

Certificate



TÜVRheinland®
Precisely Right.

Qualified
Laboratory

TUV Rheinland of North America Inc.
hereby qualifies that
Medical Equipment Compliance Associates, LLC
5060 W Ashland Way, Franklin, WI 53132, USA

Product Safety Testing Laboratory

has been designated as a Qualified Laboratory for safety testing of:

Standards: *See Appendix 1*

Under the **Partner Test Laboratory Program**.

An audit was performed against the requirements of MS-0004326.

A handwritten signature in black ink that reads "Kenneth Kamer".

Kenneth Kamer
Program Manager

Valid until 13th May, 2021

Certificate



Appendix 1 – Scope of Accreditation

Medical Equipment Compliance Associates, LLC

Base Standards (with Issue Sheets, Corrigendum, and Amendments):

IEC 60601-1, 2nd Ed.

IEC 60601-1, 3rd Ed

Including all National and Group Differences

CAN/CSA-C22.2 No. 601.1 and No. 60601-1

UL 2601, UL 60601-1,

EN 60601-1,

ANSI/AAMI ES 60601-1

Collateral Standards (with Issue Sheets, Corrigendum, and Amendments):

60601-1-1, -1-4, -1-6, -1-8, -1-10, -1-11, -1-12

Including all National and Group Differences (Canada, US, EU)

Particular Standards (with Issue Sheets, Corrigendum, and Amendments):

60601-2-2, -2-4, -2-5, -2-10, -2-16, -2-18, -2-24, -2-25, -2-26, -2-27, -2-30

-2-32, -2-33, -2-34, -2-35, -2-36, -2-38, -2-39 -2-40, -2-41, -2-46, -2-47, -2-49,
-2-51, -2-52

Including all National and Group Differences (Canada, US, EU)

Particular Standards (with Issue Sheets, Corrigendum, and Amendments):

80601-2-30, -2-35, -2-55, -2-56, -2-60, -2-61

Including all National and Group Differences (Canada, US, EU)

Particular Standards (with Issue Sheets, Corrigendum, and Amendments):

ISO 9919

Including all National and Group Differences (Canada, US, EU)

Related Standards (with Issue Sheets, Corrigendum, and Amendments):

IEC 60529, ISO 14971, IEC 62366, IEC 62304

Including all National and Group Differences (Canada, US, EU)