CSA C22.2 No. 60601-2-40:2001; CAN/CSA C22.2 No. 60601-2-40:2017
Operating Tables	IEC 60601-2-46:1998; IEC 60601-2-46:2010; IEC 60601-2-46:2016; EN 60601-2-46:2011; EN 60601-2-46:1998; CAN/CSA C22.2 No. 60601-2-46:2001; CAN/CSA C22.2 No. 60601-2-46:2012; CAN/CSA C22.2 No. 60601-2-46:2018

Test Technology:	**Test Method(s) [2,3]:**
Ambulatory Electrocardiographic Monitors	IEC 60601-2-47 Edition 2.0 2012-02 [1]; ANSI AAMI IEC 60601-2-47:2012/(R)2016 [1]; IEC 60601-2-47:2001; IEC 60601-2-47:2012; ANSI/AAMI/IEC 60601-2-47:2012; EN 60601-2-47:2001; EN 60601-2-47:2015; CAN/CSA C22.2 No. 60601-2-47:2003; CAN/CSA C22.2 No. 60601-2-47:2014
Multiparameter Patient Monitoring Equipment	IEC 60601-2-49:2001; IEC 60601-2-49:2011; EN 60601-2-49:2001; EN 60601-2-49:2015; CAN/CSA C22.2 No. 60601-2-49:2011; CAN/CSA C22.2 No. 60601-2-49:2004; IEC 80601-2-49:2018; EN IEC 80601-2-49:2019
Recording and Analyzing Single and Multichannel Electrocardiographs	IEC 60601-2-51:2003; EN 60601-2-51:2003; CAN/CSA C22.2 No. 60601-2-51:2004 (*excluding clause:* *50.102 Automated ECG interpretation for analyzing electrocardiographs*)
Safety of Medical Beds	I IEC 60601-2-52 Edition 1.0 2009-12 [1]; EC 60601-2-52:2009 + A1:2015; EN 60601-2-52:2010 + AC:2011 + A1:2015; CAN/CSA C22.2 No. 60601-2-52:2011
Respiratory Gas Monitors	ISO 80601-2-55 Second Edition 2018-02 [1]; ISO 80601-2-55:2011; ISO 80601-2-55:2018; EN ISO 80601-2-55:2011; EN 80601-2-55:2018; CAN/CSA C22.2 No. 80601-2-55:2014
Clinical Thermometers for Body Temperature Measurement	ISO 80601-2-56 Second Edition 2017-03 [1]; ISO 80601-2-56:2009; ISO 80601-2-56:2017 + A1:2018; CAN/CSA C22.2 No. 80601-2-56:2012; EN ISO 80601-2-56:2012; ISO 80601-2-56:2012 [1]; EN ISO 80601-2-56:2017
Dental Equipment	ISO 80601-2-60:2012; CAN/CSA C22.2 No. 80601-2-60:2014; EN 80601-2-60:2015; ISO 80601-2-60:2019 (*excluding clauses:* *201.10 Protection against excessive radiation hazards;*)
Pulse Oximeter Equipment	ISO 80601-2-61 Second Edition 2017-12 (Corrected Version 2018-02) [1]; ISO 80601-2-61:2011; ISO 80601-2-61:2017; EN ISO 80601-2-61:2011; CAN/CSA C22.2 No. 80601-2-61:2014

Test Technology:	**Test Method(s) [2,3]:**
Pulse Oximeter Equipment for Medical Use	ISO 9919:2005; CAN/CSA Z9919:2007 (*excluding clause:* *50.101.2 Clinical Determination of SpO2 Accuracy*)
Medical Vehicles and their Equipment	EN 1789:2007 + A1:2010 + A2:2014 (only Clause 6 [Medical Devices]) (*excluding clauses:* *6.1 Provision of medical devices;* *6.2 Medical device storage;* *6.3.5 Fixation of medical devices;* *6.3.8 Gas supply;* *6.5 List of equipment*)
Degrees of Protection Provided by Enclosures	IEC 60529:1998 + A1:1999 + A2:2013; EN 60529:1991 + A1:2000 + A2:2013 + AC:2016; CAN/CSA C22.2 No. 60529:2005; CAN/CSA C22.2 No. 60529:2016
Software Life-Cycle Processes	IEC 62304:2006 + A1:2015; EN 62304:2006 + A1:2015; ANSI/AAMI/IEC 62304:2006 + A1:2016; CAN/CSA CEI/IEC 62304:2014
Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory use – Part 1: General Requirements	IEC 61010-1:2001; IEC 61010-1 Edition 3.1 2017-01 [1]; IEC 61010-1:2010 + A1:2016 + COR1:2019 (*excluding subclause 16.2 category III & IV*); EN 61010-1:2001; EN 61010-1:2010 + A1:2019 + AC:2019; CAN/CSA C22.2 No. 61010-1:2004 (Ed. 2); CAN/CSA C22.2 No. 61010-1:2012; UL 61010-1:2004; UL 61010-1:2012 (*excluding subclause 16.2 category III & IV*)
Equipment for Heating of Materials	IEC 61010-2-010:2003; IEC 61010-2-010:2014; IEC 60601-2-010:2019; IEC 60601-2-10 Edition 2.1 2016-04 [1]; EN 61010-2-010:2003; EN 61010-2-010:2014; EN 61010-2-010:2020; CAN/CSA C22.2 No. 61010-2-010:2004; CAN/CSA C22.2 No. 61010-2-010:2015; CAN/CSA C22.2 No. 60601-2-010:2019; UL 61010-2-010:2004; UL 61010-2-010:2015; UL 60601-2-010:2019

Test Technology:	**Test Method(s) [2,3]:**
Laboratory Centrifuges	IEC 61010-2-020:2006; IEC 61010-2-020:2016 (*excluding 7.3.101 & 7.6*); EN 61010-2-020:2006; EN 61010-2-020:2017 (*excluding 7.3.101 & 7.6*); CAN/CSA C22.2 No. 61010-2-020:2009; CAN/CSA C22.2 No. 61010-2-020:2017 (*excluding 7.3.101 & 7.6*); UL 61010-2-020:2016 (*excluding 7.3.101 & 7.6*)
Equipment for Mixing and Stirring	IEC 61010-2-051:2003; IEC 61010-2-051:2015; IEC 61010-2-051:2018; EN 61010-2-051:2003; EN 61010-2-051:2015; CAN/CSA C22.2 No. 61010-2-051:2004; CAN/CSA C22.2 No. 61010-2-051:2015; CAN/CSA C22.2 No. 61010-2-051:2019; UL 61010-2-051:2003; UL 61010-2-051:2015; UL 61010-2-051:2019
Automatic & Semi-Automatic Laboratory Equipment for Analysis	IEC 61010-2-081:2001 + A1:2003; IEC 61010-2-081:2015; IEC 61010-2-081:2019; CAN/CSA C22.2 No. 61010-2-081:2004; CAN/CSA C22.2 No. 61010-2-081:2015; CAN/CSA C22.2 No. 61010-2-081:2019; EN 61010-2-081:2002 + A1:2003; EN 61010-2-081:2015; UL 61010-2-081:2015; UL 61010-2-081:2019
IVD Medical Equipment	IEC 61010-2-101:2002; IEC 61010-2-101:2015; IEC 61010-2-101:2018; EN 61010-2-101:2002; EN 61010.2-101:2017; CAN/CSA C22.2 No. 61010-2-101:2004; CAN/CSA C22.2 No. 61010-2-101:2015; CAN/CSA C22.2 No. 61010-2-101:2019; UL 61010-2-101:2015

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

Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* published on September 25th, 2020, and in accordance with all requirements of A2LA *R256 Specific Requirements- FDA ASCA Program* [1]:

Standards:
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) ANSI AAMI HA60601-1-11:2015
IEC 60601-1-2:2014 + A1:2020 ANSI/AAMI/IEC 60601-1-2:2014 + A1:2021 IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION; IEC 60601-1-6 Edition 3.1 2013-10 IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION; IEC 60601-1-8 Edition 2.1 2012-11 ANSI AAMI IEC 60601-1-8:2006 and A1:2012 IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION IEC 60601-1-10 Edition 1.1 2013-11 IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION IEC 60601-1-11 Edition 2.0 2015-01 ANSI AAMI HA60601-1-11:2015 IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION IEC 60601-1-12 Edition 1.0 2014-06
IEC 60601-2-2 Edition 6.0 2017-03 ANSI AAMI IEC 60601-2-2:2017 IEC 60601-2-10 Edition 2.1 2016-04 IEC 60601-2-16 Edition 5.0 2018-4 ANSI AAMI IEC 60601-2-16:2018 IEC 60601-2-18: Edition 3.0 2009-08 IEC 60601-2-25 Edition 2.0 2011-10 ANSI AAMI IEC 60601-2-25:2011/(R)2016 IEC 60601-2-27 Edition 3.0 2011-03 ANSI AAMI IEC 60601-2-27:2011(R)2016 IEC 60601-2-34 Edition 3.0 2011-05 IEC 60601-2-36 Edition 2.0 2014-04 IEC 60601-2-47 Edition 2.0 2012-02 ANSI AAMI IEC 60601-2-47:2012/(R)2016 IEC 60601-2-52 Edition 1.0 2009-12
Standards:
IEC 61010-1 Edition 3.1 2017-01
ANSI AAMI IEC 80601-2-30:2009 & A1:2013 (R2016) IEC 80601-2-30 Edition 1.1 2013-07 IEC 80601-2-30 Edition 2.0 2018-03 ANSI AAMI IEC 80601-2-30:2018 IEC 80601-2-35 Edition 2.1 2016-04
ISO 80601-2-55 Second Edition 2018-02 ISO 80601-2-56 Second Edition 2017-03 ISO 80601-2-61 Second Edition 2017-12 (Corrected Version 2018-02)

[1] These methods have been assessed by A2LA according to A2LA's FDA ASCA Program requirements. Accreditation by A2LA does not imply FDA ASCA-Accreditation. All ASCA-accreditation decisions for testing laboratory applications are made solely by the FDA, a list of approved laboratories can be found at www.FDA.gov.

[2] Broadband random vibration, Mechanical shock, and any requirements associated with Clinical Data and/or Clinical Trials are not included within the testing listed on the scope of accreditation.

[3] 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.

Accredited Laboratory

A2LA has accredited

MEDICAL EQUIPMENT COMPLIANCE ASSOCIATES, LLC.

Oak Creek, WI

for technical competence in the field of

Electrical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This laboratory also meets A2LA R256 - Specific Requirements - FDA ASCA Program. 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*).

Presented this 24th day of December 2020.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3392.01
Valid to January 31, 2023
Revised February 03, 2021

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