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.

3150 Pollok Drive
Conroe
TX 77303
USA

to the Product Family

Disposable Endoscopic Tubing, Bottle and Accessories and Disposable Endoscopic Function Valves

GMDN Code: 46102, 60738, 60757, 60758, 60759, 60760, 63527

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:	**252.918**
Original Approval:	**22 October 2013**
Last Amended on:	**13 May 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.

NSAI
Certification

April 2024

Notified Body Confirmation Letter

Reference: NBCL0087.01

Re: Medivators
Disposable Endoscopic Tubing, Bottle and Accessories and Disposable Endoscopic Function Valves
NSAI File Number 252.918

To whom it may concern

NSAI.ie

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 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

This letter confirms that National Standards Authority of Ireland (NSAI), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0050 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Medivators
3150 Pollok Drive, Conroe TX, 77303 US

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

NSAI
Certification

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Pamela Burdette Miller

European Medical Device Operations Manager
Medical Devices, NSAI

NSAI Certification

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes 100145	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes 100145U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes with CO2 Input 100145CO2	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes with CO2 Input 100145CO2U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes with Extended CO2 Input 100145CO2EXT	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 140/240, 160/260, 180/280 190/290 Series Endoscopes with Extended CO2 Input 100145CO2EXTU	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series Endoscopes 100150	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series Endoscopes 100150U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series	IIa	n/a	CE 0050 252.918

NSAI Certification

and PENTAX® GI Endoscopes with CO2 Input 100150CO2			
ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series and PENTAX® GI Endoscopes with CO2 Input 100150CO2U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series and PENTAX® Endoscopes with Extended CO2 Input 100150CO2EXT	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for OLYMPUS® 100/130, 200/230 Series and PENTAX® Endoscopes with Extended CO2 Input 100150CO2EXTU	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for PENTAX® Endoscopes 100160	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for PENTAX® Endoscopes 100160U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes 100164	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes 100164U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes with CO2 Input 100164CO2	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes with CO2 Input 100164CO2U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes with Extended CO2 Input 100164CO2EXT	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ 700 Series GI Endoscopes with Extended CO2 Input 100164CO2EXTU	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes	IIa	n/a	CE 0050 252.918

NSAI Certification

100165			
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes 100165U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100165CO2	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100165CO2U	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100165CO2EXT	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100165CO2EXTU	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Adaptor for ENDO SMARTCAP™ Tubing and PENTAX® GI Endoscopes 100162	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ CO2 Source Tubing with Luer Input (210 cm) 100551	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Adapter for OLYMPUS® UCR® CO2 Insufflators 100555	IIa	n/a	CE 0050 252.918
ENDO SMARTCAP™ Adapter for FUJIFILM™ GW-100 Insufflators 100560	IIa	n/a	CE 0050 252.918
ENDOGATOR Tubing for OLYMPUS™ OFP Pump, ENDO STRATUS™ Irrigation Pump, BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100130	IIa	n/a	CE 0050 252.918
ENDOGATOR Tubing for OLYMPUS™ OFP Pump, ENDO STRATUS™ Irrigation Pump, BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100130U	IIa	n/a	CE 0050 252.918
ENDOGATOR Tubing for ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ OFP Pump, OLYMPUS™ AFU-100 Pump, ERBE™ EIP2 Pump 200230	IIa	n/a	CE 0050 252.918
ENDOGATOR Tubing for ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™	IIa	n/a	CE 0050 252.918

NSAI Certification

OFP Pump, OLYMPUS™ AFU-100 Pump, ERBE™ EIP2 Pump 200230U			
ENDOGATOR Connector for OLYMPUS™ GI Endoscopes 100115	IIa	n/a	CE 0050 252.918
ENDOGATOR Connector for PENTAX™ GI Endoscopes 100116	IIa	n/a	CE 0050 252.918
ENDOGATOR Connector for FUJIFILM™ GI Endoscopes 100126	IIa	n/a	CE 0050 252.918
ENDOGATOR Connector for OLYMPUS™ GI Endoscopes 100241	IIa	n/a	CE 0050 252.918
ENDOGATOR Connector for PENTAX® Endoscopes 100242	IIa	n/a	CE 0050 252.918
ENDOGATOR Channel Adapter 4005629	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100605	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100605S	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100606	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100606S	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI	IIa	n/a	CE 0050 252.918

NSAI Certification

Endoscopes, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100609			
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100609S	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180 GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100610	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180 GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100610S	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for PENTAX™ GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100608	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for PENTAX™ GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100608S	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for FUJIFILM™ GI Endoscopes, ENDO STRATUS™ Irrigation Pump Units, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pumps 100630	IIa	n/a	CE 0050 252.918

NSAI Certification

ENDOGATOR Hybrid Tubing for FUJIFILM™ GI Endoscopes, ENDO STRATUS™ Irrigation Pump Units, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pumps 100630S	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for FUJIFILM™ GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100631	IIa	n/a	CE 0050 252.918
ENDOGATOR Hybrid Tubing for FUJIFILM™ GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100631S	IIa	n/a	CE 0050 252.918
Defendo Biopsy Valve for OLYMPUS and FUJIFILM GI Endoscopes 100301	Is	n/a	CE 0050 252.918
Defendo Biopsy Valve for PENTAX GI Endoscopes 100302	Is	n/a	CE 0050 252.918
Defendo Y-OPSY Valve for OLYMPUS and FUJIFILM GI Endoscopes 100303	Is	n/a	CE 0050 252.918
Defendo Single Use Valves for OLYMPUS GI Endoscopes 100305	Is	n/a	CE 0050 252.918
Defendo Single Use Valves for OLYMPUS GI Endoscopes 100306	Is	n/a	CE 0050 252.918
Defendo Single Use Valves for OLYMPUS GI Endoscopes 100310	Is	n/a	CE 0050 252.918
Defendo Single Use Valves for OLYMPUS GI Endoscopes 100311	Is	n/a	CE 0050 252.918
Defendo Single Use Valves for FUJIFILM GI Endoscopes 100312	Is	n/a	CE 0050 252.918
Defendo Single Use Valves for FUJIFILM GI Endoscopes 100313	Is	n/a	CE 0050 252.918

Defendo Single Use Valves for FUJIFILM GI Endoscopes 100314	**Is**	**n/a**	**CE 0050 252.918**
Defendo Single Use Valves for PENTAX GI Endoscopes 100315	**Is**	**n/a**	**CE 0050 252.918**
Defendo Single Use Valves for PENTAX GI Endoscopes 100316	**Is**	**n/a**	**CE 0050 252.918**
Defendo Single Use Valves for PENTAX GI Endoscopes 100317	**Is**	**n/a**	**CE 0050 252.918**
Defendo Single Use Valves for OLYMPUS GI Endoscopes 100322	**Is**	**n/a**	**CE 0050 252.918**
Defendo Single Use Valves for OLYMPUS GI Endoscopes 100323	Is	n/a	CE 0050 252.918
Defendo Cleaning Adapter for OLYMPUS GI Endoscopes 4000096	Is	n/a	CE 0050 252.918
Defendo Single Use Valves for OLYMPUS GI Endoscopes 4003269	Is	n/a	CE 0050 252.918
Defendo Single Use Valves for OLYMPUS GI Endoscopes 4003280	Is	n/a	CE 0050 252.918

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
n/a	n/a	n/a	n/a

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.04.03	NBCL0087.01	Initial issue

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 Drive Conroe, TX 77303 USA Coletta Cohara Director Quality & Regulatory Compliance 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 00071 Pomezia (RM) Italy
Single Registration Number (SRN) (if available)	IT-AR-000010078

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

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.

☐ 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.

[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

➢ **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: 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 (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 100164CO2EXT	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 100164CO2EXTU	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes 100165	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes 100165U	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100165CO2	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100165CO2U	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100165CO2EXT	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ Tubing for FUJIFILM™ Endoscopes with CO2 Input 100165CO2EXTU	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A

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ENDO SMARTCAP™ Adaptor for ENDO SMARTCAP™ Tubing and PENTAX® GI Endoscopes 100162	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ CO2 Source Tubing with Luer Input (210 cm) 100551	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ Adapter for OLYMPUS® UCR® CO2 Insufflators 100555	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDO SMARTCAP™ Adapter for FUJIFILM™ GW-100 Insufflators 100560	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Tubing for OLYMPUS™ OFP Pump, ENDO STRATUS™ Irrigation Pump, BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100130	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Tubing for OLYMPUS™ OFP Pump, ENDO STRATUS™ Irrigation Pump, BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100130U	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Tubing for ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ OFP Pump, OLYMPUS™ AFU-100 Pump, ERBE™ EIP2 Pump 200230	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Tubing for ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ OFP Pump, OLYMPUS™ AFU-100 Pump, ERBE™ EIP2 Pump 200230U	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Connector for OLYMPUS™ GI Endoscopes 100115	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Connector for PENTAX™ GI Endoscopes 100116	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Connector for FUJIFILM™ GI Endoscopes 100126	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Connector for OLYMPUS™ GI Endoscopes 100241	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Connector for PENTAX® Endoscopes 100242	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Channel Adapter 4005629	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100605	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A

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ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100605S	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100606	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100606S	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100609	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180/190 GI Endoscopes, OLYMPUS™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation Pump 100609S	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180 GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100610	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for OLYMPUS™ 140/160/180 GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100610S	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for PENTAX™ GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100608	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A
ENDOGATOR Hybrid Tubing for PENTAX™ GI Endoscopes, ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS™ AFU-100 Pump, OLYMPUS™ OFP Pump or ERBE™ EIP2 Pump 100608S	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™ OFP Pump or BOSTON SCIENTIFIC™ ENDOSTAT™ II Irrigation	252.918	2024-05-26	NSAI 0050	2028-12-31	N/A

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

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