



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 <sup>1</sup> requirements), accreditation is granted to this laboratory to perform the following Product Safety tests:

**Test Technology:**

**Test Method(s) <sup>2,3</sup>:**

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) <sup>1</sup>;  
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:**

Programmable Electrical  
Medical Systems

Usability

Medical Electrical Equipment and  
Medical Electrical Systems used in  
the Home Healthcare Environment

Medical Electrical Equipment and  
Medical Electrical Systems used in  
the Emergency Medical Services  
Environment

Requirements/Guidelines for Alarms  
in Medical Electrical Equipment

**Test Method(s) <sup>2,3</sup>:**

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

IEC 60601-1-6 Edition 3.2 2020-07  
CONSOLIDATED VERSION <sup>1</sup>;  
IEC 60601-1-6 Edition 3.1 2013-10 <sup>1</sup>;  
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

IEC 60601-1-11 Edition 2.1 2020-07  
CONSOLIDATED VERSION <sup>1</sup>;  
IEC 60601-1-11 Edition 2.0 2015-01 <sup>1</sup>;  
ANSI AAMI HA60601-1-11:2015 <sup>1</sup>;  
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

IEC 60601-1-12 Edition 1.1 2020-07  
CONSOLIDATED VERSION <sup>1</sup>;  
IEC 60601-1-12 Edition 1.0 2014-06 <sup>1</sup>;  
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

IEC 60601-1-8 Edition 2.2 2020-07  
CONSOLIDATED VERSION <sup>1</sup>;  
IEC 60601-1-8 Edition 2.1 2012-11 <sup>1</sup>;  
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 <sup>1</sup>

**Test Technology:**

**Test Method(s) <sup>2,3</sup>:**

Requirements for Physiological  
Closed-Loop Controllers

IEC 60601-1-10 Edition 1.2 2020-07  
CONSOLIDATED VERSION <sup>1</sup>;  
IEC 60601-1-10 Edition 1.1 2013-11 <sup>1</sup>;  
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

High Frequency  
Surgical Equipment

IEC 60601-2-2 Edition 6.0 2017-03 <sup>1</sup>;  
ANSI AAMI IEC 60601-2-2:2017 <sup>1</sup>;  
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 <sup>1</sup>;  
IEC 60601-2-10:1987 + A1:2001;  
IEC 60601-2-10:2012 <sup>1</sup>; 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 <sup>1</sup>;  
ANSI AAMI IEC 60601-2-16:2018 <sup>1</sup>;  
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

**Test Technology:****Test Method(s) <sup>2,3</sup>:**

Endoscopic Equipment

IEC 60601-2-18: Edition 3.0 2009-08 <sup>1</sup>;  
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

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 <sup>1</sup>;  
ANSI AAMI IEC 60601-2-25:2011/(R)2016 <sup>1</sup>;  
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. 60601-2-26:14Electrocardiographic  
Monitoring  
EquipmentIEC 60601-2-27 Edition 3.0 2011-03 <sup>1</sup>;  
ANSI AAMI IEC 60601-2-27:2011(R)2016 <sup>1</sup>;  
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. 60601-2-27:2011Automated Non-Invasive  
SphygmomanometersIEC 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) <sup>1</sup>;  
IEC 80601-2-30 Edition 1.1 2013-07 <sup>1</sup>;  
IEC 80601-2-30 Edition 2.0 2018-03 <sup>1</sup>;  
ANSI AAMI IEC 80601-2-30:2018 <sup>1</sup>;  
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

**Test Technology:**

**Test Method(s) <sup>2,3</sup>:**

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

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 <sup>1</sup>;  
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 <sup>1</sup>;  
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

**Test Technology:**

**Test Method(s) <sup>2,3</sup>:**

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

Ambulatory Electrocardiographic  
Monitors

IEC 60601-2-47 Edition 2.0 2012-02 <sup>1</sup>;  
ANSI AAMI IEC 60601-2-47:2012/(R)2016 <sup>1</sup>;  
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 <sup>1</sup>;  
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 <sup>1</sup>;  
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 <sup>1</sup>;  
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 <sup>1</sup>;  
EN ISO 80601-2-56:2017

**Test Technology:**

**Test Method(s) <sup>2,3</sup>:**

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;  
201.17 Electromagnetic compatibility of  
ME EQUIPMENT and ME SYSTEMS)

Pulse Oximeter Equipment

ISO 80601-2-61 Second Edition 2017-12  
(Corrected Version 2018-02) <sup>1</sup>;  
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

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 <sup>1</sup>;  
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)

**Test Technology:**

**Test Method(s) <sup>2,3</sup>:**

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 <sup>1</sup>;  
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

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



**Test Technology:**

IVD Medical Equipment

**Test Method(s) <sup>2,3</sup>:**

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

<p>Testing Activities performed under the scope of the U.S FDA ASCA Pilot Program Specifications: <i>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</i> published on September 25th, 2020, and in accordance with all requirements of A2LA R256 Specific Requirements- FDA ASCA Program <sup>1</sup>:</p>
<p><b><u>Standards:</u></b></p>
<p>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</p>
<p>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</p>
<p>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</p>



<b><u>Standards:</u></b>
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)

<sup>1</sup> 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](http://www.FDA.gov).

<sup>2</sup> 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 any requirements associated with Clinical Data and/or Clinical Trials are not included within the testing listed on the scope of accreditation.

<sup>3</sup> 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 24<sup>th</sup> day of December 2020.

A blue ink signature of the Vice President of Accreditation Services.

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.*