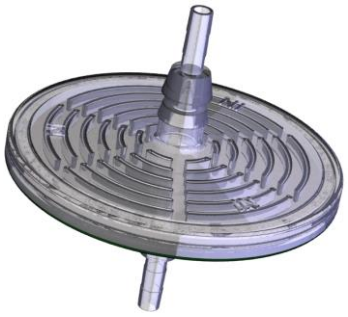
PRODUCT SPECIFICATION

Product P/N	**2200/05**	**Mod. 984A Rev. 06**
Description	**Insufflation Filter**	

2200/05

Insufflation Filter



PRODUCT DESCRIPTION	Inlet/Outlet Connectors: 5mm - 9.5mm hose barbed - both sides. Approx. dimensions: 65mm diameter x 65.8mm height. Bidirectional filter. Weight 17gm (approx.).
MANUFACTURER NAME	**GVS Filter Technology UK** NFC House Vickers Industrial Estate Mellishaw Lane, Morecambe Lancashire LA3 3EN - United Kingdom **Information** Tel. +44 (0) 1524 847600 e-mail: gvsuk@gvs.com
INTENDED USE / APPLICATION	To be used in conjunction with insufflators for intra-abdominal insufflation.
CLASS OF THE PRODUCT	Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC Rule 2 Annex VIII MDR 2017/745
MATERIALS	**Filter media:** ***Hydrophobic Glass Microfibre Media*** **Frame/Housing Polymer:** ***Clear Styrene-Butadiene Copolymer (SBC)*** **Colour:** ***Transparent Clear*** **Regulatory Documentation Required:** - Biocompatibility according ISO 10993-1 - ROHS - BSE/TSE - DEHP plasticizer Free and latex free - Aging - REACH - Conflict minerals
PRODUCT CHARACTERISTICS	**Appearance/Visual** As shown on drawing.

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	Physical/Mechanical *Approx. dimensions:* ***65mm diameter x 65.8mm height.*** *Weight:* ***17gm (approx.).*** Interfaces (ex: Input / Output connectors): ***5mm - 9.5mm hose barbed - both sides.*** Operating temperature Range: ***N/A*** Storage temperature Range: ***5 °C to 40 °C*** ***Bidirectional Filter.*** **Biological** Pyrogenicity: ***<0.3 EU/ml*** ***Biocompatibility to ISO10993*** *Category –* ***Surface device*** *Contact –* ***Skin*** *Contact Duration -* ***<24hrs*** **Functional** Air Flow Rate: ***Min. 28.4l/min @ 5PSI*** (REP 0614/15 with 20% Factor of Safety applied to Min.) Filtration Efficiency: *Filter Efficiency @ 15L/min using DEHS@0.3µm****: Min.99.9%*** (Ref. 2200/15 REP: 1218/17 with Factor of Safety) Pressure Drop: ***N/A*** Internal Volume: ***N/A*** Operating Lifetime: ***Refer to Instructions for Use.*** Shelf Lifetime: ***5 years from the date of manufacture.*** *Bacterial Filtration Efficiency in accordance with ASTM F2101-07:* ***Min. 99.999%*** *(Staphylococcus aureus @ 30L /minute)* REP: EXT846022-S01 *Viral Filtration Efficiency in accordance with ASTM F2101-07****: Min. 99.999%*** *(Bacteriophage @ 30L/ minute)* REP: EXT846021-S01 **Cleanliness** Device assembled within Class 8 Cleanroom. **Testing** Burst test: ***Min.15.7psi*** (REP 0618/15 with 20% Factor of Safety applied to Minimum) Leakage: ***Static Head Test 27" of water for 1 minute*** (REP 0622/15)
INSTRUCTIONS / WARNINGS	*Multi-language IFU available.*
PRODUCT SHELF LIFE	*5 years from the date of manufacture.* *Expiration date and date of manufacture are detailed on the product labelling.*
STERILIZATION	*Sterile version of product available (Ethylene oxide - Max 55°C*
APPLICABLE STANDARDS AND REGULATIONS	**Product Certification required:** - CE mark - FDA **Applicable Standards and Technical Regulations:**

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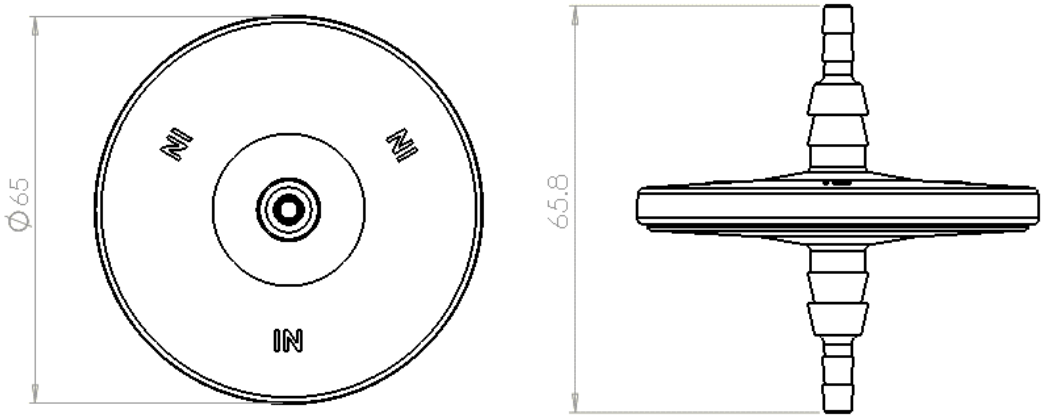
	Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1. *Medical devices- Application of risk management to medical devices - BS EN ISO 14971.* *Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements - ISO 15223-1.* *Sterilization of health care products – Ethylene oxide sterilization – ISO 11135-1.* *Sterilization of medical devices – Microbiological Methods – Part 1: Estimation of population of Microorganisms on products – ISO 11737-1.* *High Efficiency Air Filters – BS EN 1822.*
PACKAGING AND LABELING	*Number of pcs per bag is determined by the sales order.* *The first barcode label is applied to the outside of the bags.* *The second barcode label is applied onto the outside of the box.* *Each bag is labelled with the following traceability information:* ✓ *Quantity* ✓ *Product description* ✓ *Product Date* ✓ *Lot Number (OL and 5-digit batch number to trace back to raw materials used)* ✓ *Operator Code* *Different lots in one box are separately closed and separately labelled.* *Bulk products will be packaged in double PE bags*
CERTIFICATE OF COMPLIANCE	*With each shipment, GVS UK Customer Service will send the CofC to the Customer, based on the lot numbers and date of manufacture.* *Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1.* *The Quality management system is in compliance with ISO 9001, ISO 13485.*
DRAWING	*The attached drawing is part of this product specification and must not be duplicated or made accessible to a third party without written permission from GVS Filter Technology UK Ltd.*  Approximate dimensions for reference only

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ACCEPTABLE QUALITY LEVEL	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1
VISUAL REQUIREMENTS	**Visual acceptance requirements apply when inspected under below conditions:** Magnification: *Unaided eye at a distance of approximately 35-40cm.* Light type: *Lighting level must be reasonable for visual detection.* Timings: *Maximum inspection period per item is 25 seconds.* *For detailed defect list, refer to product control plan.*

	Acceptance Requirement	AQL	Sampling Plan
1	Black particle contamination	0.65	ISO 2859 Part 1 General Inspection Level 1
2	Damaged/broken item	0.65	
3	Blocked connector/luer	0.65	
4	Short fill moulding	0.65	
5	Rough surface or edges	0.65	
6	Pronounced injection gate	0.65	
7	Deformation/distortion	0.65	
8	Crack	0.65	
9	Oil/grease	0.65	
10	Wrong colour	0.65	
11	Weld fault	0.65	
12	Weld marks	0.65	

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	**Special characteristic**: *Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.* **Special Characteristic # 01:** *Air Flow rate at 5psi* **Special Characteristic # 02:** *Filter Efficiency @ 15L/min using DEHS @ 0.3µm in accordance with High Efficiency Air Filters – BS EN 1822.* **Special Characteristic # 03:** *Bacterial Filtration Efficiency in accordance with ASTM F2101-07* *Viral Filtration Efficiency in accordance with ASTM F2101-07* **Special Characteristic # 04:** *Burst Pressure* **Special Characteristic # 05:** *27" water leak test – Static head test*

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This material specification describes the properties of product above indicated. This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
27/08/2021	2	Staerilisation section and functional characteristics amended.	Kinga Gawdzik - Engineering Support Technician	Andrew Pearce – Quality Manager

CUSTOMER APPROVAL:

We accept this material specification as a part of the agreed terms of delivery.

Company Name:

Approved by:

NAME/FUNCTION

SIGNATURE

DATE

COMPANY STAMP

Please send back this document signed for approval. If we will not receive this specification signed, we consider the first order placed as implicit approval.