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

Medivators

14605 28th Avenue North
Minneapolis
MN 55447, USA

Authorised Representative Name and Address:	Cantel Medical (Italy) S.r.l. Via Laurentina 169 00071 Pomezia (RM), Italy
Authorised Representative SRN:	IT-AR-000010078
Device Group:	Rapicide PA High Level Disinfectant
Risk Class:	IIb
Intended Purpose	RAPICIDE™ PA High-Level Disinfectant is a two-part liquid disinfection system intended to be used with validated Automated Endoscope Reprocessing systems to provide high-level disinfection of non-critical and semi-critical precleaned, immersible, reusable heat sensitive devices including bronchoscopes and gastrointestinal endoscopes and their accessories. RAPICIDE™ PA High-Level Disinfectant is designed for use by trained personnel who reprocess endoscopes and their accessories in healthcare or healthcare support facilities.

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:	745.055	Re-Issued Date:	n/a
First Issue Date:	23 December 2022	Expiry Date:	22 December 2027
Site Certificate Number:	MD19.2990		

Signed:

Approved by:
Lisa Donlon
European Medical Device Operations Manager

Approved by:
Dr Majella Geraghty
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