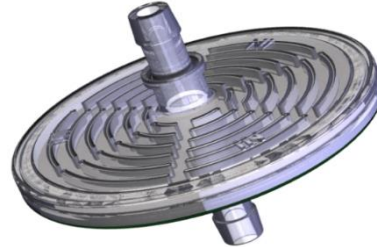


PRODUCT SPECIFICATION

Product P/N	2200/47	Mod. 984A Rev. 06
Description	Smoke Filter	

2200/47

Smoke Filter



PRODUCT DESCRIPTION	Inlet/Outlet Connectors: 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.). Unidirectional Filter.
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: <i>Glass Microfibre Media and nonwoven polyester (PET) with carbon granules</i> Frame/Housing Polymer: <i>Clear Styrene-Butadiene Copolymer (SBC)</i> Colour: <i>Transparent Clear</i> Regulatory Documentation Required: <ul style="list-style-type: none"> - Biocompatibility according ISO 10993-1 - ROHS - BSE/TSE - DEHP plasticizer Free and latex free - Aging - REACH - Conflict minerals

PRODUCT SPECIFICATION

Product P/N	2200/47	Mod. 984A
Description	Smoke Filter	Rev. 06

PRODUCT CHARACTERISTICS	Appearance/Visual As shown on drawing.	
	Physical/Mechanical <i>Approximate dimensions: 65mm diameter x 52mm height.</i> <i>Weight: 17g (approx.).</i> <i>Interfaces (ex: Input / Output connectors): 8mm – 8mm hose barbed both sides.</i> <i>Operating temperature Range: N/A</i> <i>Storage temperature Range: 5 °C to 40 °C</i> Unidirectional Filter. Flow direction indicated by IN marking on filter face.	
	Biological <i>Pyrogenicity: <0.3 EU/ml</i> Biocompatibility to ISO10993 <i>Category – Surface device</i> <i>Contact –Skin</i> <i>Contact Duration - <24hrs</i>	
	Functional <i>Air Flow Rate: Min. 50l/min @ 5 PSI (REP 0615/15 with 20% Factor of Safety applied to Min.)</i> <i>Filtration Efficiency: DEHS Efficiency using 0.3 micron @ 30l/min: Min. 99.99% (REP 0698/16 with Factor of Safety applied to Min.)</i> <i>Operating Lifetime: Refer to Instructions for Use.</i> <i>Shelf Lifetime: 3 years from the date of manufacture.</i> <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (Staphylococcus aureus @ 30L /minute) REP: EXT 846022-S01</i> <i>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (Bacteriophage @ 30L/ minute) REP: EXT846021-S01</i>	
	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. <i>Expiration date and date of manufacture are detailed on the product labelling.</i>
	STERILISATION	N/A
	APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: - CE mark - FDA

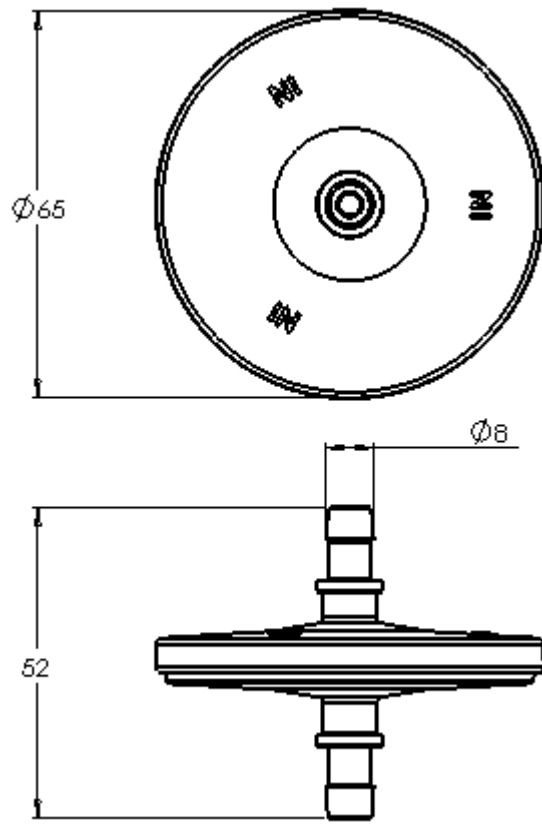
PRODUCT SPECIFICATION

Product P/N	2200/47	Mod. 984A
Description	Smoke Filter	Rev. 06

	<p>Applicable Standards and Technical Regulations:</p> <p><i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i></p> <p><i>Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration - BS EN 13274-7.</i></p> <p><i>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</i></p> <p><i>Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1.</i></p>
PACKAGING AND LABELING	<p><i>Number of pcs per bag is determined by the sales order.</i></p> <p><i>The first barcode label is applied to the outside of the bags.</i></p> <p><i>The second barcode label is applied onto the outside of the box.</i></p> <p><i>Each bag is labelled with the following traceability information:</i></p> <ul style="list-style-type: none"> ✓ Quantity ✓ Product description ✓ Product Date ✓ Lot Number (OL and 5-digit batch number to trace back to raw materials used) ✓ Operator Code <p><i>Different lots in one box are separately closed and separately labelled.</i></p> <p><i>Bulk products will be packed in double PE bags.</i></p>
CERTIFICATE OF COMPLIANCE	<p><i>With each shipment, GVS UK Customer Service will send the CofC to the Customer, based on the lot numbers and date of manufacture.</i></p> <p><i>Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1.</i></p> <p><i>The Quality management system is in compliance with ISO 9001, ISO 13485.</i></p>
DRAWING	<p><i>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.</i></p>

PRODUCT SPECIFICATION

Product P/N	2200/47	Mod. 984A Rev. 06
Description	Smoke Filter	

	<div></div> <div>Approximate dimensions for reference only</div>																	
ACCEPTABLE QUALITY LEVEL	AQL: 0.65 with sampling Plan: ISO2859.																	
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions:</p> <p>Magnification: <i>Unaided eye at a distance of approximately 35-40cm.</i> Light type: <i>Lighting level must be reasonable for visual detection.</i> Timings: <i>Maximum inspection period per item is 25 seconds.</i> <i>For detailed defect list, refer to product control plan.</i></p> <table><tr><th colspan="2">Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Black particle contamination</td><td>0.65</td><td rowspan="4">ISO 2859 Part 1 General Inspection Level 1</td></tr><tr><td>2</td><td>Damaged/broken item</td><td>0.65</td></tr><tr><td>3</td><td>Blocked connector/luer</td><td>0.65</td></tr><tr><td>4</td><td>Weld marks</td><td>0.65</td></tr></table>	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
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																

PRODUCT SPECIFICATION

Product P/N	2200/47	Mod. 984A Rev. 06
Description	Smoke Filter	

	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: <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i>			
	Special Characteristic # 01: <i>Air flow rate at 5PSI</i>			
	Special Characteristic # 02: <i>Filter Efficiency @ 30L/min using DEHS @ 0.3µm EN 1822.</i>			
	Special Characteristic # 03: <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07</i> <i>Viral Filtration Efficiency in accordance with ASTM F2101-07</i>			
	Special Characteristic # 04: <i>Burst Pressure</i>			
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	IFU section updated on Mod.984.	Kinga Gawdzik – Engineering Support Technician 	Andrew Pearce – Quality Manager 

PRODUCT SPECIFICATION

Product P/N	2200/47	Mod. 984A
Description	Smoke Filter	Rev. 06

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.