EU Quality Management System Certificate

Medical Device Regulation 2017/745

The National Standards Authority of Ireland as a duly designated Notified Body, (0050) for the purposes of the European Union under MDR 2017/745

APPROVES THE QUALITY MANAGEMENT SYSTEM APPLIED BY

Palliare Ltd

Galway Business Park
Dangan
Galway H91 P2DK
Ireland

Manufacturer SRN:	IE-MF-000000095
Device Group:	Insufflator and Smoke Evacuation System and Accessories
Risk Class:	IIb – EVA15 Insufflator IIa – LAP-200, LAP-300, END-200M and END-200S Tubesets
Intended Purpose	The EVA15 Insufflator with the LAP-200, LAP-300, END-200M and END-200S Tubesets is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend the abdomen, rectum, colon, esophagus, stomach or thoracic cavity with up to 15 mmHg pressure, by filling it with gas and to evacuate surgical smoke.

Conclusion: Quality Management System complies with the requirements of Annex IX, Chapter I & III of MDR 2017/745. The use of the NSAI Notified Body Identification Number 0050 in conjunction with CE Marking of Conformance for this product is hereby authorised.

Product Certificate Number:	745.027	Re-Issued Date:	-
First Issue Date:	06 July 2023	Expiry Date:	05 July 2028
Site Certificate Number:	MD19.8447		

Signed:

Approved by:
Dr Majella Geraghty
European Medical Device Operations Manager

Approved by:
Seán O'Callaghan
European Medical Device Operations Manager

CONDITIONS AND LIMITATIONS: this certificate remains valid on condition that the Approved Quality Management System is maintained in an adequate and efficacious manner in line with the requirements of the Regulation. This certificate is based on examination of identified relevant CS, harmonised standards, test reports and audit reports maintained on file with NSAI. Information on examination and tests as per Annex XII, section 10, is available on request. Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI. Substantial Changes to the QMS or the product range covered must receive further approval from NSAI.

The validity of this certificate depends on conditions and/or is limited to the following:

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

Appendix I			
Certificate History			
Product Certificate Number	Date of Issue	Type of Change *[supplemented, modified or re-issued]*	Details of Change
n/a	n/a	n/a	n/a