

# EC Certificate - Production Quality Assurance

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

**No.****CE 690080****Issued To:**

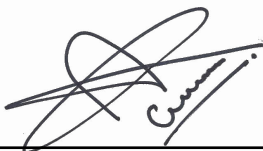
**GVS Filter Technology UK Limited  
NFC House  
Vickers Industrial Estate  
Mellishaw Lane  
Morecambe  
Lancashire  
LA3 3EN  
United Kingdom**

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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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.

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## Supplementary Information to CE 690080

Issued To:

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| Number           |         | Device Subcategory                                                                                                                                                             | Intended purpose per IFU |
|------------------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| <b>Class IIa</b> |         |                                                                                                                                                                                |                          |
| 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                       |

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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.

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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:

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| Subcontractor:                                                                                                                                                 | Service(s) supplied |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Andersen Caledonia Limited<br>Caledonian House<br>Phoenix Crescent<br>Strathclyde Business Park<br>Lanarkshire<br>ML4 3NJ<br>UK                                | ETO Sterilization   |
| GVS Technology (Suzhou) Co., Ltd.<br>No. 602 Changjiang Road<br>Fengqiao Civil-Run Scitech Park<br>Suzhou New District<br>Suzhou<br>Jiangsu<br>215129<br>China | Manufacture         |

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## Certificate History

Certificate No: **CE 690080**  
Date: **2019-02-27**  
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| Date             | Reference Number | Action                |
|------------------|------------------|-----------------------|
| 21 November 2018 | 8902128          | First Issue.          |
| Current          | 8943588          | Traceable to NB 0086. |

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