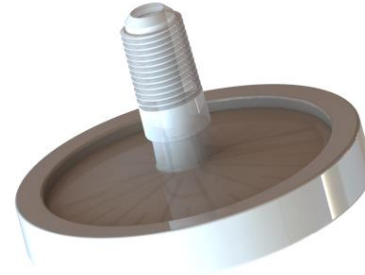


PRODUCT SPECIFICATION

Product P/N	2000/35	Mod. 984A Rev. 06
Description	Vent Filter	

2000/35

Vent Filter



PRODUCT DESCRIPTION	Inlet Outlet Connectors – 1/8th NPT Thread 25mm, 3.5mm diameter hole. Approx. Dimensions: 54mm diameter x 34mm 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.
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>Hydrophobic Glass Microfibre Media</i> Frame/Housing Polymer: <i>Transparent clear Polypropylene homopolymer (PP)</i> <i>White Polypropylene homopolymer (PP)</i> Colour: <i>Transparent White</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 CHARACTERISTICS	Appearance/Visual As shown on drawing.

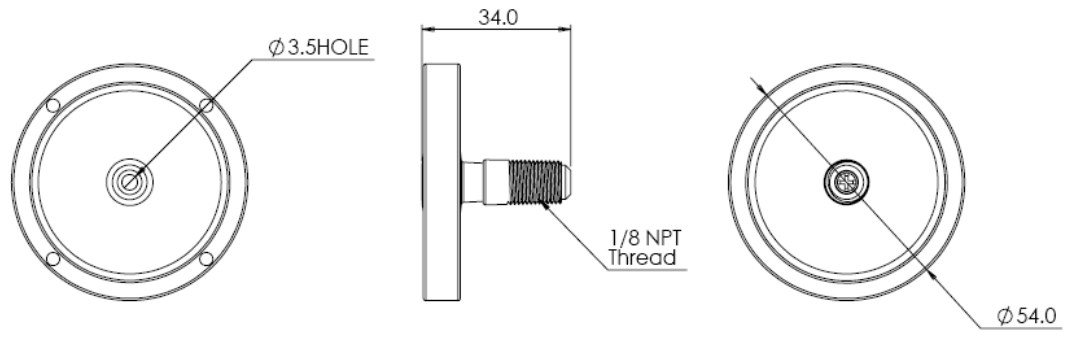
PRODUCT SPECIFICATION

Product P/N	2000/35	Mod. 984A
Description	Vent Filter	Rev. 06

	<p>Physical/Mechanical Approx. dimensions: 54mm diameter x 34mm height. Weight: 11gm (approx.). Interfaces (ex: Input / Output connectors): 1/8th NPT Thread and 3.5mm diameter hole. 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. 24 l/min @ 1PSI (REP: 2051/20 with 20% Factor of Safety applied to Min.) Filtration Efficiency: Filter Efficiency DEHS @ 0.3 microns @15L/min: Min. 99.99% (REP: 1383/17 with Factor of Safety applied to Min.) 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% (<i>Staphylococcus aureus</i> @ 30l/min) REP: EXT831477. Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (<i>Bacteriophage</i> @ 30l/min) REP: EXT831476.</p> <p>Cleanliness Device assembled within Clean Manufacturing Environment.</p> <p>Testing Static Head Test 27" for 1 minute (REP 0620/15)</p>
INSTRUCTIONS / WARNINGS	<i>IFU available in English language.</i>
PRODUCT SHELF LIFE	<i>5 years from the date of manufacture.</i> <i>Expiration date and date of manufacture are detailed on the product labelling.</i>
STERILIZATION	<i>N/A</i>
APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: <ul style="list-style-type: none"> - CE mark - FDA

PRODUCT SPECIFICATION

Product P/N	2000/35	Mod. 984A
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	<p>Applicable Standards and Technical Regulations: <i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i> <i>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</i> <i>Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1.</i> <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> <i>The first barcode label is applied to the outside of the bags.</i> <i>The second barcode label is applied onto the outside of the box.</i> <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> <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> <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> <div style="text-align: center; border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <p>Approximate dimensions for reference only</p> </div> 
ACCEPTABLE QUALITY LEVEL	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1

PRODUCT SPECIFICATION

Product P/N	2000/35	Mod. 984A
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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	

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 1psi*

Special Characteristic # 02: *Filter Efficiency @ 15L/min using DEHS @ 0.3µm*

Special Characteristic # 03: *Bacterial Filtration Efficiency in accordance with ASTM F2101-07
 Viral Filtration Efficiency in accordance with ASTM F2101-07*

Special Characteristic # 04: *27" water leak test – Static head test*



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



PRODUCT SPECIFICATION

Product P/N	2000/35	Mod. 984A
Description	Vent Filter	Rev. 06

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
15/09/2020	1	Initial release.	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.