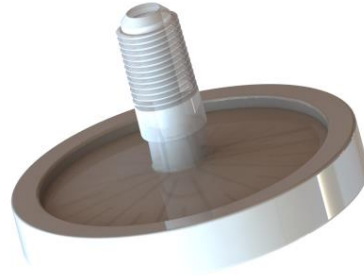


PRODUCT SPECIFICATION

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 vent 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. 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>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

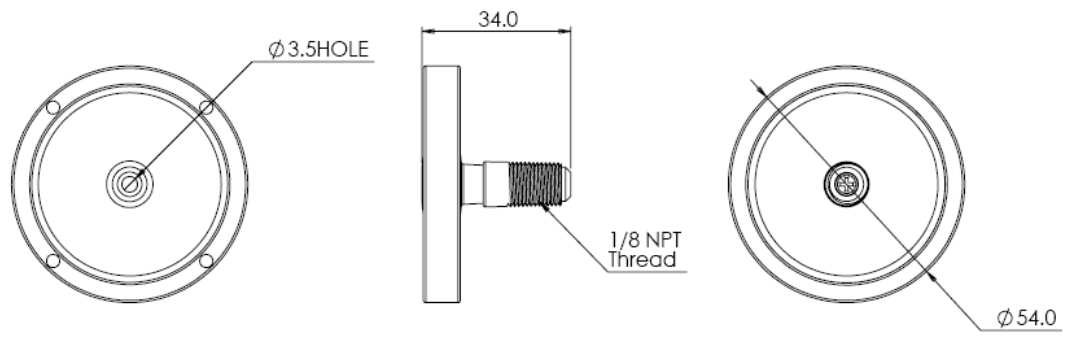
PRODUCT SPECIFICATION

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

PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <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 vent 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% (Ref. 2000/05 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. <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%</i> (<i>Staphylococcus aureus @ 30l/min</i>) Ref. 2000/05 REP: EXT831477. <i>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%</i> (<i>Bacteriophage @ 30l/min</i>) Ref. 2000/05 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>Multi-language IFU available.</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>

PRODUCT SPECIFICATION

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

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;"> <p>Approximate dimensions for reference only</p> </div> 

PRODUCT SPECIFICATION

Product P/N	2000/35	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 border="1"> <thead> <tr> <th colspan="2">Acceptance Requirement</th> <th>AQL</th> <th>Sampling Plan</th> </tr> </thead> <tbody> <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> </tbody> </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>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 1psi</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> <p>Special Characteristic # 04: <i>27" water leak test – Static head test</i></p>																																			
<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.</p>																																				



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)
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.