

# PRODUCT SPECIFICATION

Product P/N	2000/25	Mod. 984A Rev. 06
Description	Vent Filter	

## 2000/25 Vent Filter



<b>PRODUCT DESCRIPTION</b>	Inlet/Outlet Connectors: Male cone ID 2.45mm diameter OD 3.95mm diameter, female cone ID 4.3mm diameter (approx.) Approx. dimensions: 27.4mm external diameter x 22.2mm height. Weight: 2.4gm (approx.) Unidirectional 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.
<b>CLASS OF THE PRODUCT</b>	Non-classified device sold in bulk for further manufacturing.
<b>MATERIALS</b>	<b>Filter media: <i>Hydrophobic Membrane PTFE 1,0µm on a non-woven Polyester Support</i></b>  <b>Frame/Housing Polymer: <i>PVC</i></b>  <b>Colour: <i>Male cone clear, female cone with blue colorant</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><li>- Aging</li><li>- REACH</li><li>- Conflict minerals</li></ul>
<b>PRODUCT CHARACTERISTICS</b>	<b>Appearance/Visual</b> As shown on drawing.

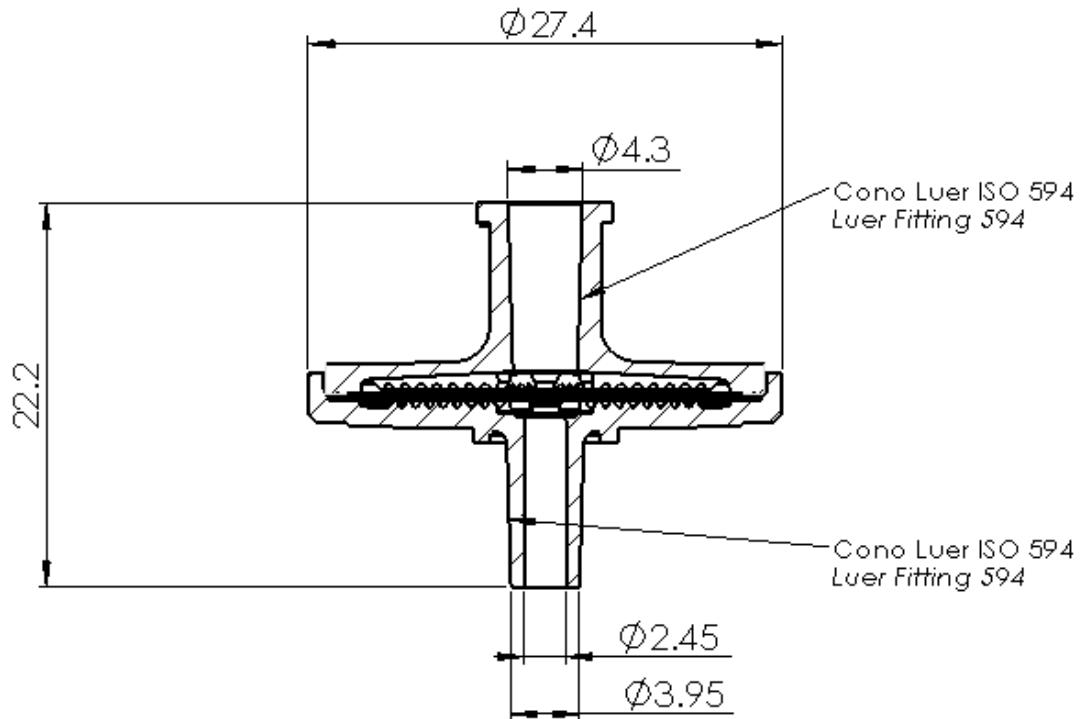
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	<p><b>Physical/Mechanical</b>  Approx. Dimensions: <b>27.4mm external diameter x 22.2mm height.</b>  Weight: <b>2.4gm (approx.)</b>  Interfaces (ex: Input / Output connectors): <b>Male cone ID 2.45 diameter OD 3.95mm diameter, female cone ID 4.3mm diameter (approx.)</b>  Operating temperature Range: <b>N/A</b>  Storage temperature Range: <b>5 °C to 40 °C</b>  <b>Unidirectional 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>Pressure 50 mm/H<sub>2</sub>O ≥ 100 ml/min.</b>  Pressure Drop: <b>N/A</b>  Internal Volume: <b>N/A</b>  Operating Lifetime: <b>N/A</b>  Shelf Lifetime: <b>5 years from the date of manufacture.</b></p> <p><b>Cleanliness</b>  Device assembled within Class 8 Cleanroom.</p> <p><b>Testing</b>  Burst test: <b>3 bar @ 15 sec</b></p>
INSTRUCTIONS / WARNINGS	No IFU required.
PRODUCT SHELF LIFE	5 years from the date of manufacture.
STERILIZATION	N/A
APPLICABLE STANDARDS AND REGULATIONS	<p><b>Product Certification required:</b>  N/A</p> <p><b>Applicable Standards and Technical Regulations:</b>  Dimensions of luer cones comply with ISO 80369-7.</p> <p>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</p>
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"> <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> </ul>

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	<p>✓ Operator Code</p> <p><i>Different lots in one box are separately closed and separately labelled. Bulk products will be packaged 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. 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>  <p>The drawing shows a cross-section of a Vent Filter. It features a central vertical tube with a horizontal filter element in the middle. The top of the tube has a Luer fitting. Dimensions are indicated: a total height of 22.2, a top diameter of Ø27.4, a fitting diameter of Ø4.3, a bottom diameter of Ø2.45, and a base diameter of Ø3.95. Two labels point to the top and bottom fittings, both reading 'Cono Luer ISO 594 Luer Fitting 594'.</p> <p>Approximate dimensions for reference only</p>
<b>ACCEPTABLE QUALITY LEVEL</b>	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1
<b>VISUAL REQUIREMENTS</b>	<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></p> <p>Light type: <i>Lighting level must be reasonable for visual detection.</i></p> <p>Timings: <i>Maximum inspection period per item is 25 seconds.</i></p> <p><i>For detailed defect list, refer to product control plan.</i></p>

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	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	
	11	Weld fault	0.65	
	12	Weld marks	0.65	
GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	<b>Special characteristic:</b> <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i>			
	<b>Special Characteristic # 01:</b> <i>Air Flow rate at 50mm/H<sub>2</sub>O.</i>			
	<b>Special Characteristic # 02:</b> <i>Burst Pressure.</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.				

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## REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
03/09/2021	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.