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Location: Moldova

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):

Albert Roossien, Regulatory Lead

First Issued: **2018-11-21** Date: **2019-02-27** 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: **2019-02-27** Expiry Date: **2023-11-20**

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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:	**2019-02-27**
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 Lanarkshire ML4 3NJ UK	**ETO Sterilization**
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: **2019-02-27**

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

Date	Reference Number	Action
21 November 2018	8902128	First Issue.
Current	8943588	Traceable to NB 0086.