By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 690080**

Issued To: **GVS Filter Technology UK Limited**
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

In respect of:

Manufacture of sterile heat and moisture exchanger (HME) filters and attachments, heat and moisture exchanger and bacterial/viral (HMEF) filters and attachments, electrostatic filters and attachments, pleated mechanical filters and attachments for anaesthesia, ventilation, respiratory and critical care; sterile activated carbon and surgical smoke evacuation filters; for vent, suction, insufflation and irrigation applications.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-11-21** Date: **2021-05-13** Expiry Date: **2023-11-20**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 690080

Issued To:

GVS Filter Technology UK Limited
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

Number		**Device Subcategory**	**Intended purpose per IFU**
Class IIa			
NBOG code	MD 0101	HME devices for anaesthesia, respiratory and critical care/HMEF filters and attachments for anaesthesia, respiratory and critical care	NA
NBOG code	MD 0101	Electrostatic filters and attachments for anaesthesia, respiratory and critical care/pleated mechanical filters and attachments for anaesthesia, respiratory and critical care	NA
NBOG code	MD 0101	Activated carbon and smoke evacuation filters	NA
NBOG code	MD 0101	Vent suction insufflation and irrigation	NA

First Issued: **2018-11-21** Date: **2021-05-13** Expiry Date: **2023-11-20**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 690080**
Date:	**2021-05-13**
Issued To:	**GVS Filter Technology UK Limited** **NFC House** **Vickers Industrial Estate** **Mellishaw Lane** **Morecambe** **Lancashire** **LA3 3EN** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Andersen Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park, Bellshill ML4 3NJ United Kingdom	**ETO Sterilization**
GVS S.P.A. Via Roma 50 Zola Predosa (BO) 40069 Italy	**EU Representative**
GVS Technology (Suzhou) Co., Ltd. No. 602 Changjiang Road Fengqiao Civil-Run Scitech Park Suzhou New District Suzhou Jiangsu 215129 China	**Manufacture**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 690080**

Date: **2021-05-13**

Issued To: **GVS Filter Technology UK Limited**
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

Date	Reference Number	Action
21 November 2018	8902128	First Issue.
27 February 2019	8943588	Traceable to NB 0086.
Current	3371294	Addition of EU Representative to List of Significant Subcontractors.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

GVS Filter Technology UK Limited
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

11 September 2023

Notified Body Confirmation Letter

Reference: EU2023-607/685684

To whom it may concern,

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

GVS Filter Technology UK Limited
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 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.

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 BSI Group The Netherlands B.V.,

Lizzy Szott Digitally signed by Lizzy Szott Date: 2023.09.11 10:47:50 -04'00'

Lizzy Szott, PhD

BSI Scheme Manager

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
4244/03 ECO MAXI Pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/711 MAXI HME Pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/712 MAXI HME Pleat Without Port	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/761 Eco-therm HEPA filter with coil paper HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4331/01 ECO HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4331/01DFK Eco HMEF With Connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4331/01DGK Eco HMEF With Connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4331/50 ECO Maxi HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/01 Eco HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/01BNK Eco HMEF and elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/01DBK Eco HMEF + tube + connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/01DEK Eco HMEF + tube + connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
4333/01DDK Eco HMEF + tube + connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/01DFK HMEF, Luer Lid with Expandable Tube	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/01DGK Eco HMEF with connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/50 ECO Maxi Straight HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/710 MAXI Angled HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/711 MAXI Straight HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/711BNK MAXI Straight HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/712 MAXI Straight HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/712BNK MAXI Straight HMEF + elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/714 ECO Maxi Angled HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/721 Eco Range HMEF (white foam)	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/750 MAXI Angled HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/751 MAXI HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/752 ECO Maxi HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/754 Eco Maxi Angled HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/760 Eco MAXI angled coil paper HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
4333/761 Eco MAXI straight coil paper HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/770 Eco MAXI angled coil paper HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/771 Eco MAXI straight coil paper HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4333/772 Eco MAXI straight coil paper HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
8866/50 Comfort fit HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
8866/100 Comfort fit HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
8866/100DEK Comfort fit HMEF +tube+ connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9064/711 MIDI HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9064/711BNK MIDI HMEF + elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9064/751 MIDI HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9064/761 Eco MIDI straight coil paper HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9065/710 MIDI Angled HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9065/750 MIDI Angled HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9065/760 Eco MIDI angled coil paper HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9065/770 Eco MIDI angled coil paper HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9066/711 MINI HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
9066/751 MINI HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9066/761 Eco MINI straight coil paper HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9067/710 MINI Angled HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9067/750 MINI Angled HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9067/760 Eco MINI angled coil paper HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9080/100 Neo-natal HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9080/100BNK Neo Natal HMEF with elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9080/710 MICRO MINI angled HMEF	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9080/750 MICRO angled HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9085/751 MICRO Lo-Volume HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9085/771 ECO Micro Lo-Volume coil paper HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9500/01 Tracheal HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9500/03 Tracheal Blue HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9500/710 Micro tracheal	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9500/750 Micro Tracheal HME	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A540 Elbow with sampling port	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
A541 Elbow without sampling port	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A542 Double Swivel Elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A543 Double Swivel Elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A620/40/61 Expandable Tubing with Gas Sampling Elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A620/41/61 Expandable Tubing with Elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A620/42/61 Expandable Tubing with Double Swivel Elbow and Port	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A620/43/61 Expandable Tubing with Double Swivel Elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A620/60/61 Attachment	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
1200/08 Medipleat Autoclavable Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
1200/20 Medipleat Autoclavable Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
1210/09 Autoclavable Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
1420/01 Medguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
1420/01 Medguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
1420/03BOK Medguard + Connector	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/01 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/01BFK Spiroguard with Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2800/01BMK Spiroguard with Bite Grip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/01DAK Spiroguard with Nose Clip and Bite Grip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/01DHK Spiroguard with Bite Grip, Mouthpiece, Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/01DJK Spiroguard with Mouthpiece and Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/02 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/02BFK Spiroguard with Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/02BWK Spiroguard with Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/02DAK Spiroguard with Nose Clip and Bite Grip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/03 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/03BFK Spiroguard with Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/03DAK Spiroguard with Nose Clip and Bite Grip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/03DJK Spiroguard with Mouthpiece and Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/10 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/10DAK Spiroguard with Nose Clip and Bite Grip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/11 Spiroguard Integral Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/15 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2800/17 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/17BFK Spiroguard with Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/17DAK Spiroguard with Nose Clip and Bite Grip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/21 Spiroguard Integral Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/21BFK Spiroguard Integral Mouthpiece with Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/22 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/22BFK Spiroguard with Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/22DAK Spiroguard with Nose Clip and Bite Grip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/23 Spiroguard with Integral mouthpiece side	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/24 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/25 Spiroguard with Integral mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/26 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/27 Spiroguard with Integral Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/30 Spiroguard Integral Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/31 Spiroguard Integral Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2800/31BFK Spiroguard Integral Mouthpiece with Nose Clip	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/32 Spiroguard	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/728 Compact Electrostatic Spirometry Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/729 Compact Electrostatic Spirometry Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/R1 Spiroguard Re-usable	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/R2 Spiroguard Re-usable	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2800/R3 Spiroguard Re-usable	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/01 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/02 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/03 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/04 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/05 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/06 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/07 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/08 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/09 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2802/10 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/11 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/12 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/13 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/14 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/15 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/16 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/17 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/18 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/19 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/20 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/21 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/22 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/23 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/24 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/25 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2802/26 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/27 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/28 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/29 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/30 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/31 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2802/32 Spiroguard Adaptor	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
3000/03 Multi-vent	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
3000/04 Multi-vent tapered	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
3000/07 Multi-vent	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
3000/11 Multi-vent flat top	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
3000/12 Multi-vent flat top	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
3000/740 Expiratory Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4020/01 ECO Machine Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4020/03 Single Walled Machine Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4020/06 ECO Machine Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
4020/10 Machine Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4220/01 Eco maxipleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4220/04 ECO Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/01 ECO slimline	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/01BWK Eco slimline and mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/01DFK Eco slimline, Luer Lid + Expandable Tube	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/01DDK Eco slimline+tube+connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/02 ECO slimline	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/02BWK Eco slimline and mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/03 ECO slimline	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/700 MAXI Maxi Angled Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/701 Eco Maxi Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/702 MAXI Maxi Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4222/703 MAXI Maxi Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/01 Eco maxi-pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/01DBK Pleated filter and collapsible tube	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
4244/01DEK Maxi Pleat with connectors	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/02 ECO Maxi Pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/04 ECO Maxi Pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/06 ECO Maxi Pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/700 MAXI Maxi Angled Pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/701 Eco Maxi Pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4244/702 MAXI Maxi Pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4444/01 Slimline Bacterial/Viral	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4444/01BWK Slimline Electrostatic with mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4444/06 Slimline Electrostatic with Integral Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
4444/66 Ultra-High Efficiency Slimline	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
6888/01 Maxi pleat/2	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
6888/20 Maxi pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
6888/21 Maxi pleat ULPA Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
8444/01 Maxi pleat/1	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
8444/27 Maxi pleat	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
8866/01 Comfort fit bacterial/viral	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9066/701 MINI Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9066/701BNK MINI Filter + elbow	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9067/700 MINI Angled Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9080/01 Neo-natal/bacterial/viral	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
9080/700 MICRO Angled Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A539 Bitegrip Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
A571 Mouthpiece	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/47 Smoke Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/47BBK Smoke Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/47BDK Smoke Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/947 90mm Smoke Evacuation Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/01 Vent filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/02 Vent Filter - Autoclavable	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/05 Vent filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/05BAK Vent Filter Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2000/05DLK Vent Filter Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/05DTK Vent Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/05DUK Vent Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/05DWK Vent Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/05DXK Vent Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/06 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/07 Vent Filter - Autoclavable	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/08 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/09 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/12 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/16 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/17 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/18 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/18BEK Vent Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/20 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/22 Transducer filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2000/31 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/35 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/37 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/38 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/39 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/42 Vent Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2000/53 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/01 Insufflation Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/01BCK Insufflation Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/01DKK Insufflation Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/02 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/02DIK Suction Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/05 Insufflation Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/05BRK Insufflation Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/06 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/15 Insufflation Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2200/16 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/21 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/25 Insufflation Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/25BUK Insufflation Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/25DSK Insufflation Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/26 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/33 Insufflation Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/35 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/36 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/48 Insufflation filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/48BIK Insufflation Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/55 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/56 Insufflation Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/60 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/62BHK Insufflation Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/65 Insufflation filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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
2200/70 Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
2200/902 90MM Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
200/911 90MM Suction Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
6421/04 Insufflation Filter	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
6421/04BGK Hi Flow Insufflation Kit	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797
6421/04DVK Insufflation Set	Class IIa	N/A	MDD Certificate #CE 690080 and expiry date - 20th November 2023; NB# 2797

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	Action
2023/09/11	Initial issue