SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

TUV RHEINLAND TAIWAN, LTD. TAOYUAN TESTING LABORATORIES
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ELECTRICAL

Valid To: January 31, 2024 Certificate Number: 6344.01

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 requirements[1]) accreditation is granted to this laboratory to perform the following product safety tests:

Test Technology:	**Test Method(s)[2,3,4]:**
Product Safety, Medical Equipment	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) *(Excluding 11.4 and 11.5)*[5]; IEC 60601-1 (*Excluding AP, APG and flammable apparatus*); ANSI/UL/CSA 60601-1 (*Excluding AP, APG and flammable apparatus*); IEC 60601-1-4; IEC 60601-1-6 Edition 3.1 2013-10; IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION; IEC 60601-1-8 Edition 2.1 2012-11; IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION; IEC 60601-1-9; IEC 60601-1-10 Edition 1.1 2013-11; IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION; IEC 60601-1-11 Edition 2.0 2015-01; IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION; IEC 60601-2-10 Edition 2.1 2016-04; IEC 60601-2-18: Edition 3.0 2009-08; IEC 60601-2-22 Edition 3.1 2012-10; IEC 60601-2-22 Edition 4.0 2019-11; IEC 60601-2-25 Edition 2.0 2011-10 (*Excluding Protection against hazardous output; Clause 201.12.4*); IEC 60601-2-26;

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Test Technology:	**Test Method(s)[2,3,4]:**
Product Safety, Medical Equipment (*continued*)	IEC 60601-2-27 Edition 3.0 2011-03; ANSI AAMI IEC 60601-2-27:2011(R)2016; IEC 60601-2-30; IEC 60601-2-35 (E*xcluding Annex BB*); IEC 60601-2-37 Edition 2.1 2015; IEC 60601-2-41 (*Excluding Characteristics of illumination*); IEC 60601-2-46; IEC 60601-2-47 Edition 2.0 2012-02; ANSI AAMI IEC 60601-2-47:2012/(R)2016; IEC 60601-2-49; IEC 60601-2-52 Edition 1.0 2009-12; IEC 60601-2-57 Edition 1.0 2011-01; IEC 61010-1 Edition 3.1 2017-01; IEC 80601-2-30; 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; ANSI AAMI IEC 80601-2-35:2009/A1:2016; ANSI AAMI IEC 80601-2-35:2009/A1:2016; IEC 80601-2-35 *(Excluding 201.13.1.2.101.2);* ISO 80601-2-56 Second edition 2017-03; IEC 80601-2-60 Edition 2.0 2019-06; ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02); UL/CSA 61010-1; IEC 61010-2-101

On the following products or types of products:
Medical Electrical 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]

Standards	**Document ID**
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) *(Excluding 11.4 and 11.5)*	19-4
IEC 60601-1-6 Edition 3.1 2013-10	5-89
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	5-132
IEC 60601-1-8 Edition 2.1 2012-11	5-76
IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION	5-131
IEC 60601-1-10 Edition 1.1 2013-11	19-9

IEC 60601-1-10 Edition 1.2 2020-07 CONSOLIDATED VERSION	19-37
IEC 60601-1-11 Edition 2.0 2015-01	19-14
IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION	19-38
IEC 60601-2-10 Edition 2.1 2016-04	17-16
IEC 60601-2-18: Edition 3.0 2009-08	9-114
IEC 60601-2-22 Edition 3.1 2012-10	12-268
IEC 60601-2-25 Edition 2.0 2011-10 (*Excluding Protection against hazardous output; Clause 201.12.4*)	3-105
IEC 60601-2-27 Edition 3.0 2011-03	3-126
IEC 60601-2-47 Edition 2.0 2012-02	3-155
IEC 60601-2-52 Edition 1.0 2009-12	6-321
IEC 60601-2-57 Edition 1.0 2011-01	12-242
IEC 80601-2-30: Edition 2.0 2018-03	3-123
IEC 80601-2-35 Edition 2.1 2016-04 *(Excluding 201.13.1.2.101.2)*	6-390
ISO 80601-2-56 Second edition 2017-03	6-421
IEC 80601-2-60 Edition 2.0 2019-06	4-262
ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)	1-139

[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, revision or edition of a test method standard is not identified on the scope of accreditation, the laboratory is required to be using the current version within one year of the date of publication, per part C., Section 1 of A2LA *R101 - General Requirements - Accreditation of ISO-IEC 17025 Laboratories*.

[3] This laboratory meets performs field testing activities for these tests.

[4] 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.

[5] Note: Exclusions listed for ANSI AAMI ES60601-1 also apply to other collaterals and particulars in the 60601/80601 family of standards except where otherwise stated.

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Accredited Laboratory

A2LA has accredited

TÜV RHEINLAND TAIWAN, LTD. TAOYUAN TESTING LABORATORIES

Taoyuan City, Taiwan (R.O.C.)

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 A2LA 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 19th day of May 2022.

Vice President, Accreditation Services
For the Accreditation Council
Certificate Number 6344.01
Valid to January 31, 2024

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