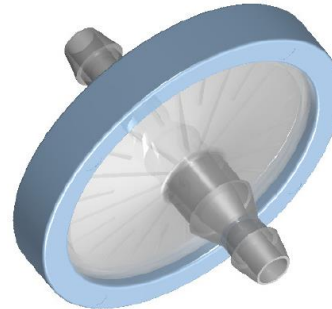


PRODUCT SPECIFICATION

Product P/N	2000/45	Mod. 984A
Description	Vent Filter	Rev. 06

2000/45

Vent Filter



PRODUCT DESCRIPTION	<p>Inlet/Outlet Connectors – OD 8mm (approx.) hose barbed and ID 4.8mm (approx.) - both sides</p> <p>Approx. dimensions: 54mm diameter x 51mm height</p> <p>Weight: 11g (approx.)</p> <p>Bidirectional filter</p>
MANUFACTURER NAME	<p>GVS Filter Technology UK</p> <p>NFC House Vickers Industrial Estate Mellishaw Lane, Morecambe Lancashire LA3 3EN - United Kingdom</p> <p>Information Tel. +44 (0) 1524 847600 e-mail: gvsuk@gvs.com</p>
INTENDED USE / APPLICATION	Filters, hydrophobic and non-hydrophobic for use within oxygen concentrators and other medical equipment such as ventilators.
CLASS OF THE PRODUCT	Non-classified device sold in bulk for further manufacturing.
MATERIALS	<p>Filter media: <i>Hydrophobic Glass Microfibre Media</i></p> <p>Frame/Housing Polymer: <i>Transparent Clear Polypropylene homopolymer (PP)</i> <i>Blue Polypropylene homopolymer (PP)</i></p> <p>Colour: <i>Transparent with Blue overmould ring</i></p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> - Biocompatibility according ISO 10993-1 - ROHS - BSE/TSE - DEHP plasticizer Free and latex free

PRODUCT SPECIFICATION

Product P/N	2000/45	Mod. 984A
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	<ul style="list-style-type: none"> - Aging - REACH - Conflict minerals
PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <p>Physical/Mechanical Dimensions (Approx.): 54mm diameter x 51mm height Weight: 11gm (approx.) Interfaces (ex: Input / Output connectors): OD 8mm (approx.) hose barbed and ID 4.8mm (approx.) – both sides</p> <p>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 - <24hr</p> <p>Functional Air Flow Rate: Min. 85 l/min @ 5PSI (REP 0612/15 with 20% Factor of Safety applied to Min.)</p> <p>Filtration Efficiency: Filter Efficiency DEHS @ 0.3 microns @ 15L/min: Min. 99.98% (REP: 1383/17 with Factor of Safety applied to Min.)</p> <p>Pressure Drop: N/A Internal Volume: N/A Operating Lifetime: N/A</p> <p>Shelf Lifetime: 5 years from the date of manufacture.</p> <p>Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (<i>Staphylococcus aureus</i> @ 30l/min) REP: EXT831477.</p> <p>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>

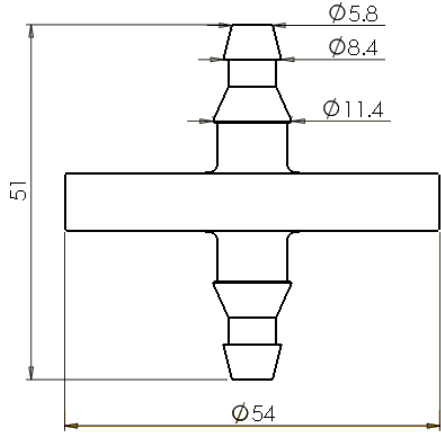
PRODUCT SPECIFICATION

Product P/N	2000/45	Mod. 984A
Description	Vent Filter	Rev. 06

	Testing Leakage: Static Head Test 27" for 1 minute (REP 0620/15)
INSTRUCTIONS / WARNINGS	No IFU required.
PRODUCT SHELF LIFE	5 years from the date of manufacture.
STERILIZATION	N/A.
APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: N/A. Applicable Standards and Technical Regulations: Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1. High Efficiency Air Filters – BS EN 1822.
PACKAGING AND LABELING	<p>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:</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>Different lots in one box are separately closed and separately labelled. Bulk products will be packed in double PE bags.</p>
CERTIFICATE OF COMPLIANCE	<p>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.</p> <p>The Quality management system is in compliance with ISO 9001, ISO 13485.</p>
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.

PRODUCT SPECIFICATION

Product P/N	2000/45	Mod. 984A
Description	Vent Filter	Rev. 06

	 <p>Approximate dimensions for reference only</p>
ACCEPTABLE QUALITY LEVEL	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1

PRODUCT SPECIFICATION

Product P/N	2000/45	Mod. 984A
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VISUAL REQUIREMENTS	Visual acceptance requirements apply when inspected under below conditions:																																					
	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>																																					
	<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	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 @ 15L/min using DEHS @ 0.3µm</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>27" water leak test – Static head test</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.																																						

PRODUCT SPECIFICATION

Product P/N	2000/45	Mod. 984A
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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
06/08/2021	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.