

# Certificate



**TÜVRheinland®**  
Precisely Right.

Qualified  
Laboratory

TUV Rheinland of North America Inc.  
hereby qualifies that

**Medical Equipment Compliance  
Associates, LLC (MECA)**

140 East Rawson Ave, Suite 301  
Oak Creek, WI 53154  
USA

**Product Testing Laboratory**

has been designated as a Qualified Laboratory for testing of:

**See Appendix 1 for scope.**

Under the **Partner Test Laboratory Program.**

An evaluation was performed against the requirements of  
MS-0004326. Report No. US22DDHB 001

A handwritten signature in blue ink, appearing to read "Chan Wang".

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Chan Wang  
PTL Program Manager

**Valid until 18th of August 2024**

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## Appendix 1 – Scope of Qualification

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

IEC 60601-1, 2<sup>nd</sup> Ed  
IEC 60601-1, 3<sup>rd</sup> Ed, including all amendments and corrigendum  
Including all national and group differences  
CAN/CSA C22.2 No. 601-1 and No. 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, -0  
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)