



NSAI

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:

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

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.

Supplementary information to AR120 832501

Non-significant changes approved on the 26th May 2021 under the Transitional Provisions of MDN Article 1.21.3

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

Date: 04 February 2026

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.
04 February 2026	30629026	Change of Authorised Representative to STERIS Ireland Limited

04 February 2026

Medivators Inc.
3150 Pollok Drive
Conroe
Texas
77303
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/AIMDD 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	30629026	Change of Authorised Representative to STERIS Ireland Limited

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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Manufacturer's Declaration

In relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Medivators Inc.
Manufacturer address and contact details	3150 Pollok Dr. Conroe, Texas 77303, USA Coletta Cohara Director Quality & Regulatory Compliance coletta_cohara@steris.com
Single Registration Number (SRN) (if available)	US-MF-000043422

Authorised Representative name (if applicable)	STERIS Ireland Limited
Authorised Representative address and contact details	IDA Business and Technology Park Tullamore, Co. Offaly R35 X865, Ireland
Single Registration Number (SRN) (if available)	IE-AR-000010065

Notified body name (if applicable)	BSI <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	2797 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	AR120 832501 <input type="checkbox"/> See attached schedule

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Manufacturer's Declaration

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 <input type="checkbox"/> See attached schedule
End date of extended validity/transition period	2028-12-31 <input type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*
 - Expired *before* 20 March 2023:
 - Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device
 - A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)
 - A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)
 - Expired/expires *after* 20 March 2023:
 - A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Manufacturer's Declaration

- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**


- *Choose one applicable statement:*

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name Medivators Inc.
Location & Date 3150 Pollok Drive, Conroe Texas, 77303 USA
Signature 
Print Name, Coletta Cohara
Title Director Quality & Regulatory Compliance

Manufacturer's Declaration

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number	End date of extended validity/transition period	Substitute Device (if applicable)
Endogator Irrigation Pump EGP100	AR120 832501	2024-05-26	BSI, 2797	2028-12-31	N/A
Endogator Irrigation Pump EGP100E	AR120 832501	2024-05-26	BSI, 2797	2028-12-31	N/A
Endo Stratus Irrigation Pump EGA500	AR120 832501	2024-05-26	BSI, 2797	2028-12-31	N/A
Endo Stratus Irrigation Pump EGA500E	AR120 832501	2024-05-26	BSI, 2797	2028-12-31	N/A
Endo Stratus CO2 Insufflator EGA501	AR120 832501	2024-05-26	BSI, 2797	2028-12-31	N/A
Endo Stratus CO2 Insufflator EGA501E	AR120 832501	2024-05-26	BSI, 2797	2028-12-31	N/A