

# PRODUCT SPECIFICATION

Product P/N	2000/17	Mod. 984A Rev. 06
Description	Vent Filter	

**2000/17**

**Vent Filter**



<b>PRODUCT DESCRIPTION</b>	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.
<b>MANUFACTURER NAME</b>	<b>GVS Filter Technology UK</b> NFC House Vickers Industrial Estate Mellishaw Lane, Morecambe Lancashire LA3 3EN - United Kingdom  <b>Information</b> Tel. +44 (0) 1524 847600 e-mail: gvsuk@gvs.com
<b>INTENDED USE / APPLICATION</b>	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.
<b>CLASS OF THE PRODUCT</b>	Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC Rule 2 Annex VIII MDR 2017/745
<b>MATERIALS</b>	<b>Filter media: <i>Hydrophobic Glass Microfibre Media</i></b>  <b>Frame/Housing Polymer: <i>Transparent Clear Polypropylene homopolymer (PP)</i> <i>Yellow Polypropylene homopolymer (PP)</i></b>  <b>Colour: <i>Transparent with Yellow overmould ring</i></b>  <b>Regulatory Documentation Required:</b> <ul style="list-style-type: none"><li>- Biocompatibility according ISO 10993-1</li><li>- ROHS</li><li>- BSE/TSE</li><li>- DEHP plasticizer Free and latex free</li></ul>

# PRODUCT SPECIFICATION

Product P/N	2000/17	Mod. 984A Rev. 06
Description	Vent Filter	

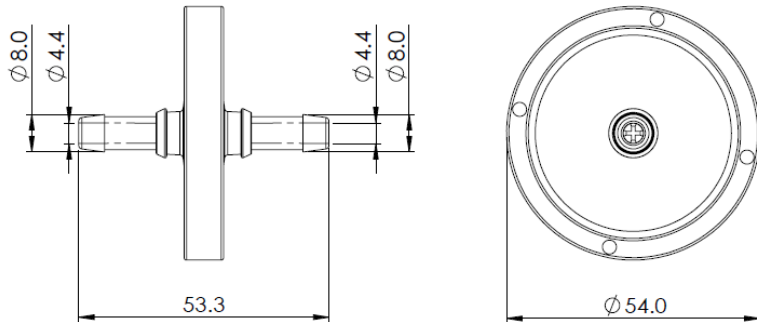
	<ul style="list-style-type: none"> <li>- Aging</li> <li>- REACH</li> <li>- Conflict minerals</li> </ul>
<b>PRODUCT CHARACTERISTICS</b>	<p><b>Appearance/Visual</b> As shown on drawing.</p> <p><b>Physical/Mechanical</b> Approx. dimensions: <b>54mm diameter x 53.3mm height.</b> Weight: <b>11gm (approx.).</b> Interfaces (ex: Input / Output connectors): <b>OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) – both sides.</b> Operating temperature Range: <b>N/A</b> Storage temperature Range: <b>5 °C to 40 °C</b> <b>Bidirectional Filter.</b></p> <p><b>Biological</b> Pyrogenicity: <b>&lt;0.3 Eu/ml</b> <b>Biocompatibility to ISO10993</b> Category – <b>Surface device</b> Contact – <b>Skin</b> Contact Duration - <b>&lt;24hrs</b></p> <p><b>Functional</b> Air Flow Rate: <b>Min. 85 l/min @ 5PSI</b> (Ref 2000/05 REP 0612/15 with 20% Factor of Safety applied to Min.) Filtration Efficiency: <b>Filter Efficiency DEHS @ 0.3 microns @ 15L/min: Min. 99.99%</b> (Ref. 2000/05 REP: 1383/17 with Factor of Safety applied to Min.) Pressure Drop: <b>N/A</b> Internal Volume: <b>N/A</b> Operating Lifetime: <b>Refer to Instructions for Use.</b> Shelf Lifetime: <b>5 years from the date of manufacture.</b>  <b>Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%</b> (<i>Staphylococcus aureus</i> @ 30l/min) Ref.2000/05 REP: EXT831477.  <b>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%</b> (<i>Bacteriophage</i> @ 30l/min) Ref.2000/05 REP: EXT831476.  <b>Cleanliness</b> Device assembled within Clean Manufacturing Environment.</p> <p><b>Testing</b> Burst test: <b>Min. 64psi</b> (REP 0616/15 with 20% Factor of Safety) Leakage: <b>Static Head Test 27" for 1 minute</b> (REP 0620/15)</p>

# PRODUCT SPECIFICATION

<b>Product P/N</b>	<b>2000/17</b>	<b>Mod. 984A Rev. 06</b>
<b>Description</b>	<b>Vent Filter</b>	
<b>INSTRUCTIONS / WARNINGS</b>	<i>Multi-language IFU available.</i>	
<b>PRODUCT SHELF LIFE</b>	<i>5 years from the date of manufacture.</i> <i>Expiration date and date of manufacture are detailed on the product labelling.</i>	
<b>STERILIZATION</b>	<i>N/A</i>	
<b>APPLICABLE STANDARDS AND REGULATIONS</b>	<p><b>Product Certification required:</b></p> <ul style="list-style-type: none"> <li>- CE mark</li> <li>- FDA</li> </ul> <p><b>Applicable Standards and Technical Regulations:</b></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>	
<b>PACKAGING AND LABELING</b>	<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"> <li>✓ Quantity</li> <li>✓ Product description</li> <li>✓ Product Date</li> <li>✓ Lot Number (OL and 5-digit batch number to trace back to raw materials used)</li> <li>✓ Operator Code</li> </ul> <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>	
<b>CERTIFICATE OF COMPLIANCE</b>	<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>	
<b>DRAWING</b>	<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;"> <p>Approximate dimensions for reference only</p> </div>	

# PRODUCT SPECIFICATION

Product P/N	2000/17	Mod. 984A Rev. 06
Description	Vent Filter	



																																				
ACCEPTABLE QUALITY LEVEL	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1																																			
VISUAL REQUIREMENTS	<p><b>Visual acceptance requirements apply when inspected under below conditions:</b></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
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	<p><b>Special characteristic:</b> <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i></p> <p><b>Special Characteristic # 01:</b> <i>Air Flow rate at 5psi</i></p>																																			

# PRODUCT SPECIFICATION

Product P/N	2000/17	Mod. 984A Rev. 06
Description	Vent Filter	

	<b>Special Characteristic # 02:</b> <i>Filter Efficiency @ 15L/min using DEHS @ 0.3µm</i> <b>Special Characteristic # 03:</b> <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07</i> <i>Viral Filtration Efficiency in accordance with ASTM F2101-07</i> <b>Special Characteristic # 04:</b> <i>Burst Pressure</i> <b>Special Characteristic # 05:</b> <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.	

## REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
27/08/2021	2	Intended use amended.	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.