

EC Certificate - Production Quality Assurance

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

No.

CE 690080

Issued To:

**GVS Filter Technology UK Ltd
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**

...making excellence a habit.™

Page 1 of 2

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.

EC Certificate - Production Quality Assurance

Supplementary Information to CE 690080

Issued To:

GVS Filter Technology UK Ltd
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**

...making excellence a habit.™

Page 2 of 2

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.

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 Ltd**
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 Filter Technology de Mexico, S de RL de CV Universal No. 550 Apodaca NL 66626 Mexico | Manufacture |
| GVS Microfiltrazione SRL Sat Cioranii de Sus, NR 1E Judet Prahova 107 160 Comuna Ciorani Romania | Manufacture |

...making excellence a habit.™

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 Ltd**
NFC House
Vickers Industrial Estate
Mellishaw Lane
Morecambe
Lancashire
LA3 3EN
United Kingdom

Subcontractor:

Service(s) supplied

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

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Certificate History

Certificate No: **CE 690080**
Date: **2021-05-13**
Issued To: **GVS Filter Technology UK Ltd**
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. |
| 13 May 2021 | 3371294 | Addition of EU Representative to List of Significant Subcontractors. |
| Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3 | | |
| 26 April 2022 | 3653361 | Addition of critical subcontractors GVS Microfiltrazione SRL and GVS Filter Technology de Mexico. |

...making excellence a habit.™

Page 1 of 1

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.

26 April 2022

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

To whom it may concern,

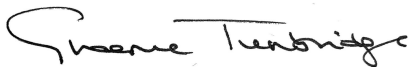
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

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) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

| Certificate | Directive and Annex | Reference Number | Changes approved |
|--------------------|----------------------------|-------------------------|---|
| CE 690080 | 93/42/EEC Annex V | 3653361 | Addition of critical subcontractors GVS Microfiltrazione SRL and GVS Filter Technology de Mexico. |

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