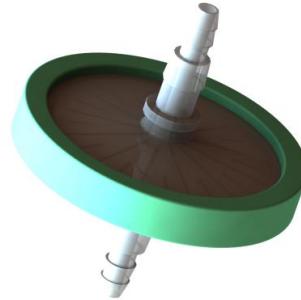


PRODUCT SPECIFICATION

Product P/N	2000/08	Mod. 984A Rev. 06
Description	Vent Filter	

2000/08

Vent Filter



PRODUCT DESCRIPTION	Inlet Outlet Connectors: 5.9mm-8mm hose barbed both sides. Approximate dimensions: 54mm diameter x 61mm 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. Autoclavable - Normal cycle 3 minutes at 134°C. Maximum Autoclave cycles: 10.
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>Green Polypropylene Homopolymer (PP)</i> Colour: <i>Transparent with Green 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	2000/08	Mod. 984A Rev. 06
Description	Vent Filter	

PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <p>Physical/Mechanical Approximate dimensions: 54mm diameter x 61mm height. Weight: 11g (approx.). Interfaces (ex: Input / Output connectors): 5.9mm-8mm hose barbed both sides. 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. 34.7 l/min @ 5 PSI (REP: 0665/15 with 20% Factor of Safety applied to Min.) Filtration Efficiency: DEHS Filter Efficiency using 0.3 microns @ 15L/min: Min. 99.99% (REP: 1383/17 with Factor of Safety) 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 Leakage: 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. Expiration date and date of manufacture are detailed on the product labelling.</i>
STERILIZATION	<i>N/A</i>

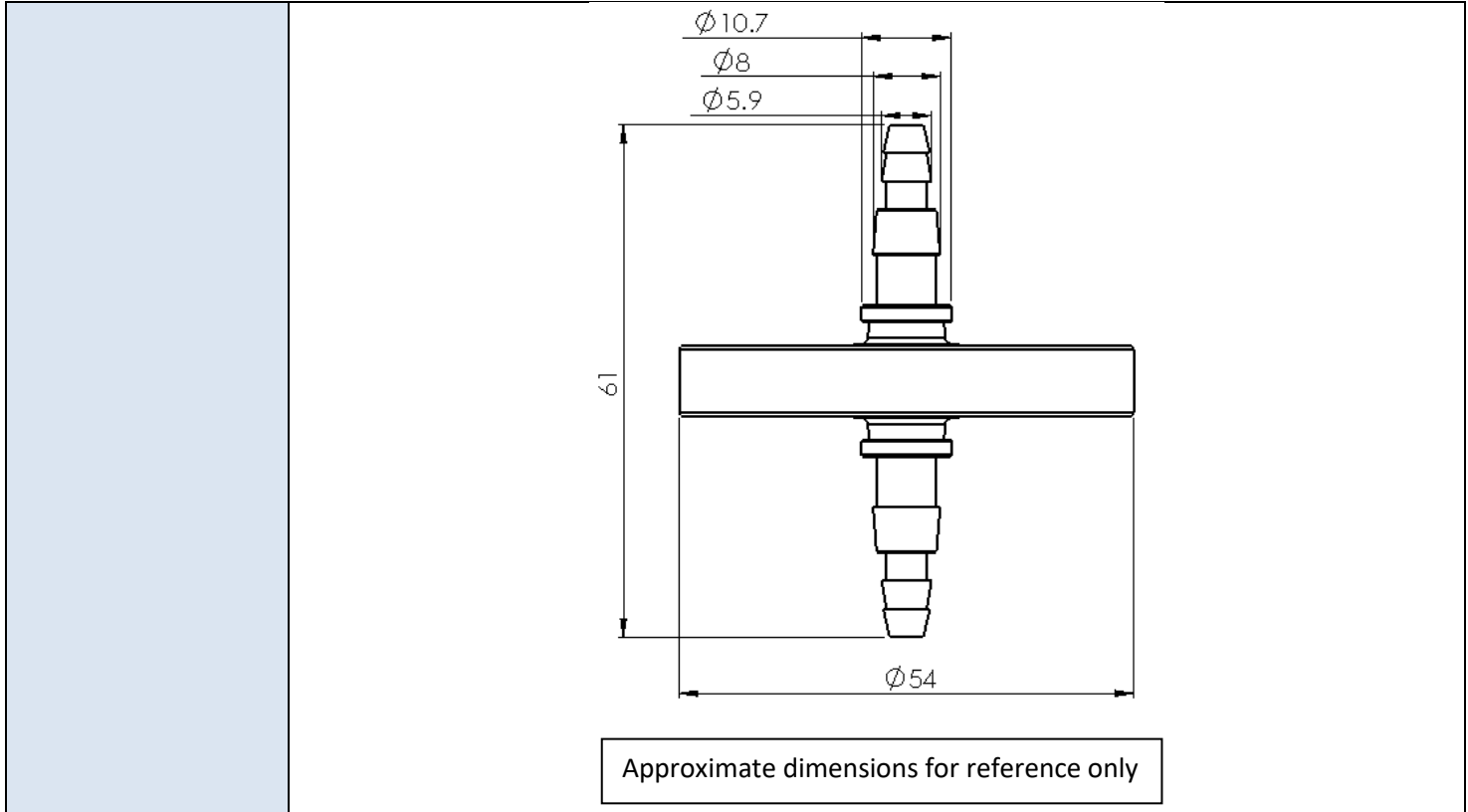
PRODUCT SPECIFICATION

Product P/N	2000/08	Mod. 984A Rev. 06
Description	Vent Filter	

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>Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration - BS EN 13274-7.</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>
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>

PRODUCT SPECIFICATION

Product P/N	2000/08	Mod. 984A Rev. 06
Description	Vent Filter	



ACCEPTABLE QUALITY LEVEL AQL: 0.65 with sampling Plan: ISO2859.

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	

PRODUCT SPECIFICATION

Product P/N	2000/08	Mod. 984A Rev. 06
Description	Vent Filter	

	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 5PSI</i></p> <p>Special Characteristic # 02: <i>Filter Efficiency @ 15L/min using DEHS @ 0.3µm EN 1822.</i></p> <p>Special Characteristic # 03: <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07 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>
--	---

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)
10/09/2020	1	Initial release.	Kinga Gawdzik – Engineering Support Technician 	Andrew Pearce – Quality Manager 



PRODUCT SPECIFICATION

Product P/N	2000/08	Mod. 984A Rev. 06
Description	Vent Filter	

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.