Digitally signed by Iurchevici Valeriu
Date: 2025.05.05 14:07:12 EEST
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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**

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

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