bsi.

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):

Digitally signed by Iarovoi Petru
Date: 2020.05.08 16:39:19 EEST
Reason: MoldSign Signature
Location: Moldova

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:

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NFC House
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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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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
Morecambe
Lancashire
LA3 3EN
United Kingdom

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

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www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. / *CERTIFICATE N.* 9124.GVS3

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

GVS SPA

VIA ROMA 50 - 40069 ZOLA PREDOSA (BO)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA ROMA 50 - 40069 ZOLA PREDOSA (BO)

VIA ROMA 48 - 40069 ZOLA PREDOSA (BO)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e fabbricazione di dispositivi medici sterili quali set di infusione, set per terapia infusionale di anestetici ed anestesia epidurale, set leucodeplezione e componenti non sterili
Design and manufacturing of sterile medical devices such as infusion set, sets for infusion therapy of anesthetics and epidural anesthesia, leucodepletion set and not sterile components

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2005-03-11	2020-02-21	2023-03-10

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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Organismo di Certificazione Federato CISQ
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FEDERAZIONE CISQ

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CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.