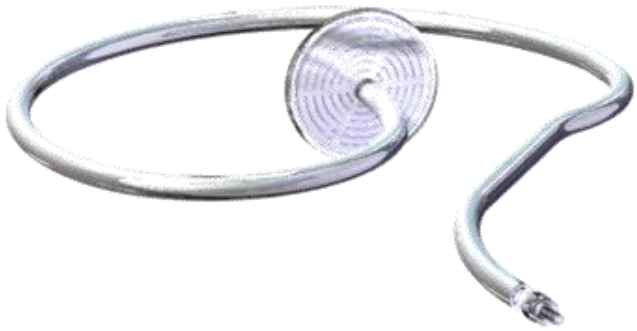
PRODUCT SPECIFICATION

Product P/N	**2200/47BDK**	**Mod. 984A Rev. 06**
Description	**Smoke Set**	

2200/47BDK

Smoke Set



PRODUCT DESCRIPTION	Inlet/Outlet Connectors of **2200/47:** 8mm-8mm hose barbed both sides. Flow direction indicated by IN marking on filter face. Approximate dimensions: 65mm diameter x 52mm height. Weight: 17g (approx.). 400mm PVC tube with mobile luer lock, tube attached to the filter. Mobile male luer lock connector: OD6.6mm/ID3.8mm, OD ISO 4mm/ID 2.6mm with approx. dimensions: 32mm height. PVC tubing: OD=9.55mm, ID=6.35mm with approx. dimensions: 400mm length.
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	The combination particle and gas filter is used as part of a smoke evacuation system which reduces particulate and odour causing noxious chemicals from surgical smoke generated in laparoscopic procedures while maintaining a clear field of vision. It is indicated for use during any minimally invasive surgery involving insufflation, electro cautery, laser, or ultrasonic scalpel use.
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:** ***Glass Microfibre Media and nonwoven polyester (PET) with carbon granules*** **Frame/Housing Polymer:** *2200/47:* ***Clear Styrene-Butadiene Copolymer (SBC)*** *Tube:* ***PVC*** *Mobile luer lock:* ***Acrylonitryle Butadiene Styrene (ABS)*** **Colour:** ***Transparent Clear*** **Adhesive:** ***UV curable adhesive*** **Regulatory Documentation Required:**

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	- 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. **Physical/Mechanical** *Approximate dimensions of 2200/47:* ***65mm diameter x 52mm height.*** *Weight:* ***17g (approx.).*** ***400mm tube with mobile luer lock, tube attached to the filter.*** Interfaces (ex: Input / Output connectors): *2200/47:* ***8mm – 8mm hose barbed both sides.*** *Mobile male luer lock connector:* ***OD6.6mm/ID3.8mm, OD ISO 4mm/ID 2.6mm with approx. dimensions: 32mm height.*** *PVC tubing:* ***OD=9.55mm, ID=6.35mm with approx. dimensions: 400mm length.*** Operating temperature Range: ***N/A*** Storage temperature Range: ***5 °C to 40 °C*** ***Unidirectional Filter. Flow direction indicated by IN marking on filter face.*** **Biological** Pyrogenicity: ***<0.3 EU/ml*** ***Biocompatibility to ISO10993*** *Category –* ***Surface device*** *Contact -* ***Skin*** *Contact Duration -* ***<24hrs*** For kit performance characteristics for 2200/47BDK – Please refer to 2200/47 Technical data sheet. **Functional** Air Flow Rate: ***Min. 50l/min @ 5 PSI*** (REP 0615/15 with 20% Factor of Safety applied to Min.) Filtration Efficiency: *DEHS Efficiency using 0.3 micron @ 30l/min:* ***Min. 99.99%*** (REP 0698/16 with Factor of Safety applied to Min.) Operating Lifetime: ***Refer to Instructions for Use.*** Shelf Lifetime: ***3 years from the date of manufacture.*** *Bacterial Filtration Efficiency in accordance with ASTM F2101-07:* ***Min. 99.999%*** *(Staphylococcus aureus @ 30L /minute)* REP: EXT 846022-S01 *Viral Filtration Efficiency in accordance with ASTM F2101-07:* ***Min. 99.999%*** *(Bacteriophage @ 30L/ minute)* REP: EXT846021-S01

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	Cleanliness Device assembled within Class 8 Cleanroom. **Testing** Burst test: ***Min. 13 psi*** (REP 0619/15 with 20% Factor of Safety) ***Leak test at 4.5PSI.***
INSTRUCTIONS / WARNINGS	*Multi-language IFU available.*
PRODUCT SHELF LIFE	*3 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:** *Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.* *Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration - BS EN 13274-7.* *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 - Part1: 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.*
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 packed 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.*

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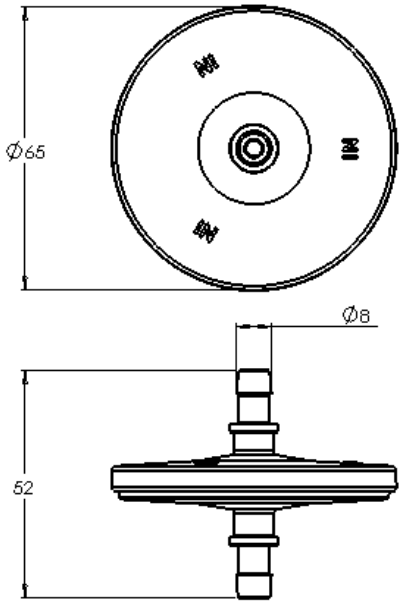
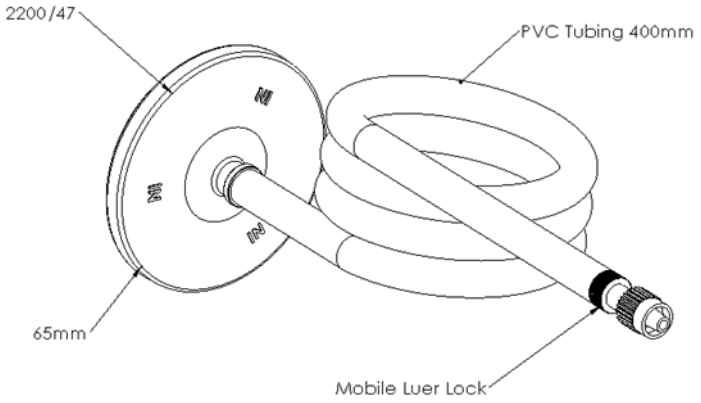
DRAWING	*The attached drawing is part of this product specification and must not be duplicated or made accessible to a third party without written permission from GVS Filter Technology UK Ltd.*  Approximate dimensions for reference only 
ACCEPTABLE QUALITY LEVEL	AQL: 0.65 with sampling Plan: ISO2859.
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.*

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	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	Weld marks	0.65	
	5	Short fill moulding	0.65	
	6	Rough surface or edges	0.65	
	7	Pronounced injection gate	0.65	
	8	Deformation/distortion	0.65	
	9	Crack	0.65	
	10	Oil/grease	0.65	
	11	Wrong colour	0.65	
	12	Weld fault	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 @ 30L/min using DEHS @ 0.3µm 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*			
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)
20/08/2021	3	Sterilisation section updated.	Kinga Gawdzik – Engineering Support Technician	Andrew Pearce – Quality Manager

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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.