By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 772036 R000

Manufacturer: GVS Filter Technology UK Limited

Address:
Caton Road
Lancaster
LA1 3PE
United Kingdom

Single Registration Number: UK-MF-000045036

EU Authorised Representative: GVS S.P.A.

Address:
Via Roma 50
Zola Predosa (BO)
40069
Italy

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-04-25**

Current Issue Date: **2025-11-10**

Starting Validity Date: **2025-11-10**

Expiry Date: **2029-04-24**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Anaesthesia and Resuscitation Connectors	Class IIa
Catheter Mounts	Class IIa
Humidification Systems	Class IIa
Natural Breathing Filters	Class IIa
Respiratory Filters – Various	Class IIa
Respiratory Mouthpieces	Class IIa
Ventilation Filters	Class IIa
Respiratory Filters	Class Is
Gas Filters	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-04-25	3694431	Issued
2024-08-21	30204194	Supplemented – addition of device groups Anaesthesia and Resuscitation Connectors, Catheter Mounts, Humidification Systems, Natural Breathing Filters, Respiratory Filters – Various, Respiratory Mouthpieces and Ventilation Filters
Current	30467622	Amended – change of manufacturer address to: Caton Road Lancaster LA1 3PE United Kingdom

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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