eurofins | E&E Classification Record

Listing#: E115006
Report #: 132492
Original Certification Date: December 18, 2025

This Certification is issued to:
Palliare Ltd.
Galway Business Park
Dangan, Galway H91 P2DK, Ireland

Stating that the product(s):
Insufflator,
EVA15, EVA5, ERBE ECO2 Plus

Product Rating(s):
EVA 15, EVA 5, and ERBE ECO2: 100-240VAC, 50/60Hz, 110VA

Achieved Certification to the following standard(s):
AAMI ES60601-1:2005/(R)2012/A2:2021, Third Edition: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
CAN/CSA-C22.2 NO. 60601-1:14 + A2:22, Third Edition: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010 + A1:2013 + A2:2020, Third Edition: Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
CAN/CSA-C22.2 No. 60601-1-6:11/A2:2021, Third Edition: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8:2006 + A1:2012 + A2:2020, Second Edition: Medical Electrical Equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
CAN/CSA C22.2 No. 60601-1-8-08 (R2018), Second Edition: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Hon Keung Ip
Certification Officer,
Eurofins Electrical and Electronic Testing North America, Inc.

All changes proposed in the previously identified product that affects the above information must be submitted to Eurofins for evaluation prior to implementation to assure continued MET Certification status. The covered product(s) shall be subject to follow-up inspections to ensure that the Certified product(s) are identical to the product sample evaluated by Eurofins E&E NA and that all responsibilities are being fulfilled as specified in the Applicants' Responsibility section of the Certification Report. The Applicant named above has been authorized Eurofins E&E NA to represent the product(s) listed in this record as "MET Certified" and to mark this/these product(s) according to the terms and conditions of the Eurofins E&E NA Applicant Contract, Listing Reports, and the

applicable agreements. Only the product(s) bearing the MET Mark and under a follow-up service are considered to be included in this Certification program. This certification has been granted under a System 3 program as defined in ISO/IEC 17067.

Eurofins E&E North America, Inc. is accredited by OSHA and the Standards Council of Canada.