



# 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.*

|                             |                         |
|-----------------------------|-------------------------|
| <b>Registration Number:</b> | <b>252.878</b>          |
| <b>Original Approval:</b>   | <b>14 November 2013</b> |
| <b>Last Amended on:</b>     | <b>22 July 2020</b>     |
| <b>Remains valid until:</b> | <b>26 May 2024</b>      |

**Signed:**

Approved by:  
Dr. Caroline Dore Geraghty  
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***(Not significant changes approved after the 26 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:** 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 26<sup>th</sup> 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 26<sup>th</sup> May 2022.

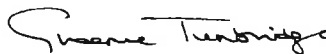
This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 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<br>832501      | 93/42/EEC<br>Annex II<br>excluding<br>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<sup>1</sup>
- 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 Drive<br>Conroe, TX 77303 USA<br>Coletta Cohara<br>Director Quality & Regulatory Compliance<br>Coletta_Cohara@STERIS.com |
| Single Registration Number (SRN) (if available) | No available                                                                                                                         |

|                                                       |                                                 |
|-------------------------------------------------------|-------------------------------------------------|
| Authorised Representative name (if applicable)        | Cantel Medical (Italy) S.r.l.                   |
| Authorised Representative address and contact details | Via Laurentina, 169<br>00071 Pomezia (RM) Italy |
| Single Registration Number (SRN) (if available)       | IT-AR-000010078                                 |

|                                                                                                                       |                                                              |
|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Notified body name (if applicable)                                                                                    | NSAI<br><input type="checkbox"/> See attached schedule       |
| Notified body number (if applicable)                                                                                  | 0050<br><input type="checkbox"/> See attached schedule       |
| Directive Certificate number(s) to which this confirmation is made (if applicable)                                    | 252.918<br><input type="checkbox"/> See attached schedule    |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 2024-05-26<br><input type="checkbox"/> See attached schedule |
| End date of extended validity/transition period                                                                       | 2028-12-31<br><input type="checkbox"/> See attached schedule |

<sup>1</sup> 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, 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*<sup>2</sup>
- 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.
- ☐ 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.

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<sup>2</sup> 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

### ➤ Unclassified 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.

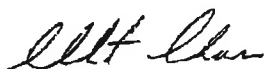
### Signed for and on behalf of the manufacturer:

Full Company Name: Medivators Inc.

Location: 3150 Pollok Drive, Conroe, TX 77303, USA

Date: 2024-04-04

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<br>(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) |
|------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------------|-----------------------------------|
| ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes 100145                                | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes 100145U                               | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes with CO2 Input 100145CO2              | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes with CO2 Input 100145CO2U             | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes with Extended CO2 Input 100145CO2EXT  | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes with Extended CO2 Input 100145CO2EXTU | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series Endoscopes 100150                                                 | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series Endoscopes 100150U                                                | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series and PENTAX® GI Endoscopes with CO2 Input 100150CO2                | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series and PENTAX® GI Endoscopes with CO2 Input 100150CO2U               | 252.918                                                                            | 2024-05-26                                                                                                            | NSAI 0050                     | 2028-12-31                                      | N/A                               |

## Manufacturer's Declaration

|                                                                                                                         |         |            |           |            |     |
|-------------------------------------------------------------------------------------------------------------------------|---------|------------|-----------|------------|-----|
| ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series and PENTAX® Endoscopes with Extended CO2 Input 100150CO2EXT  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series and PENTAX® Endoscopes with Extended CO2 Input 100150CO2EXTU | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for PENTAX® Endoscopes 100160                                                                     | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for PENTAX® Endoscopes 100160U                                                                    | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes 100164                                                     | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes 100164U                                                    | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes with CO2 Input 100164CO2                                   | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes with CO2 Input 100164CO2U                                  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes with Extended CO2 Input 100184CO2EXT                       | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes with Extended CO2 Input 100184CO2EXTU                      | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes 100185                                                                   | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes 100185U                                                                  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100185CO2                                                 | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100185CO2U                                                | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100185CO2EXT                                              | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100185CO2EXTU                                             | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |

## Manufacturer's Declaration

|                                                                                                                                                     |         |            |           |            |     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|-----------|------------|-----|
| ENDO SMARTCAP™ Adaptor for ENDO SMARTCAP™ Tubing and PENTAX® GI Endoscopes<br>100162                                                                | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ CO2 Source Tubing with Luer Input (210 cm)<br>100551                                                                                 | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Adapter for OLYMPUS® UCR® CO2 Insufflators<br>100555                                                                                 | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO SMARTCAP™ Adapter for FUJIFILM™ GW-100 Insufflators<br>100560                                                                                  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Tubing for OLYMPUS™ OFF Pump, ENDO STRATUS™ Irrigation Pump, BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump<br>100130                   | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Tubing for OLYMPUS™ OFF Pump, ENDO STRATUS™ Irrigation Pump, BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump<br>100130U                  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Tubing for ENDO GATOR™ EGP-100 Irrigation Pump, OLYMPUS™ OFF Pump, OLYMPUS™ AFU-100 Pump, ERBE™ EIP2 Pump<br>200230                      | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Tubing for ENDO GATOR™ EGP-100 Irrigation Pump, OLYMPUS™ OFF Pump, OLYMPUS™ AFU-100 Pump, ERBE™ EIP2 Pump<br>200230U                     | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Connector for OLYMPUS™ GI Endoscopes<br>100115                                                                                           | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Connector for PENTAX™ GI Endoscopes<br>100116                                                                                            | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Connector for FUJIFILM™ GI Endoscopes<br>100128                                                                                          | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Connector for OLYMPUS™ GI Endoscopes<br>100241                                                                                           | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Connector for PENTAX® Endoscopes<br>100242                                                                                               | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Channel Adapter<br>4005629                                                                                                               | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFF Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump<br>100805 | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |

## Manufacturer's Declaration

|                                                                                                                                                                                  |         |            |           |            |     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|-----------|------------|-----|
| ENDO GATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFF Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump<br>100605S                             | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, ENDO GATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFF Pump or ERBE™ EIP2 Pump<br>100606  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, ENDO GATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFF Pump or ERBE™ EIP2 Pump<br>100606S | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFF Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump<br>100609                              | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFF Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump<br>100608S                             | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for OLYMPUS™ 140/160/180 GI Endoscopes, ENDO GATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFF Pump or ERBE™ EIP2 Pump<br>100610      | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for OLYMPUS™ 140/160/180 GI Endoscopes, ENDO GATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFF Pump or ERBE™ EIP2 Pump<br>100610S     | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for PENTAX™ GI Endoscopes, ENDO GATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFF Pump or ERBE™ EIP2 Pump<br>100608                   | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for PENTAX™ GI Endoscopes, ENDO GATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFF Pump or ERBE™ EIP2 Pump<br>100608S                  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDO GATOR Hybrid Tubing for FUJIFILM™ GI Endoscopes, ENDO STRATUS™ Irrigation Pump Units, OLYMPUS™ OFF Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation                       | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |

## Manufacturer's Declaration

|                                                                                                                                                                            |         |            |           |            |     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|-----------|------------|-----|
| Pumps<br>100630                                                                                                                                                            | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDOGATOR Hybrid Tubing for FUJIFILM™ GI Endoscopes, ENDO STRATUS™ Irrigation Pump Units, OLYMPUS™ OFF Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pumps<br>100630S |         |            |           |            |     |
| ENDOGATOR Hybrid Tubing for FUJIFILM™ GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFF Pump or ERBE™ EIP2 Pump<br>100631             | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| ENDOGATOR Hybrid Tubing for FUJIFILM™ GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFF Pump or ERBE™ EIP2 Pump<br>100631S            | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Biopsy Valve for OLYMPUS and FUJIFILM GI Endoscopes<br>100301                                                                                                      | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Biopsy Valve for PENTAX GI Endoscopes<br>100302                                                                                                                    | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Y-OPSY Valve for OLYMPUS and FUJIFILM GI Endoscopes<br>100303                                                                                                      | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for OLYMPUS GI Endoscopes<br>100305                                                                                                              | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for OLYMPUS GI Endoscopes<br>100306                                                                                                              | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for OLYMPUS GI Endoscopes<br>100310                                                                                                              | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for OLYMPUS GI Endoscopes<br>100311                                                                                                              | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for FUJIFILM GI Endoscopes<br>100312                                                                                                             | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for FUJIFILM GI Endoscopes<br>100313                                                                                                             | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for FUJIFILM GI Endoscopes<br>100314                                                                                                             | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for PENTAX GI Endoscopes<br>100315                                                                                                               | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for PENTAX GI Endoscopes<br>100316                                                                                                               | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for PENTAX GI Endoscopes<br>100317                                                                                                               | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |

## Manufacturer's Declaration

|                                                                |         |            |           |            |     |
|----------------------------------------------------------------|---------|------------|-----------|------------|-----|
| Defendo Single Use Valves for OLYMPUS GI Endoscopes<br>100322  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for OLYMPUS GI Endoscopes<br>100323  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Cleaning Adapter for OLYMPUS GI Endoscopes<br>4000096  | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for OLYMPUS GI Endoscopes<br>4003269 | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |
| Defendo Single Use Valves for OLYMPUS GI Endoscopes<br>4003280 | 252.918 | 2024-05-26 | NSAI 0050 | 2028-12-31 | N/A |