



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: January 31, 2027

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:

IEC 60601-1, Edition 3 Series		
<u>Test Technology:</u>	<u>Test Method(s) ^{2,3,4:}</u>	<u>National / Regional Variation(s) ^{2,3,4:}</u>
Medical Electrical Equipment– Part 1: General Requirements for Basic Safety and Essential Performance <i>(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])</i>	IEC 60601-1:2005;	ANSI/AAMI ES 60601-1:2005; CAN/CSA C22.2 No. 60601-1-08; EN 60601-1:2006 + A11:2011;
IEC 60601-1, Edition 3 Collateral Standards		
Usability	IEC 60601-1-6:2010;	CAN/CSA C22.2 No. 60601-1-6:2011; EN 60601-1-6:2010;
	IEC 62366:2007;	ANSI/AAMI/IEC 62366:2007; EN 62366:2008; CAN/CSA 62366:14

Requirements/Guidelines for Alarms in Medical Electrical Equipment	IEC 60601-1-8:2006;	CAN/CSA C22 No. 60601-1-8:2008; EN 60601-1-8:2007; YY 0709:2009
Requirements for Physiological Closed-Loop Controllers	IEC 60601-1-10:2007;	CAN/CSA C22.2 No. 60601-1-10-09; EN 60601-1-10:2008;
Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment	IEC 60601-1-11:2010;	ANSI/AAMI HA 60601-1-11:11; CSA C22.2 No. 60601-1-11:11; EN 60601-1-11:2010;
<u>IEC 60601-1, Edition 3 Particular Standards</u>		
High Frequency Surgical Equipment	IEC 60601-2-2:2009;	CAN/CSA C22.2 No. 60601-2-2:2009; EN 60601-2-2:2009 + A11:2011;
Cardiac Defibrillators, Defibrillator-Monitors	IEC 60601-2-4:2010;	ANSI/AAMI/IEC 60601-2-4:2010; EN 60601-2-4:2011; CAN/CSA C22.2 No. 60601-2-4:2012;
Nerve and Muscle Stimulators	IEC 60601-2-10:2012;	CAN/CSA C22.2 No. 60601-2-10:2014; EN 60601-2-10:2015;
Hemodialysis Equipment	IEC 60601-2-16:2012;	AAMI/IEC 60601-2-16:2012; EN 60601-2-16:2015; CAN/CSA C22.2 No. 60601-2-16:2014;
	IEC 60601-2-16:2008;	CAN/CSA C22.2 No. 60601-2-16:2009;
Endoscopic Equipment	IEC 60601-2-18:2009 ¹ ;	EN 60601-2-18:2015; CAN/CSA C22.2 No. 60601-2-18:2011;
Electrocardiographs	IEC 60601-2-25 ¹ ;	ANSI AAMI IEC 60601-2-25 ¹ ; EN 60601-2-25; CAN/CSA C22.2 No. 60601-2-25:2012;

Electroencephalographs	IEC 60601-2-26:2012;	EN 60601-2-26:2015; GB 9706.226-2021; CAN/CSA C22.2 No. 60601-2-26:14;
Electrocardiographic Monitoring Equipment	IEC 60601-2-27:2011 + COR1:2012 ¹ ;	CAN/CSA C22.2 No. 60601-2-27:2011; EN 60601-2-27:2014; GB 9706.227-2021; ANSI/AAMI/IEC 60601-2-27:2011 ¹ ;
Automated Non-Invasive Sphygmomanometers	IEC 80601-2-30:2009;	EN ISO 80601-2-30:2010; CAN/CSA C22.2 No. 80601-2-30:2010; ANSI/AAMI/IEC 80601-2-30:2009;
Invasive Blood Pressure Monitoring Equipment	IEC 60601-2-34:2011 ¹ ;	EN 60601-2-34:2014; CSA-C22.2 No. 60601-2-34:2012;
Heating Devices Using Blankets, Pads, and Mattresses <i>excluding: Ed.1 Clause 59.2.101 [Spark Ignition Test]</i>	IEC 80601-2-35:2009;	ANSI/AAMI/IEC 80601-2-35:2009; EN ISO 80601-2-35:09 + A11:2011 + AC:2015; CAN/CSA C22.2 No. 80601-2-35:2012;
Ultrasonic Monitoring and Diagnostic Equipment	IEC 60601-2-37:2007;	CSA C22.2 No. 60601-2-37:2008; EN 60601-2-37:2008;
Peritoneal Dialysis Equipment	IEC 60601-2-39:2007;	EN 60601-2-39:2008; +A11:2009; CAN/CSA C22.2 No. 60601-2-39:2009; JIS T 60601-2-39:2013;
Ambulatory Electrocardiographic Monitors	IEC 60601-2-47 ¹ ;	ANSI AAMI IEC 60601-2-47 ¹ ; EN 60601-2-47; CAN/CSA C22.2 No. 60601-2-47; YY 0885:2013;

Multiparameter Patient Monitoring Equipment	IEC 60601-2-49:2011;	EN 60601-2-49:2015; CSA C22.2 No. 60601-2-49:2011;
Safety of Medical Beds	IEC 60601-2-52:2009 ¹ ;	EN 60601-2-52:2010 + AC:2011 + A1:2015; CAN/CSA C22.2 No. 60601-2-52:2011;
Respiratory Gas Monitors	ISO 80601-2-55:2011;	EN 80601-2-55:2011; CAN/CSA C22.2 No. 80601-2-55:2014;
Clinical Thermometers for Body Temperature Measurement	ISO 80601-2-56:2009;	CAN/CSA C22.2 No. 80601-2-56:2012; EN ISO 80601-2-56:2012
Dental Equipment (excluding clauses: 201.10 Protection against excessive radiation hazards)	ISO 80601-2-60:2012;	CAN/CSA C22.2 No. 80601-2-60:2014; EN 80601-2-60:2015; GB 9706.260:2020;
Pulse Oximeter Equipment	ISO 80601-2-61:2011;	EN ISO 80601-2-61:2011; CAN/CSA C22.2 No. 80601-2-61:2014;

IEC 60601-1, Edition 3.1 Series		
Test Technology:	Test Method(s)^{2,3,4}:	National / Regional Variation(s)^{2,3,4}:
Medical Electrical Equipment– Part 1: General Requirements for Basic Safety and Essential Performance (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])	IEC 60601-1:2005 + A1:2012;	ANSI/AAMI ES 60601-1:2005 + A1:2012, C1:2009 + A2:2010; CAN/CSA C22.2 No. 60601-1:14; EN60601-1:2006 + A1:2013; GB 9706-1:2020; JIS T 0601-1:2012 + A1:2014;

IEC 60601-1, Edition 3.1 Collateral Standards

Usability	IEC 60601-1-6:2010 + A1:2013;	CAN/CSA C22.2 No. 60601-1-6:2015; EN 60601-1-6:2010 + A1:2015; NBR IEC 60601-1-6:2011 + A1:2020; YY/T 9706.106:2021;
	IEC 62366;	ANSI/AAMI/IEC 62366; CAN/CSA IEC 62366; EN 62366;
Requirements/Guidelines for Alarms in Medical Electrical Equipment	IEC 60601-1-8:2012;	ANSI AAMI IEC 60601-1-8:2006 + A1:2012; CAN/CSA C22.2 No. 60601-1-8A-08; EN 60601-1-8:2007 + A1:2013 + AC:2014 + A11:2017; YY 9706.108:2021;
Requirements for Physiological Closed-Loop Controllers	IEC 60601-1-10: 2007 + A1:2013;	EN 60601-1-10:2008 + A1:2015; CAN/CSA C22.2 No. 60601-1-10A-09; YY 9706.110:2021;
Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment	IEC 60601-1-11: 2015;	ANSI/AAMI HA 60601-1-11:2015; CAN/CSA C22.2 No. 60601-1-11:2015; EN 60601-1-11:2015; 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 60601-1-12:2014;	ANSI/AAMI/IEC 60601-1-12:2016; CAN/CSA C22.2 No. 60601-1-12:2015; EN 60601-1-12:2015; YY 9706.112:2021;

IEC 60601-1, Edition 3.1 Particular Standards

High Frequency Surgical Equipment (excluding: Ed. 2, 3, 4 Clause 59.104.7; Ed. 5 Clause 201.15.101.7 [Neutral Electrode Adhesion])	IEC 60601-2-2:2017 ¹ ;	ANSI/AAMI/IEC 60601-2-2:2017 ¹ ; CAN/CSA C22.2 No. 60601-2-2:2019; EN 60601-2-2:2018;
Cardiac Defibrillators, Defibrillator-Monitors	IEC 60601-2-4:2010 + A1:2018;	CAN/CSA C22.2 No. 60601-2-4:2012 + A1:2019 EN 60601-2-4:2011 + A1:2019; ANSI/AAMI/IEC 60601-2-4:2010 + A1:2018;
Nerve and Muscle Stimulators	IEC 60601-2-10:2010 + A1:2016 ¹ ;	EN 60601-2-10:2015 + A1:2016; YY 9706.210-2021;
Hemodialysis Equipment	IEC 60601-2-16:2018 ¹ ;	ANSI AAMI IEC 60601-2-16:2018 ¹ ; EN 60601-2-18:2019; CSA C22.2 No. 60601-2-18:2019; GB 9706.216:2021;
Infusion Pumps and Controllers	IEC 60601-2-24:2012;	EN 60601-2-24:2015; CAN/CSA C22.2 No. 60601-2-24:2015;
Automated Non-Invasive Sphygmomanometers	IEC 80601-2-30:2013 ¹ ;	EN 80601-2-30:2010 + A1:2015; ANSI AAMI IEC 80601-2-30:2009 & A1:2013 (R2016) ¹ ;
	IEC 80601-2-30:2018 ¹ ;	ANSI/AAMI/IEC 80601-2-30:2018 ¹ ; CSA C22.2 No. 80601-2-30:2019;
Heating Devices Using Blankets, Pads, and Mattresses	IEC 60601-2-35:2020 ¹ ;	EN 60601-2-35:2021;
	IEC 80601-2-35:2009 + A1:2016;	ANSI/AAMI/IEC 80601-2-35:2009 + A1:2016;
Extracorporeally Induced Lithotripsy	IEC 60601-2-36:2014 ¹ ;	CAN/CSA C22.2 No. 60601-2-36:2016;
		EN 60601-2-36:2015;
Ultrasonic Monitoring and Diagnostic Equipment	IEC 60601-2-37; IEC 60601-2-37:2007 + A1:2015 ¹ ;	CSA C22.2 No. 60601-2-37;
		EN 60601-2-37; GB 9706.237:2020;

Peritoneal Dialysis Equipment	IEC 60601-2-39:2018 ¹ ;	EN 60601-2-39:2019; GB 9706.239:2021; CSA C22.2 No. 60601-2-39:2023;
Electromyographs and Evoked Response Equipment	IEC 60601-2-40:2016;	CAN/CSA C22.2 No. 60601-2-40:2017; EN 60601-2-40:2019; YY 9706.240:2021;
Multiparameter Patient Monitoring Equipment	IEC 80601-2-49:2018;	EN IEC 60601-2-49:2019;
Safety of Medical Beds	IEC 60601-2-52:2009 + A1:2015 ¹ ;	EN 60601-2-52:2010 + A1:2015;
Respiratory Gas Monitors	ISO 80601-2-55:2018 ¹ ;	EN ISO 80601-2-55:2018;
Clinical Thermometers for Body Temperature Measurement	ISO 80601-2-56:2017 ¹ ;	EN ISO 80601-2-56:2017;
	ISO 80601-2-56:2017 + A1:2018;	
Dental Equipment	ISO 80601-2-60:2019;	
Pulse Oximeter Equipment	ISO 80601-2-61:2017 ¹ (Corrected 2018);	EN ISO 80601-2-61:2019;

IEC 60601-1, Edition 3.2 Series		
Test Technology:	Test Method(s)^{2,3,4}:	National / Regional Variation(s)^{2,3,4}:
Medical Electrical Equipment– Part 1: General Requirements for Basic Safety and Essential performance <i>(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])</i>	IEC 60601-1; IEC 60601-1:2005 + A1:2012 + A2:2020 ¹ ;	ANSI/AAMI ES60601-1; ANSI/AAMI ES 60601-1:2005 + A1:2012 + C1:2009 + A2:2010 + AMD2:2021 ¹ ; CAN/CSA C22.2 No. 60601-1; EN 60601-1; JIS T 0601-1;
IEC 60601-1, Edition 3.2 Collateral Standards		
Usability	IEC 60601-1-6; IEC 60601-1-6:2010 + A1:2013 + A2:2020 ¹ ;	CAN/CSA C22.2 No. 60601-1-6; EN 60601-1-6; NBR IEC 60601-1-6;

Usability (<i>continued</i>)	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;
Requirements/Guidelines for Alarms in Medical Electrical Equipment	IEC 60601-1-8; IEC 60601-1-8:2006 + A1:2012 + A2:2020 ¹ ;	ANSI/AAMI/IEC 60601-1-8; ANSI/AAMI/IEC 60601-1-8:2006 + A1:2012 + A2:2021 ¹ ; CAN/CSA C22 No. 60601-1-8; EN 60601-1-8;
Requirements for Physiological Closed-Loop Controllers	IEC 60601-1-10; IEC 60601-1-10:2007 + A1:2013 + A2:2020 ¹ ;	CAN/CSA C22.2 No. 60601-1-10; EN 60601-1-10;
Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment	IEC 60601-1-11; IEC 60601-1-11:2015 + A1:2020 ¹ ;	ANSI AAMI HA60601-1-11; ANSI/AAMI HA 60601-1-11:2015 + AMD1:2021 ¹ ; CAN/CSA C22.2 No. 60601-1-11; EN 60601-1-11; NBR IEC 60601-1-11;
Medical Electrical Equipment and Medical Electrical Systems used in the Emergency Medical Services Environment	IEC 60601-1-12; IEC 60601-1-12:2014 + A1:2020 ¹ ;	ANSI/AAMI/IEC 60601-1-12; ANSI/AAMI/IEC 60601-1-12:2016 + A1:2021 ¹ ; CAN/CSA C22.2 No. 60601-1-12; EN 60601-1-12;
<u>IEC 60601-1, Edition 3.2 Particular Standards</u>		
High Frequency Surgical Equipment (<i>excluding:</i> <i>Ed. 2, 3, 4 Clause 59.104.7;</i> <i>Ed. 5 Clause 201.15.101.7</i> <i>[Neutral Electrode Adhesion]</i>)	IEC 60601-2-2;	
Cardiac Defibrillators, Defibrillator-Monitors	IEC 60601-2-4;	
Nerve and Muscle Stimulators	IEC 60601-2-10;	
Hemodialysis Equipment	IEC 60601-2-16;	
Endoscopic Equipment	IEC 60601-2-18;	

Infusion Pumps and Controllers	IEC 60601-2-24;	
Electroencephalographs	IEC 80601-2-26;	
Automated Non-Invasive Sphygmomanometers	IEC 80601-2-30;	
Heating Devices Using Blankets, Pads, and Mattresses <i>(excluding: Ed.1 Clause 59.2.101 [Spark Ignition Test])</i>	IEC 60601-2-35;	
Extracorporeally Induced Lithotripsy	IEC 60601-2-36;	
Ultrasonic Monitoring and Diagnostic Equipment	IEC 60601-2-37;	
Peritoneal Dialysis Equipment	IEC 60601-2-39;	
Electromyographs and Evoked Response Equipment	IEC 60601-2-40;	
Multiparameter Patient Monitoring Equipment	IEC 80601-2-49;	
Respiratory Gas Monitors	ISO 80601-2-55;	
Clinical Thermometers for Body Temperature Measurement	ISO 80601-2-56;	
Dental Equipment <i>(excluding clauses: 201.10 Protection against excessive radiation hazards)</i>	ISO 80601-2-60;	
Pulse Oximeter Equipment	ISO 80601-2-61;	

Miscellaneous Standards		
<u>Test Technology:</u>	<u>Test Method(s) ^{2, 3, 4:}</u>	<u>National / Regional Variation(s) ^{2, 3, 4:}</u>
Software Life-Cycle Processes	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;

Medical Vehicles and their Equipment	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)	-
Degrees of Protection Provided by Enclosures	IEC 60529; IEC 60529:1998 + A1:1999 + A2:2013; (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)	EN 60529; EN 60529:1991 + A1:2000 + A2:2013 + AC:2016; CAN/CSA C22.2 No. 60529; CAN/CSA C22.2 No. 60529:2005;

IEC 61010-1 Series		
<u>Test Technology:</u>	<u>Test Method(s) ^{2,3,4:}</u>	<u>National / Regional Variation(s) ^{2,3,4:}</u>
Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory use – Part 1: General Requirements (excluding subclause 16.2 category III & IV);	IEC 61010-1; IEC 61010-1:2010 + A1:2016 + COR1:2019 ¹ ; IEC 61010-1:2001; IEC 61010-1:2010;	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 61010-1:2012 + C1:2019 ¹ ; UL 61010-1:2004;
Equipment for Heating of Materials	IEC 61010-2-010 ¹ ; 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;

<p>Laboratory Centrifuges <i>(excluding 7.3.101 & 7.6)</i></p>	<p>IEC 61010-2-020; IEC 61010-2-020:2006;</p>	<p>EN 61010-2-020; EN 61010-2-020:2006;</p> <p>CAN/CSA C22.2 No. 61010-2-020; CAN/CSA C22.2 No. 61010-2-020:2009;</p> <p>UL 61010-2-020;</p>
<p>Equipment for Mixing and Stirring</p>	<p>IEC 61010-2-051; IEC 61010-2-051:2015; IEC 61010-2-051:2003;</p>	<p>EN 61010-2-051; EN 61010-2-051:2015; EN 61010-2-051:2003;</p> <p>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;</p> <p>UL 61010-2-051; UL 61010-2-051:2015; UL 61010-2-051:2003;</p>
<p>Automatic & Semi-Automatic Laboratory Equipment for Analysis</p>	<p>IEC 61010-2-081; IEC 61010-2-081:2015; IEC 61010-2-081:2001 + A1:2003;</p>	<p>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;</p> <p>EN 61010-2-081; EN 61010-2-081:2015; EN 61010-2-081:2002 + A1:2003;</p> <p>UL 61010-2-081; UL 61010-2-081:2015;</p>
<p>IVD Medical Equipment</p>	<p>IEC 61010-2-101; IEC 61010-2-101:2015; IEC 61010-2-101:2002;</p>	<p>EN 61010-2-101; EN 61010-2-101:2017; EN 61010-2-101:2002;</p> <p>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;</p> <p>UL 61010-2-101; UL 61010-2-101:2015;</p>

EMC Test Standards		
Test Technology:	Test Method(s) ^{2, 3, 4:}	National / Regional Variation(s) ^{2, 3, 4:}
Electromagnetic Compatibility *(excluding Radiated Emissions)	IEC 60601-1-2:2014;	EN 60601-1-2:2015; YY 9706.102:2021; ANSI/AAMI/IEC 60601-1-2:2014; CAN/CSA C22.2 No. 60601-1-2:2016;
Medical electrical equipment – Electromagnetic disturbances *(excluding Radiated Emissions)	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 ^{1*} ; EN 60601-1-2*; EN 60601-1-2:2014*;
Conducted Emissions (excluding Radiated Emissions)	CISPR 11:2015 + A1:2016 + A2:2019;	
Harmonic Distortion	IEC 61000-3-2:2014	
Voltage changes, fluctuations & flicker	IEC 61000-3-3:2013	
ESD Immunity	IEC 61000-4-2:2008;	
Immunity to radiated, radio-frequency electromagnetic fields	IEC 61000-4-3:2020	
EFT / Burst Immunity	IEC 61000-4-4:2012;	
Surge Immunity	IEC 61000-4-5:2014 + A1:2017;	
Conducted Immunity	IEC 61000-4-6:2013;	
Power Frequency Magnetic Field Immunity	IEC 61000-4-8:2009;	
Voltage Dips & Interrupts	IEC 61000-4-11:2004 + A1:2017;	
Immunity to radiated fields in close proximity	IEC 61000-4-39:2017	
Laboratory Equipment Electromagnetic Compatibility (excluding Radiated Emissions)	IEC 61326-1:2020	
Laboratory Equipment Electromagnetic Compatibility (IVD Equipment) (excluding Radiated Emissions)	IEC 61326-2-6:2020	

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

<u>Standards</u>	<u>Recognition Number</u>
ANSI AAMI ES60601-1	19-46
ANSI AAMI HA60601-1-11	19-47
IEC 60601-1-2*	19-36
ANSI/AAMI/IEC 60601-1-2*	19-36
IEC 60601-1-6	5-132
IEC 60601-1-8	5-131
ANSI AAMI IEC 60601-1-8	5-131
IEC 60601-1-10	19-37
IEC 60601-1-11	19-38
IEC 60601-1-12	19-39
ANSI/AAMI/IEC 60601-1-12	19-39
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
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
ISO 80601-2-55	1-140
ISO 80601-2-56	6-421
ISO 80601-2-61	1-139
IEC 60601-1	19-49
IEC 60601-2-39	9-149
IEC 60601-2-52	6-489
IEC 60601-2-35	6-483
IEC 80601-2-60	4-262

*(Excluding Radiated Emissions).

*Limited to: ISM, Powerline Harmonics, Voltage Fluctuations and Flicker, Radiated Immunity, Conducted Immunity, Radiated Field in Close Proximity, 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.

¹These 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.

²Broadband 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.

⁴ 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 test method, per Annex A, Part C of A2LA's *RI01 - General Requirements: Accreditation of Conformity Assessment Bodies*.



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 the requirements of any additional program requirements in the Electrical field. 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 28th day of January, 2025.

A blue ink signature of Mr. Trace McInturff.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 3392.01
Valid to January 31, 2027

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