EU Medical Device Directive
93/42/EEC as Amended by 2007/47/EC
Declaration of Conformity

Product(s): Advantage/MDS Series Automatic Endoscope Reprocessing System

Manufacturer:	Medivators Inc.	EU Representative:	Cantel Medical Italy
Address:	14605 28th Avenue North Minneapolis MN 55447 USA	Address:	Cantel Medical (Italy) S.r.l., Via Laurentina,169, 00040 Pomezia (RM), Italy

Model(s): **ADV-2001, ADV-2002, ADV-2005, ADV-2006, ADV-4001, ADV-4002**
Other: previously Advantage Single Shot (SS), MDS US SS, MDS 10L SS

Assessment of Product Based Upon:

Quality System Certification — ISO 13485 Certificate No: MD19.2990
Issued By: NSAI (0050)

CE Certification — CE Certificate No: 252.380
Conformity Assessment Route: Annex II
Issued By: NSAI (0050)

Essential Requirements Checklist — Prepared by: Regulatory Affairs

Technical File — Prepared by: Regulatory Affairs

Product Classification: Product classification based on the requirements of MDD Annex IX and EU Guidelines for Classification of Medical Devices MEDDEV 2.4.

☐	Class I	☐	Class IIa
☒	Class IIb	☐	Class III

Based on a review of the above documents, we hereby declare that the above product complies with the requirements of the EC Directive 93/42/EEC as amended by 2007/47/EC.

Approvals:

Ann Moua
Regulatory Affairs Specialist
Cantel
18 March 2020

Distribution:

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