By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 832608 R000

Manufacturer: Medivators Inc.

Address:
14605 28th Avenue North
Minneapolis
Minnesota
55447
USA

Single Registration Number: US-MF-000043421

EU Authorised Representative: Cantel Medical (Italy) S.r.l.

Address:
Via Laurentina 169
00071 Pomezia
Italy

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-09-23**

Current Issue Date: **2025-09-23**

Starting Validity Date: **2025-09-26**

Expiry Date: **2027-12-22**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Rapicide PA High Level Disinfectant	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 noncritical 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.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30497421	Issued – Voluntary change of Notified Body.

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