SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

CRITERION, A BIOTEX, INC. SERVICE
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ELECTRICAL

Valid to: December 31, 2025 Certificate Number: 6538.01

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, EMC, and Package Validation tests:

Test Technology:	**Test Method(s) [2,3]:**
Product Safety	IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION[4]; ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 CONSOLIDATED VERSION [Including AMD2:2021][4]; IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION; IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION[4]; IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION[4]; ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021][4]; IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION[4]; IEC 60601-2-18: Edition 3.0 2009-08; IEC 60601-2-22 Edition 3.1 2012-10; IEC 60601-2-24 Edition 2.0 2012-10; IEC 80601-2-56 Second edition 2017-03; IEC 60695-10-2 Edition 3.0 2014-02; ISO 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION; IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION

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Test Technology:	**Test Method(s) [2,3]:**
EMC	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION [Including only Clause 4 – General Requirements, Clause 5 - ME Equipment and ME Systems Identification, Marking and Documents]

MECHANICAL

Test Technology:	**Test Method(s) [2]:**
Conditioning	ASTM D4332; ASTM D685; ASTM E171/E171M; ASTM F2825
Seal Strength of Flexible Materials	ASTM F1886/F1886M; ASTM F88/F88M
Accelerated Aging	ASTM F1980
Package Integrity	ASTM F1929; ASTM F2096

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	**ASCA Doc Number**
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Including AMD2:2021]	19-46
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	5-132
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	5-131
ANSI AAMI HA60601-1-11:2015 [Including AMD1:2021]	19-47
IEC 60601-1-12 Edition 1.1 2020-07 CONSOLIDATED VERSION	19-39
IEC 60601-2-18: Edition 3.0 2009-08	9-114
IEC 60601-2-22 Edition 3.1 2012-10	12-268
IEC 80601-2-56 Second edition 2017-03	6-421

[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 FDA.gov.

[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 measurement method, per part C., Section 1 of A2LA *R101 - General Requirements- Accreditation of ISO-IEC 17025 Laboratories*.

[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] Exclusion Table:

Standard:	**Clause:**	**Test:**
IEC 60601-1; ANSI AAMI ES 60601-1	8.5.5.1	Defibrillation Protection
	8.5.5.2	Energy Reduction Test
	8.8.4.2	Resistance to Environmental Stress (Natural Rubber Latex Test Only)
	9.6.2.1	Audible Acoustic Energy
	9.6.3	Hand-transmitted Vibration
	10.1	X-radiation
	11.2.2.1	Risk of Fire in an Oxygen Rich Environment
	11.2.3	Single Fault Conditions Related to Oxygen Rich Environments in Conjunction with ME Equipment and ME Systems
	11.6.5	Ingress of Water or Particulate Matter
	15.4.7.3	Entry of Liquids
	Annex G	Protection Against Hazards of Ignition of Flammable Anesthetic Mixtures
	Annex L	Insulated Winding Wires for use Without Interleaved Insulation
IEC 60601-1-8	6.3.3.2	Volume of Auditory Alarm Signals and Information Signals
IEC 60601-1-11; ANSI AAMI HA60601-1-11	4.2.3.1	Continuous Operating Conditions (Pressure Only)
	4.2.3.2	Environmental shock to Transit-Operable ME Equipment
	10.1.2	Requirements for Mechanical Strength for NON-Transit-Operable ME Equipment / Shock and Vibration
	10.1.3	Requirements for Mechanical Strength for Transit-Operable ME Equipment / Shock, Vibration and Free Fall
	10.1.2	Requirements for Mechanical Strength for Fixed or Permanently Installed ME Equipment Intended for use in a Road Ambulance/ Shock and Vibration
	10.1.3	Requirements for Mechanical Strength for Transportable ME Equipment/ Shock, Vibration and Free Fall
IEC 60601-1-12	4.2.2.1	Continuous Operating Conditions (Pressure Only)

	10.1.2	Requirements for mechanical strength for fixed or permanently installed ME Equipment intended for use in a road ambulance / Shock and Vibration
	10.1.3	Requirements for mechanical strength for Transportable ME Equipment / Shock, Vibration and Free Fall
	10.1.4	Requirements for mechanical strength for ME Equipment intended for airborne use / Shock and Vibration

Accredited Laboratory

A2LA has accredited

CRITERION, A BIOTEX, INC. SERVICE

Houston, TX

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 23rd day of October 2023.

Mr. Trace McInturff, Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6538.01
Valid to December 31, 2025

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