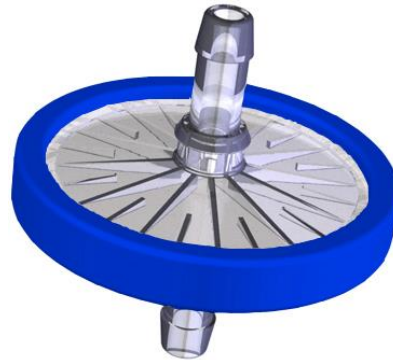


PRODUCT SPECIFICATION

Product P/N	2000/09	Mod. 984A Rev. 06
Description	Vent Filter	

2000/09

Vent Filter



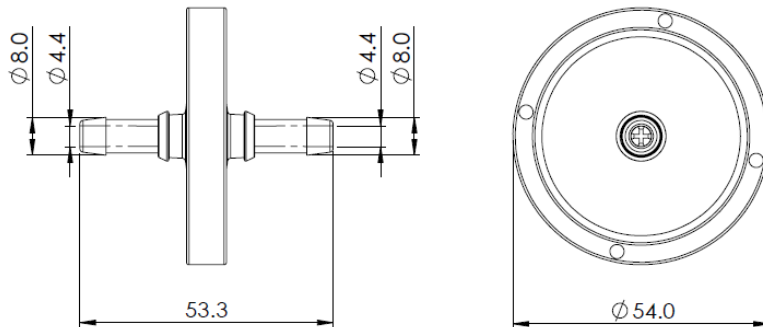
PRODUCT DESCRIPTION	Inlet Outlet Connectors – OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) - both sides. Approx. Dimensions: 54mm diameter x 53.3mm height. Weight: 11g (approx.). Bidirectional filter.
MANUFACTURER NAME	GVS Filter Technology UK NFC House Vickers Industrial Estate Mellishaw Lane, 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>Electrostatic Blended Synthetic Fibre</i> Frame/Housing Polymer: <i>Transparent Clear Polypropylene homopolymer (PP)</i> <i>Blue Polypropylene homopolymer (PP)</i> Colour: <i>Transparent with Reflex Blue 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 - Conflict minerals

PRODUCT SPECIFICATION

Product P/N	2000/09	Mod. 984A Rev. 06
Description	Vent Filter	

PRODUCT CHARACTERISTICS	Appearance/Visual As shown on drawing.
	Physical/Mechanical Approx. dimensions: 54mm diameter x 53.3mm height. Weight: 11gm (approx.). Interfaces (ex: Input / Output connectors): OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – 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.112 l/min @ 5PSI (REP:1437/18 with 20% Factor of Safety applied to Min.) Filtration Efficiency: Filter Efficiency DEHS @ 0.3 microns @ 15L/min: Min. 97.2% (REP: 1438/18 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. 99.9% (Staphylococcus aureus @ 30l/min) REP: EXT1073947-S01. Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99% (Bacteriophage @ 30l/min) REP: EXT1072934-S01.
INSTRUCTIONS / WARNINGS	Cleanliness Device assembled within Clean Manufacturing Environment.
PRODUCT SHELF LIFE	Testing N/A
	Multi-language IFU available.
	5 years from the date of manufacture.
	Expiration date and date of manufacture are detailed on the product labelling.

PRODUCT SPECIFICATION

Product P/N	2000/09	Mod. 984A Rev. 06
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STERILIZATION	N/A	
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required:</p> <ul style="list-style-type: none"> - CE mark - FDA <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>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>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> <div style="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: fit-content;"> Approximate dimensions for reference only </div>  <p>The drawing shows two views of the Vent Filter. The left view is a side elevation showing a central vertical rectangular body with two horizontal cylindrical ports on either side. Dimensions for the ports are given as outer diameter (Ø 8.0) and inner diameter (Ø 4.4). The total width of the device is 53.3. The right view is a top-down circular view of the filter, showing a central circular element surrounded by a ring with four mounting points. The overall diameter is 54.0.</p>	

PRODUCT SPECIFICATION



Product P/N	2000/09	Mod. 984A
Description	Vent Filter	Rev. 06

ACCEPTABLE QUALITY LEVEL	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1																																						
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="10">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>Short fill moulding</td><td>0.65</td></tr><tr><td>5</td><td>Rough surface or edges</td><td>0.65</td></tr><tr><td>6</td><td>Pronounced injection gate</td><td>0.65</td></tr><tr><td>7</td><td>Deformation/distortion</td><td>0.65</td></tr><tr><td>8</td><td>Crack</td><td>0.65</td></tr><tr><td>9</td><td>Oil/grease</td><td>0.65</td></tr><tr><td>10</td><td>Wrong colour</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	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
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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</i></p> <p>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></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.																																							

PRODUCT SPECIFICATION

Product P/N	2000/09	Mod. 984A Rev. 06
Description	Vent Filter	

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
10/09/2020	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.