Quality System Approval Certificate
Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Medivators Inc.

14605 28th Ave N
Minneapolis
MN 55447
USA

to the Product Family

Endoscopic Irrigation Pump and Insufflator

GMDN Code: 33579, 41617

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

*The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product family is hereby authorised.*

Registration Number:	**252.878**
Original Approval:	**14 November 2013**
Last Amended on:	**22 July 2020**
Remains valid until:	**26 May 2024**

Signed:

C Dore Geraghty

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Elaine Darcy

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

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

By Royal Charter

Supplementary information to AR120 832501 - Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to: Medivators Inc.
14605 28th Ave N
Minneapolis
MN 55447
USA

Date: 24 September 2025

Changes Approved:

Date	Reference Number	Action
24 September 2025	30496728	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Endoscopic Irrigation Pump and Insufflator. Original NB Certificate Number: 252.878. Change in legal manufacturer address.

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Inspiring trust for a more resilient world.

24 September 2025

Medivators Inc.
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USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD certificates from 26th May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Original certificate number	BSI reference number	Directive and Annex	Reference Number	Changes approved
252.878	AR120 832501	93/42/EEC Annex II excluding Section 4	30496728	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Endoscopic Irrigation Pump and Insufflator. Original NB Certificate Number: 252.878. Change in legal manufacturer address.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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