

PRODUCT SPECIFICATION

Product P/N	2000/06	Mod. 984A Rev. 06
Description	Vent Filter	

2000/06

Vent Filter



PRODUCT DESCRIPTION	Inlet/Outlet Connectors: 5.9mm-8mm hose barbed both sides. Approximate dimensions: 54mm diameter x 61mm height. Weight: 11g (approx.). Bidirectional 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	Filters, hydrophobic and non-hydrophobic for use within oxygen concentrators and other medical equipment such as ventilators. Filters are typically inserted into the gas sampling line to prevent a measuring equipment and it's system from becoming contaminated to reduce the risk of patient cross-contamination.
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 with polypropylene nonwoven layer (PP)</i> Frame/Housing Polymer: <i>Transparent Clear Polypropylene Homopolymer (PP)</i> <i>White Polypropylene Homopolymer (PP)</i> Colour: <i>Transparent with white overmould ring.</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

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	- Conflict minerals
PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <p>Physical/Mechanical Approximate dimensions: 54mm diameter x 61mm height. Weight: 11g (approx.). Interfaces (ex: Input / Output connectors): 5.9mm-8mm hose barbed both sides. Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Bidirectional Filter.</p> <p>Biological Pyrogenicity: <0.3 EU/ml Biocompatibility to ISO10993 Category - Surface device Contact - Skin Contact Duration - <24hrs</p> <p>Functional Air Flow Rate: Min. 55.6l/min @ 5 PSI (REP 1426/17 with 20% Factor of Safety applied to Min.) Filtration Efficiency: DEHS Filter Efficiency using 0.3 microns @ 15L/min: Min. 99.9% (REP: 1385/17 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.</p> <p>Cleanliness Device assembled within Clean Manufacturing Environment.</p> <p>Testing N/A</p>
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	<p>Product Certification required:</p> <ul style="list-style-type: none"> - CE mark - FDA <p>Applicable Standards and Technical Regulations: Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</p>

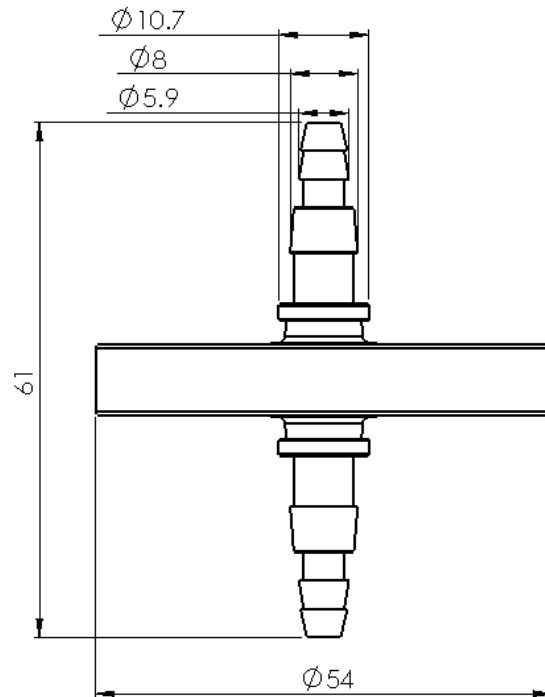
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	<p><i>Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration - BS EN 13274-7.</i></p> <p><i>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</i></p> <p><i>Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1.</i></p> <p><i>Sterilization of health care products – Ethylene oxide sterilization – ISO 11135-1.</i></p> <p><i>Sterilization of medical devices – Microbiological Methods – Part 1: Estimation of population of Microorganisms on products – ISO 11737-1.</i></p> <p><i>High Efficiency Air Filters – BS EN 1822.</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>

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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.

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	

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	8	Crack	0.65		
	9	Oil/grease	0.65		
	10	Wrong colour	0.65		
GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	<p>Special characteristic: <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i></p> <p>Special Characteristic # 01: <i>Air flow rate at 5PSI.</i></p> <p>Special Characteristic # 02: <i>Filter Efficiency @ 15L/min using DEHS @ 0.3µm EN 1822.</i></p>				
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)
07/09/2021	2	Sterilization information and intended use 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.