Certificate of Registration of Quality Management System to ISO 13485:2016

Australia - Therapeutic Goods (Medical Devices) Regulations, 2002,
☒ Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure
Brazil - RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada - Medical Devices Regulations – Part 1- SOR 98/282
Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)
United States- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,
☒ 21 CFR 820 - Quality Management System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

Palliare Ltd
Galway Business Park
Dangan, Galway, H91 P2 DK
Ireland

Facility ID: F008581

The quality management system has been audited against stated criteria above and found to conform to the criteria for the scope listed below:

The design, manufacture, and distribution of insufflation and surgical smoke and gas evacuation systems, used for open, laparoscopic and endoscopic surgery and associated sterile and non-sterile tube sets.

Pamela Burdette Miller
Approved by:
Pamela Burdette Miller
Certification Manager

Certificate Number: MP19.8447 / Rev 1
Certification Granted: 2026/03/06
Effective Date: 2026/03/06
Expiry Date: 2029/03/05

MDSAP
Medical Device Single Audit Program

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All valid certifications are listed on NSAI's website – www.nsaiinc.com and may be verified under "Approved Client Listing"