SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ELEMENT MATERIALS TECHNOLOGY – HULL
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ELECTRICAL

Valid To: June 30, 2027 Certificate Number: 7493.01

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 at the location listed above to perform the following electrical tests:

Test Technology:	**Test Method(s) [2]:**
Electrical Product Safety *IEC 60601-1 Exclusions:* *8.8.4.2 (environmental stress)* *8.11.1e (supply mains switch)* *9.6.3 (hand transmitted vibration)* *10.1 (x-rays)* *10.4 (laser and LED emissions)* *10.5 (Other visible electromagnetic radiation)* *10.6 (Infra-red radiation)* *10.7 (Ultra violet radiation)* *11.6.7 (sterilization)* *11.7 (biocompatibility)* *12.4.5 (diagnostic or therapeutic radiation)* *15.4.3.4 (lithium batteries)* *Annex L (insulated winding wire)* *ANSI/AAMI exclusion:* *6.6 X-ray systems* *7.2.1 1 X-ray systems* *8.6.1 X-ray systems* *8.11 X-ray systems*	IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION; ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]; CAN/CSA-C22.2 NO. 60601-1:14/A2:22 (R2022); IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION; ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021]; CSA CAN/CSA-C22.2 No. 60601-1-8:08 - Medical electrical equipment - Part 1-8; IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION; IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION; CSA CAN/CSA-C22.2 No. 60601-1-6:11 - Medical electrical equipment — Part 1-6: Edition 3.2; IEC 62366-1:2020 1.1 Edition; IEC 62304:2015 1.1 Edition; IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION; ANSI AAMI IEC 60601-1-12:2016 [Including AMD 1:2021]; CSA CAN/CSA-C22.2 No. 60601-1-12:15 + A1:21 Medical electrical equipment — Part 1-12; IEC 60601-1-11:2015; IEC 60601-2-24:2012

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Test Technology:	**Test Method(s) [2]:**
EMC – Medical	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION; ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]; ISO 14708-4 Ed 2.0 (2022-02) – (only *Section 27.103 and Section 27.104)*; ISO 14708-4 Ed 1.0 (2008-11-15) – (only *Section 27.103 and Section 27.104)*; IEC 80601-2-49:2018 Ed.1.0 (*Only Section 202.8.102*); AIM Standard 7351731 Rev. 3.00 2021-06-04 (*Only Annex A, B, C and D devices only*)
EMC – Commercial Unintentional Radiated & Conducted Emissions	CISPR 11:2015 +A1:2016 & A2:2019; CISPR 11; CISPR 32:2015; CISPR 32
EMC – Commercial Harmonics & Flicker	EN/IEC 61000-3-2:2005 +A1:2008 & A2:2009; EN/IEC 61000-3-2; EN/IEC 61000-3-3:2013; EN/IEC 61000-3-3
EMC – Commercial Immunity: ESD	EN/IEC 61000-4-2:2008; EN/IEC 61000-4-2
EMC – Commercial Immunity: Radiated Immunity	EN/IEC 61000-4-3:2006 +A1:2007 & A2:2010; EN/IEC 61000-4-3
EMC – Commercial Immunity: EFT	EN/IEC 61000-4-4:2012; EN/IEC 61000-4-4
EMC – Commercial Immunity: Surge	EN/IEC 61000-4-5:2005; EN/IEC 61000-4-5
EMC – Commercial Immunity: Conducted Immunity	EN/IEC 61000-4-6:2013; EN/IEC 61000-4-6
EMC – Commercial Immunity: Power Frequency Magnetic Field	EN/IEC 61000-4-8:2009; EN/IEC 61000-4-8
EMC – Commercial Immunity: Pulse Magnetic Fields	EN/IEC 61000-4-9:2016; EN/IEC 61000-4-9
EMC – Commercial Immunity: Voltage dips, short interruptions, and voltage variation	EN/IEC 61000-4-11:2004; EN/IEC 61000-4-11
EMC – Commercial Immunity: Radiated Fields in Close Proximity	EN/IEC 61000-4-39:2017; EN/IEC 61000-4-39
EMC – Automotive	CISPR 25 Ed 4.0:2016; CISPR 25

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Test Technology:	**Test Method(s) [2]:**
EMC – Railway	EN 50121-3-2:2016+A1:2019; EN 50121-3-2

On the following types of products:
Aerospace Equipment/Systems, Automotive Equipment/Sub-assemblies, Computers and Peripherals, Domestic Appliances, Electrical/Electronic Components, Electrical/Electronic Products, Electrically Driven Wheelchairs, Electro-Mechanical Devices, Instruments, Indicating/Recording, IT Equipment, Laboratory Equipment/Systems, Lamps, Electrical Luminaries, Marine Equipment, Test & Measuring Equipment, Medical Equipment/Systems, Micro Electronic Circuits and Components
Military Equipment/Systems, Office Equipment: Electrical, Power Supplies: Electrical, Rail Equipment/Systems, Safety Appliances/Equipment, Security Devices and Alarms, Telecoms 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* [3]:

Standards	**ASCA Doc Number**
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	19-49
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	19-46
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION; ANSI AAMI IEC 60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	5-131
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	19-38
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	5-132
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION; ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	19-36
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION; ANSI AAMI IEC 60601-1-12:2016 [Including AMD 1:2021]	19-39

[1] 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.

[2] 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 R101 - *General Requirements: Accreditation of Conformity Assessment Bodies.*

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[3] 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 FDA.gov.

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