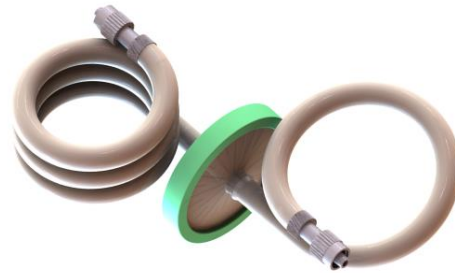


PRODUCT SPECIFICATION

Product P/N	2000/05BAK	Mod. 984A Rev. 06
Description	Vent Filter set	

2000/05BAK

Vent Filter set



PRODUCT DESCRIPTION	<p>Inlet Outlet Connectors: 2000/05 – OD 8mm (approx.) hose barbed and ID 4.4mm (approx.) - both sides.</p> <p>Approx. Dimensions: 54mm diameter x 53.3mm height.</p> <p>Weight: 11g (approx.).</p> <p>Bidirectional filter.</p> <p>This filter has PVC tubing OD 9mm and ID 6mm attached to both connectors, 600mm tubing on one side and 2500mm tubing on the other side. Both pieces of tubing have mobile luer locks attached to their ends.</p>
MANUFACTURER NAME	<p>GVS Filter Technology UK 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	<p>Disposable medical device - Class IIa</p> <p>Rule 2 Annex IX 93/42 / EEC</p> <p>Rule 2 Annex VIII MDR 2017/745</p>
MATERIALS	<p>Filter media: <i>Hydrophobic Glass Microfibre Media</i></p> <p>Frame/Housing Polymer: <i>2000/05: Transparent Clear Polypropylene homopolymer (PP)</i> <i>Green Polypropylene homopolymer (PP)</i></p> <p>Colour: <i>Transparent with Green overmould ring</i></p> <p>Other insert(s): <i>Tube: PVC</i> <i>Mobile luer lock: Acrylonitrile Butadiene Styrene (ABS)</i> <i>Adhesive: UV curable adhesive</i></p> <p>Regulatory Documentation Required: - Biocompatibility according ISO 10993-1</p>

PRODUCT SPECIFICATION

Product P/N	2000/05BAK	Mod. 984A Rev. 06
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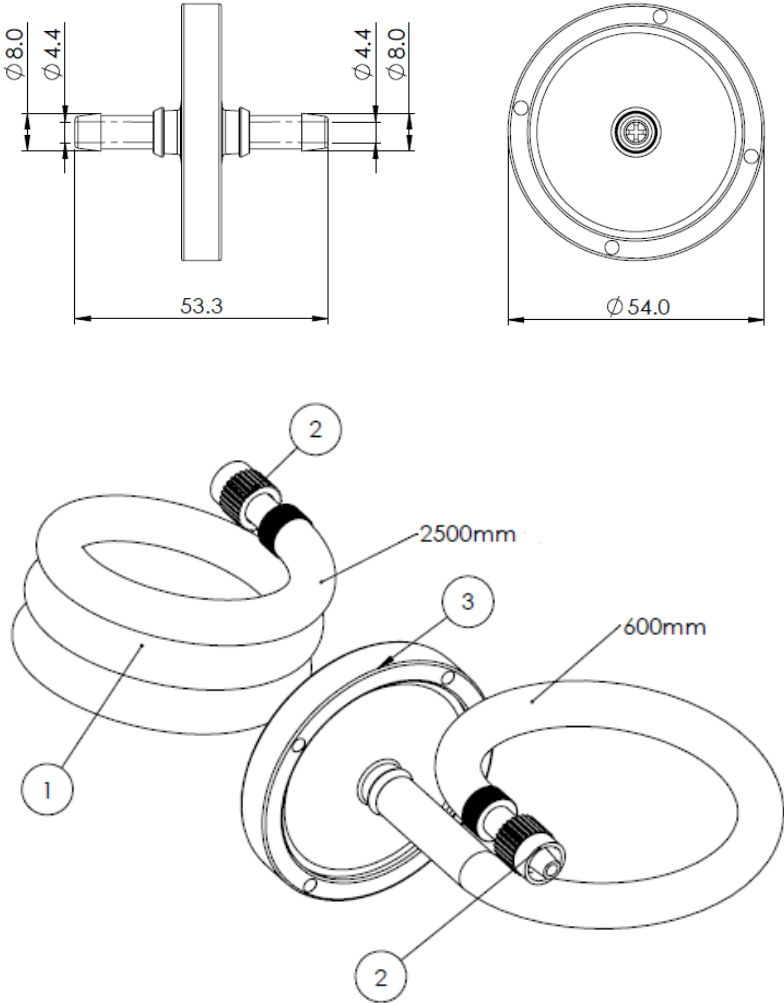
	<ul style="list-style-type: none"> - ROHS - BSE/TSE - DEHP plasticizer Free and latex free - Aging - REACH - Conflict minerals
PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <p>Physical/Mechanical Dimensions (Approx.): 2000/05: 54mm diameter x 53.3mm height. PVC tube: OD 9mm and ID 6mm, 600mm length and 2500mm length. Weight of filter: 11gm (approx.).</p> <p>Interfaces (ex: Input / Output connectors): OD 8mm (approx.) hose barbed and ID 4.4mm (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 - <24hrs</p> <p>For kit performance characteristics for 2000/05BAK– Please refer to 2000/05 Technical data sheet.</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. 99.99% (REP: 1383/17 with Factor of Safety applied to Min.)</p> <p>Pressure Drop: Flow Resistance @ 15l/min in accordance with EN ISO 9360-1: Max. 1925Pa (REP: 1383/17 with 10% Factor of Safety applied to Max.)</p> <p>Internal Volume: N/A</p> <p>Operating Lifetime: Refer to Instructions for Use.</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>

PRODUCT SPECIFICATION

Product P/N	2000/05BAK	Mod. 984A
Description	Vent Filter set	Rev. 06
	<p><i>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (Bacteriophage @ 30l/min) REP: EXT831476.</i></p> <p>Cleanliness Device assembled within Clean Manufacturing Environment.</p> <p>Testing Burst test: Min. 64psi (REP 0616/15 with 20% Factor of Safety) Leakage: Static Head Test 27" for 1 minute (REP 0620/15)</p>	
INSTRUCTIONS / WARNINGS	<i>Multi-language IFU available.</i>	
PRODUCT SHELF LIFE	<p><i>5 years from the date of manufacture.</i></p> <p><i>Expiration date and date of manufacture are detailed on the product labelling.</i></p>	
STERILIZATION	<i>Device can be sterilised with EtO (Ethylene oxide - Max 55°C)</i>	
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required:</p> <ul style="list-style-type: none"> - CE mark - FDA <p>Applicable Standards and Technical Regulations: <i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i> <i>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</i> <i>Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1.</i> <i>Sterilization of health care products – Ethylene oxide sterilization – ISO 11135-1.</i> <i>Sterilization of medical devices – Microbiological Methods – Part 1: Estimation of population of Microorganisms on products – ISO 11737-1.</i> <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> <i>The first barcode label is applied to the outside of the bags.</i> <i>The second barcode label is applied onto the outside of the box.</i> <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> <i>Bulk products will be packed in double PE bags.</i></p>	
CERTIFICATE OF COMPLIANCE	<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>	

PRODUCT SPECIFICATION

Product P/N	2000/05BAK	Mod. 984A Rev. 06
Description	Vent Filter set	

	<p>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	<p>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.</p>  <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	2000/05BAK	Mod. 984A
Description	Vent Filter set	Rev. 06

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	
7	Deformation/distortion	0.65	
8	Crack	0.65	
9	Oil/grease	0.65	
10	Wrong colour	0.65	

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

Special characteristic: *Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.*

Special Characteristic # 01: *Air Flow rate at 5psi*

Special Characteristic # 02: *Filter Efficiency @ 15L/min using DEHS @ 0.3µm*

Special Characteristic # 03: *Bacterial Filtration Efficiency in accordance with ASTM F2101-07*

Viral Filtration Efficiency in accordance with ASTM F2101-07

Special Characteristic # 04: *Burst Pressure*



Special Characteristic # 05: *27" water leak test – Static head test*

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	2000/05BAK	Mod. 984A
Description	Vent Filter set	Rev. 06

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.