



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

MEDICAL EQUIPMENT COMPLIANCE ASSOCIATES, LLC.  
140 East Rawson Avenue, Suite 301  
Oak Creek, WI 53154  
Mr. Alex Grob Phone: 262 672 6022  
Email: ag@60601-1.com

ELECTRICAL

Valid to: February 28, 2025

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, 4:</sup>**

Medical Electrical Equipment– Part 1:  
General Requirements for Safety

IEC 60601-1;  
EN 60601-1;  
UL 60601-1;  
CAN/CSA C22 No. 601.1-M90;  
GB 9706.1:2007  
(excluding clauses:  
29 X-Radiation;  
39 Category AP and APG Testing)

**Test Technology:**

Medical Electrical Equipment– Part 1:  
General Requirements for Basic Safety  
and Essential Performance

**Test Method(s) <sup>2,3,4</sup>:**

IEC 60601-1;  
IEC 60601-1:2005 + A1:2012;  
IEC 60601-1:2005;  
  
EN 60601-1;  
EN60601-1:2006 + A1:2013EN 60601-1:2006;  
  
ANSI/AAMI ES60601-1<sup>1</sup>;  
ANSI/AAMI ES 60601-1:2005 + A1:2012, C1:2009 +  
A2:2010<sup>1</sup>;  
ANSI/AAMI ES 60601-1:2005;  
  
CAN/CSA C22.2 No. 60601-1;  
CAN/CSA C22.2 No. 60601-1:14;  
CAN/CSA C22.2 No. 60601-1-08;  
  
GB 9706-1:2020;  
  
JIS T 0601-1;  
JIS T 0601-1:2012 + A1:2014  
*(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;  
  
EN 60601-1-1;  
  
CAN/CSA C22.2 No. 60601-1-1

Medical electrical equipment –  
Electromagnetic disturbances

General Requirements:  
IEC 60601-1-2\*;  
IEC 60601-1-2:2014 + A1:2020\*;  
  
ANSI/AAMI ES 60601-1-2\*;  
ANSI/AAMI ES 60601-1-2:2014 + A1:2021\*;  
  
EN 60601-1-2\*;  
EN 60601-1-2:2014\*;  
  
CAN/CSA C22.2 No. 60601-1-2:2016\*;  
  
YY 9706.102:2021\*  
\*(excluding ISM, Powerline Harmonics, Voltage  
Fluctuation and Flicker, Radiated Immunity, Conducted  
Immunity, Radiated Field in Close Proximity)

**Test Technology:**

Programmable Electrical  
Medical Systems

Usability

**Test Method(s) <sup>2,3,4</sup>:**

IEC 60601-1-4;

EN 60601-1-4;

CAN/CSA C22.2 No. 60601-1-4

IEC 60601-1-6<sup>1</sup>;  
IEC 60601-1-6:2010 + A1:2013<sup>1</sup>;  
IEC 60601-1-6:2010;

EN 60601-1-6;  
EN 60601-1-6:2010 + A1:2015;  
EN 60601-1-6:2010;

CAN/CSA C22.2 No. 60601-1-6;  
CAN/CSA C22.2 No. 60601-1-6:2015;  
CAN/CSA C22.2 No. 60601-1-6:2011;

NBR IEC 60601-1-6;  
NBR IEC 60601-1-6:2011 + A1:2020;

YY/T 9706.106:2021;

IEC 62366;  
IEC 62366:2007;

EN 62366;  
EN 62366:2008;

ANSI/AAMI/IEC 62366;  
ANSI/AAMI/IEC 62366:2007;

CAN/CSA IEC 62366;

IEC 62366-1;  
IEC 62366-1:2015;

ANSI/AAMI/IEC 62366-1;  
ANSI/AAMI/IEC 62366-1:2015;

CAN/CSA-IEC 62366-1;  
CAN/CSA-IEC 62366-1:2015;

EN 62366-1;  
EN 62366-1:2015;

JIS T 62366-1;  
JIS T 62366-1:2019

**Test Technology:**

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

**Test Method(s) <sup>2,3,4:</sup>**

IEC 60601-1-11<sup>1</sup>;  
IEC 60601-1-11:2015<sup>1</sup>;  
IEC 60601-1-11:2010;  
  
ANSI AAMI HA60601-1-11<sup>1</sup>;  
ANSI/AAMI HA 60601-1-11:2015<sup>1</sup>;  
ANSI/AAMI HA 60601-1-11:11;  
  
EN 60601-1-11;  
EN 60601-1-11:2015;  
EN 60601-1-11:2010;  
  
CAN/CSA C22.2 No. 60601-1-11;  
CAN/CSA C22.2 No. 60601-1-11:2015;  
CSA C22.2 No. 60601-1-11:11;  
  
NBR IEC 60601-1-11;  
NBR IEC 60601-1-11:2021;  
  
YY 9706.111:2021

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

IEC 60601-1-12<sup>1</sup>;  
IEC 60601-1-12:2014<sup>1</sup>;  
  
ANSI/AAMI/IEC 60601-1-12<sup>1</sup>;  
ANSI/AAMI/IEC 60601-1-12:2016<sup>1</sup>;  
  
CAN/CSA C22.2 No. 60601-1-12;  
CAN/CSA C22.2 No. 60601-1-12:2015;  
  
EN 60601-1-12;  
EN 60601-1-12:2015;  
  
YY 9706.112:2021

Requirements/Guidelines for Alarms  
in Medical Electrical Equipment

IEC 60601-1-8<sup>1</sup>;  
IEC 60601-1-8:2012<sup>1</sup>;  
IEC 60601-1-8:2006;  
  
EN 60601-1-8;  
EN 60601-1-8:2007 + A1:2013;  
EN 60601-1-8:2007;  
  
CAN/CSA C22 No. 60601-1-8;  
CAN/CSA C22 No. 60601-1-8:2008;  
  
ANSI/AAMI/IEC 60601-1-8;  
ANSI AAMI IEC 60601-1-8:2006 + A1:2012  
  
YY 9706.108;  
YY 0709:2009

**Test Technology:**

Requirements for Physiological  
Closed-Loop Controllers

High Frequency  
Surgical Equipment

Cardiac Defibrillators,  
Defibrillator-Monitors

**Test Method(s) <sup>2,3,4</sup>:**

IEC 60601-1-10<sup>1</sup>;  
IEC 60601-1-10: 2007 + A1:2013<sup>1</sup>;  
IEC 60601-1-10:2007;  
  
EN 60601-1-10;  
EN 60601-1-10:2008 + A1:2015;  
EN 60601-1-10:2008;  
  
CAN/CSA C22.2 No. 60601-1-10;  
CAN/CSA C22.2 No. 60601-1-10-09;  
  
YY 9706.110:2021

IEC 60601-2-2;  
IEC 60601-2-2 2017<sup>1</sup>;  
IEC 60601-2-2:2009;  
IEC 60601-2-2:2006;  
  
ANSI AAMI IEC 60601-2-2:2017<sup>1</sup>;  
ANSI/AAMI/IEC 60601-2-2:2009;  
  
EN 60601-2-2:2018;  
EN 60601-2-2:2009 + A11:2011;  
EN 60601-2-2:2007;  
  
CAN/CSA C22.2 No. 60601-2-2;  
CAN/CSA C22.2 No. 60601-2-2:2008;  
CAN/CSA C22.2 No. 60601-2-2:2009;  
  
GB 9706.4:2009  
*(excluding:*  
*Ed. 2, 3, 4 Clause 59.104.7;*  
*Ed. 5 Clause 201.15.101.7*  
*[Neutral Electrode Adhesion])*

IEC 60601-2-4;  
IEC 60601-2-4:2010 + A1:2018;  
IEC 60601-2-4:2002;  
  
ANSI/AAMI/IEC 60601-2-4;  
ANSI/AAMI/IEC 60601-2-4:2010;  
  
EN 60601-2-4;  
EN 60601-2-4:2011;  
EN 60601-2-4:2003;  
  
CAN/CSA C22.2 No. 60601-2-4;  
CAN/CSA C22.2 No. 60601-2-4:2012;  
CAN/CSA C22.2 No. 60601-2-4:2004;  
  
GB 9706.8;  
GB 9706.8:2009

**Test Technology:**

**Test Method(s) <sup>2,3,4</sup>:**

Nerve and Muscle Stimulators

IEC 60601-2-10<sup>1</sup>;  
IEC 60601-2-10:2016;  
IEC 60601-2-10:2012;  
IEC 60601-2-10:1987 + A1:2001;  
  
CAN/CSA C22.2 No. 60601-2-10:2014;  
CSA C22.2 No. 601.2.10:1992;  
  
EN 60601-2-10:2015 + A1:2016;  
EN 60601-2-10:2015;  
EN 60601-2-10:2000 + A1:2001;  
  
YY 0607:2007;  
YY 9706.210:2021

Hemodialysis Equipment

IEC 60601-2-16 <sup>1</sup>;  
IEC 60601-2-16:2012;  
IEC 60601-2-16:1998;  
  
ANSI AAMI IEC 60601-2-16:2018<sup>1</sup>;  
AAMI/IEC 60601-2-16:2012;  
  
EN 60601-2-16;  
EN 60601-2-16:2015;  
EN 60601-2-16:1998;  
  
CAN/CSA C22.2 No. 60601-2-16;  
CAN/CSA C22.2 No. 60601-2-16:2009;  
CAN/CSA C22.2 No. 60601-2-16:2014;  
CAN/CSA C22.2 No. 60601-2-16:2001;  
  
GB 9706.216:2021;  
GB 9706.2:2003

Endoscopic Equipment

IEC 60601-2-18<sup>1</sup>;  
IEC 60601-2-18:1996 + A1:2000;  
IEC 60601-2-18:1996;  
  
EN 60601-2-18;  
EN 60601-2-18:1996 + A1:2000;  
  
CAN/CSA C22.2 No. 60601-2-18;  
CAN/CSA C22.2 No. 60601-2-18:2001;  
  
GB 9706.19:2000

**Test Technology:**

**Test Method(s) <sup>2,3,4</sup>:**

Infusion Pumps and Controllers

IEC 60601-2-24;  
IEC 60601-2-24:1998;

EN 60601-2-24;  
EN 60601-2-24:1998;

CAN/CSA C22.2 No. 60601-2-24;  
CAN/CSA C22.2 No. 60601-2-24:2001;

GB 9706.24:2005

Electrocardiographs

IEC 60601-2-25<sup>1</sup>;  
IEC 60601-2-25:1993 + A1:1999;

ANSI AAMI IEC 60601-2-25<sup>1</sup>;

EN 60601-2-25;  
EN 60601-2-25:1995 + A1:1999;

CAN/CSA C22.2 No. 601.2.25;  
CAN/CSA C22.2 No. 60601-2-25:1994

Electroencephalographs

IEC 60601-2-26;  
IEC 60601-2-26:2002;

EN 60601-2-26;  
EN 60601-2-26:2003;

CAN/CSA C22.2 No. 60601-2-26;  
CAN/CSA C22.2 No. 60601-2-26:04;

GB 9706.226:2021;  
GB 9706.26:2005;

IEC 80601-2-26

Electrocardiographic  
Monitoring  
Equipment

IEC 60601-2-27<sup>1</sup>;  
IEC 60601-2-27:1994;

ANSI AAMI IEC 60601-2-27<sup>1</sup>;

CAN/CSA C22.2 No. 60601-2-27;  
CAN/CSA C22.2 No. 60601-2-27:2006;

EN 60601-2-27;  
EN 60601-2-27:2006;

GB 9706.227:2021;  
GB 9706.25:2005

**Test Technology:**

Automated Non-Invasive  
Sphygmomanometers

**Test Method(s) <sup>2,3,4</sup>:**

IEC 60601-2-30;  
CAN/CSA C22.2 No. 60601-2-30;  
EN 60601-2-30;  
YY 0667:2008;  
IEC 80601-2-30<sup>1</sup>;  
IEC 80601-2-30:2013<sup>1</sup>;  
IEC 80601-2-30:2009;  
ANSI/AAMI/IEC 80601-2-30<sup>1</sup>;  
ANSI AAMI IEC 80601-2-30:2009 & A1:2013 (R2016)<sup>1</sup>;  
EN ISO 80601-2-30;  
EN 80601-2-30:2010 + A1:2015;  
EN ISO 80601-2-30:2010;  
CAN/CSA C22.2 No. 80601-2-30;  
CAN/CSA C22.2 No. 80601-2-30:2009

Invasive Blood Pressure  
Monitoring Equipment

IEC 60601-2-34;  
IEC 60601-2-34:2000;  
EN 60601-2-34;  
EN 60601-2-34:2004;  
CAN/CSA C22.2 No. 60601-2-34;  
CAN/CSA C22.2 No. 60601-2-34:2002;  
YY 0783:2010

Heating Devices Using Blankets,  
Pads, and Mattresses

IEC 60601-2-35;  
IEC 60601-2-35:1996;  
EN 60601-2-35;  
EN 60601-2-35:1996;  
YY 0834:2011;  
IEC 80601-2-35<sup>1</sup>;  
IEC 80601-2-35:2009;  
ANSI AAMI IEC 80601-2-35;  
ANSI/AAMI/IEC 80601-2-35:2009;  
EN 80601-2-35;  
EN ISO 80601-2-35:09 + A11:2011 + AC:2015;  
CAN/CSA C22.2 No. 80601-2-35;  
CAN/CSA C22.2 No. 80601-2-35:2012;  
(excluding: Ed.1 Clause 59.2.101 [Spark Ignition Test])



**Test Technology:**

**Test Method(s) <sup>2,3,4</sup>:**

Extracorporeally Induced Lithotripsy

IEC 60601-2-36<sup>1</sup>;  
IEC 60601-2-36:1997;  
  
EN 60601-2-36;  
EN 60601-2-36:1997;  
  
CAN/CSA C22.2 No. 60601-2-36;  
CAN/CSA C22.2 No. 60601-2-36:1998;  
  
GB 9706.22:2003

Ultrasonic Monitoring and Diagnostic Equipment

IEC 60601-2-37<sup>1</sup>;  
IEC 60601-2-37:2007;  
  
CSA C22.2 No. 60601-2-37;  
CSA C22.2 No. 60601-2-37:2008;  
  
EN 60601-2-37;  
EN 60601-2-37:2008;  
  
GB 9706.237:2020

Electrically Operated Hospital Beds

IEC 60601-2-38;  
  
EN 60601-2-38;  
  
CAN/CSA C22.2 No. 60601-2-38

Peritoneal Dialysis Equipment

IEC 60601-2-39;  
IEC 60601-2-39:2007;  
IEC 60601-2-39:1999;  
  
EN 60601-2-39;  
EN 60601-2-39:2008;  
EN 60601-2-39:1999;  
  
CAN/CSA C22.2 No. 60601-2-39;  
CAN/CSA C22.2 No. 60601-2-39:2009;  
CAN/CSA C22.2 No. 60601-2-39:2002;  
  
GB 9706.239:2021;  
GB 9706.36:2008;  
  
JIS T 0601-2-39:2013

**Test Technology:**

**Test Method(s) <sup>2,3,4</sup>:**

Electromyographs and Evoked  
Response Equipment

IEC 60601-2-40;  
IEC 60601-2-40:1998;

EN 60601-2-40;  
EN 60601-2-40:1998;

CAN/CSA C22.2 No. 60601-2-40;  
CAN/CSA C22.2 No. 60601-2-40:2001;

YY 9706.240:2021;  
YY 0896:2013

Ambulatory Electrocardiographic  
Monitors

IEC 60601-2-47<sup>1</sup>;  
IEC 60601-2-47:2001;

ANSI AAMI IEC 60601-2-47<sup>1</sup>;

EN 60601-2-47;  
EN 60601-2-47:2001;

CAN/CSA C22.2 No. 60601-2-47;  
CAN/CSA C22.2 No. 60601-2-47:2003;

YY 0885:2013

Multiparameter Patient  
Monitoring Equipment

IEC 60601-2-49;  
IEC 60601-2-49:2001;

EN 60601-2-49;  
EN 60601-2-49:2001;

CAN/CSA C22.2 No. 60601-2-49;  
CAN/CSA C22.2 No. 60601-2-49:2004;

YY 0668:2008;

IEC 80601-2-49;

EN IEC 80601-2-49

Safety of Medical Beds

IEC 60601-2-52<sup>1</sup>;  
IEC 60601-2-52:2009;

EN 60601-2-52;  
EN 60601-2-52:2010 + AC:2011 + A1:2015;

CAN/CSA C22.2 No. 60601-2-52;  
CAN/CSA C22.2 No. 60601-2-52:2011

**Test Technology:**

**Test Method(s) <sup>2,3,4</sup>:**

Respiratory Gas Monitors

ISO 80601-2-55<sup>1</sup>;  
ISO 80601-2-55:2011;

EN ISO 80601-2-55;  
EN 80601-2-55:2011;

CAN/CSA C22.2 No. 80601-2-55;  
CAN/CSA C22.2 No. 80601-2-55:2014

Clinical Thermometers for  
Body Temperature Measurement

ISO 80601-2-56<sup>1</sup>;  
ISO 80601-2-56:2017<sup>1</sup>;  
ISO 80601-2-56:2009;

CAN/CSA C22.2 No. 80601-2-56;  
CAN/CSA C22.2 No. 80601-2-56:2012;

EN ISO 80601-2-56;  
EN ISO 80601-2-56:2012

Dental Equipment

ISO 80601-2-60;  
ISO 80601-2-60:2012;

CAN/CSA C22.2 No. 80601-2-60;  
CAN/CSA C22.2 No. 80601-2-60:2014;

EN 80601-2-60;  
EN 80601-2-60:2015;

GB 9706.260:2020  
*(excluding clauses:  
201.10 Protection against excessive radiation hazards)*

Pulse Oximeter Equipment

ISO 80601-2-61<sup>1</sup>;  
ISO 80601-2-61:2011;

EN ISO 80601-2-61;  
EN ISO 80601-2-61:2011;

CAN/CSA C22.2 No. 80601-2-61;  
CAN/CSA C22.2 No. 80601-2-61:2014

Pulse Oximeter Equipment for  
Medical Use

ISO 9919;  
CAN/CSA Z9919;

YY 0784:2010  
*(excluding clause:  
50.101.2 Clinical Determination of SpO2 Accuracy)*

**Test Technology:**

Medical Vehicles and  
their Equipment

Degrees of Protection Provided  
by Enclosures

Software Life-Cycle Processes

**Test Method(s) <sup>2,3,4</sup>:**

EN 1789;  
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)*

IEC 60529;  
IEC 60529:1998 + A1:1999 + A2:2013;  
  
EN 60529;  
EN 60529:1991 + A1:2000 + A2:2013 + AC:2016;  
  
CAN/CSA C22.2 No. 60529;  
CAN/CSA C22.2 No. 60529:2005  
  
(Protection against ingress of solid foreign objects:  
IP0X, IP1X, IP2X, IP3X, IP4X  
  
Protection against ingress of water with harmful  
effects:  
IPX0, IPX1, IPX2, IPX3, IPX4, IPX5, IPX6, IPX7,  
IPX8)

IEC 62304;  
IEC 62304:2006;  
  
EN 62304;  
EN 62304:2006;  
  
ANSI/AAMI/IEC 62304;  
ANSI/AAMI/IEC 62304:2006;  
  
CAN/CSA CEI/IEC 62304;  
  
YY/T 0664:2020;  
YY/T 0664:2008

**Test Technology:**

Safety Requirements for Electrical  
Equipment for Measurement, Control,  
and Laboratory use – Part 1: General  
Requirements

**Test Method(s) <sup>2,3,4</sup>:**

IEC 61010-1<sup>1</sup>;  
IEC 61010-1:2001;  
IEC 61010-1:2010  
*(excluding subclause 16.2 category III & IV);*

EN 61010-1;  
EN 61010-1:2010;  
EN 61010-1:2001;

CAN/CSA C22.2 No. 61010-1;  
CAN/CSA C22.2 No. 61010-1:2004;

UL 61010-1;  
UL 61010-1:2004  
*(excluding subclause 16.2 category III & IV)*

Equipment for Heating of Materials

IEC 61010-2-010<sup>1</sup>;  
IEC 61010-2-010:2014;  
IEC 61010-2-010:2003;

EN 61010-2-010;  
EN 61010-2-010:2014;  
EN 61010-2-010:2003;

CAN/CSA C22.2 No. 61010-2-010;  
CAN/CSA C22.2 No. 60601-2-010:2015;  
CAN/CSA C22.2 No. 61010-2-010:2004;

UL 61010-2-010;  
UL 60601-2-010:2015;  
UL 61010-2-010:2004

Laboratory Centrifuges

IEC 61010-2-020;  
IEC 61010-2-020:2006;

EN 61010-2-020;  
EN 61010-2-020:2006;

CAN/CSA C22.2 No. 61010-2-020;  
CAN/CSA C22.2 No. 61010-2-020:2009;

UL 61010-2-020  
*(excluding 7.3.101 & 7.6)*

**Test Technology:**

**Test Method(s) <sup>2,3,4</sup>:**

Equipment for Mixing and Stirring

IEC 61010-2-051;  
IEC 61010-2-051:2015;  
IEC 61010-2-051:2003;

EN 61010-2-051;  
EN 61010-2-051:2015;  
EN 61010-2-051:2003;

CAN/CSA C22.2 No. 61010-2-051;  
CAN/CSA C22.2 No. 61010-2-051:2015;  
CAN/CSA C22.2 No. 61010-2-051:2004;

UL 61010-2-051;  
UL 61010-2-051:2015;  
UL 61010-2-051:2003

Automatic & Semi-Automatic  
Laboratory Equipment for Analysis

IEC 61010-2-081;  
IEC 61010-2-081:2015;  
IEC 61010-2-081:2001 + A1:2003;

CAN/CSA C22.2 No. 61010-2-081;  
CAN/CSA C22.2 No. 61010-2-081:2015;  
CAN/CSA C22.2 No. 61010-2-081:2004;

EN 61010-2-081;  
EN 61010-2-081:2015;  
EN 61010-2-081:2002 + A1:2003;

UL 61010-2-081;  
UL 61010-2-081:2015

IVD Medical Equipment

IEC 61010-2-101;  
IEC 61010-2-101:2015;  
IEC 61010-2-101:2002;

EN 61010-2-101;  
EN 61010-2-101:2017;  
EN 61010.2-101:2002;

CAN/CSA C22.2 No. 61010-2-101;  
CAN/CSA C22.2 No. 61010-2-101:2015;  
CAN/CSA C22.2 No. 61010-2-101:2004;

UL 61010-2-101;  
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*<sup>1</sup>

<u>Standards</u>	<u>Recognition Number</u>
ANSI/AAMI ES 60601-1	19-4
ANSI AAMI ES60601-1	19-46
ANSI AAMI HA60601-1-11	19-16
ANSI AAMI HA60601-1-11	19-47
IEC 60601-1-2*	19-36
IEC 60601-1-2*	19-8
ANSI/AAMI/IEC 60601-1-2*	19-36
ANSI/AAMI/IEC 60601-1-2*	19-8
IEC 60601-1-6	5-132
IEC 60601-1-6	5-89
IEC 60601-1-8	5-131
IEC 60601-1-8	5-76
ANSI AAMI IEC 60601-1-8	5-131
IEC 60601-1-10	19-37
IEC 60601-1-10	19-9
IEC 60601-1-11	19-38
IEC 60601-1-11	19-14
ANSI AAMI HA60601-1-11	19-16
IEC 60601-1-12	19-39
ANSI/AAMI/IEC 60601-1-12	19-39
IEC 60601-1-12	19-15
ANSI/AAMI/IEC 60601-1-12	19-15
IEC 60601-2-2	6-389
ANSI AAMI IEC 60601-2-2	6-389
IEC 60601-2-10	17-16
IEC 60601-2-16	9-121
ANSI AAMI IEC 60601-2-16	9-121
IEC 60601-2-18	9-114
IEC 60601-2-25	3-105
ANSI AAMI IEC 60601-2-25	3-105
IEC 60601-2-27	3-126
ANSI AAMI IEC 60601-2-27	3-126
IEC 60601-2-34	3-115
IEC 60601-2-36	9-119
IEC 60601-2-37	12-293
IEC 60601-2-47	3-155
ANSI AAMI IEC 60601-2-47	3-155

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*<sup>1</sup>

<b>Standards</b>	<b>Recognition Number</b>
IEC 60601-2-52	6-321
IEC 61010-1	19-34
ANSI/UL 61010-1	19-41
IEC 80601-2-30	3-123
ANSI AAMI IEC 80601-2-30	3-123
IEC 80601-2-35	6-390
ANSI/AAMI/IEC 80601-2-35	6-390
ISO 80601-2-55	1-140
ISO 80601-2-56	6-421
ISO 80601-2-61	1-139

\*(Excluding ISM, Powerline Harmonics, Voltage Fluctuation and Flicker, Radiated Immunity, Conducted Immunity, Radiated Field in Close Proximity).

\*Limited to: ESD, EFT/Burst Immunity, Surge Immunity, Power Frequency Magnetic Field Immunity, Voltage Dips, short interruptions & variation immunity – equipment up to 16A/phase, Electrical disturbances from conducting & coupling / electrical transient conduction along supply lines only.

<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> 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.

<sup>4</sup> When the date, edition, version, etc. is not identified in the scope of accreditation, laboratories may use the version that immediately precedes the current version for a period of one year from the date of publication of the standard measurement method, per part C., Section 1 of A2LA R101 – *General Requirements – Accreditation of ISO-IEC 17025 Laboratories*.





## Accredited Laboratory

A2LA has accredited

# MEDICAL EQUIPMENT COMPLIANCE ASSOCIATES, LLC.

*Oak Creek, Wisconsin*

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 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 12<sup>th</sup> day of January 2023.

A blue ink signature of Mr. Trace McInturff, written over a horizontal line.

Mr. Trace McInturff, Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 3392.01  
Valid to February 28, 2025  
Revised January 16, 2025

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