

# PRODUCT SPECIFICATION

Product P/N	2200/70	Mod. 984A Rev. 06
Description	Suction Filter	

**2200/70**

**Suction Filter**



<b>PRODUCT DESCRIPTION</b>	<p>Inlet/Outlet Connectors: IN - 8.1mm conical, OUT - 12mm hose barbed.          Approx. dimensions: 65mm diameter x 60.3mm height.          Flow direction indicated by "IN" marking on filter face.          Weight: 17gm (approx.).          Unidirectional filter.</p>
<b>MANUFACTURER NAME</b>	<p><b>GVS Filter Technology UK</b>          NFC House          Vickers Industrial Estate          Mellishaw Lane, Morecambe          Lancashire LA3 3EN - United Kingdom</p> <p><b>Information</b>          Tel. +44 (0) 1524 847600          e-mail: gvsuk@gvs.com</p>
<b>INTENDED USE / APPLICATION</b>	The hydrophobic filter protects surgical suction vacuum pump equipment from contamination.
<b>CLASS OF THE PRODUCT</b>	<p>Disposable medical device - Class IIa          Rule 2 Annex IX 93/42 / EEC          Rule 2 Annex VIII MDR 2017/745</p>
<b>MATERIALS</b>	<p><b>Filter media:</b> <i>Hydrophobic PTFE 1.0µm</i></p> <p><b>Frame/Housing Polymer:</b> <i>Clear Styrene-Butadiene Copolymer (SBC)</i></p> <p><b>Colour:</b> <i>Transparent Clear.</i></p> <p><b>Regulatory Documentation Required:</b></p> <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>

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PRODUCT CHARACTERISTICS	<p><b>Appearance/Visual</b> As shown on drawing.</p> <p><b>Physical/Mechanical</b> Approx. dimensions: <b>65mm diameter x 60.3mm height.</b> Weight: <b>17gm (approx.).</b> Interfaces (ex: Input / Output connectors): <b>IN - 8.1mm conical, OUT - 12mm hose barbed.</b> Operating temperature Range: <b>N/A</b> Storage temperature Range: <b>5 °C to 40 °C</b> <b>Unidirectional Filter.</b> <b>Flow direction indicated by "IN" marking on filter face.</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. 26l/min @ 1PSI</b> (REP: 2219/21 with 20% Factor of Safety applied to Min.) Water Break Through Pressure: <b>0.8bar (600mmHG) Vacuum for 20s</b> (REP:2220/21) Filtration Efficiency: <b>Filter Efficiency @ 30L/min using DEHS @0.3µm: Min.99.99%</b> (Ref.2200/02 REP: 0696/16 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 /minute) Ref.2200/02 REP: EXT846022-S01  <b>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%</b> (<i>Bacteriophage</i> @ 30L / minute) Ref.2200/02 REP: EXT846021-S01</p> <p><b>Cleanliness</b> Device assembled within Class 8 Cleanroom.</p> <p><b>Testing</b> Burst test: <b>Min.15.4 psi</b> (REP: 2221/21 with 20% Factor of Safety applied to Min.)</p>
	<p><b>INSTRUCTIONS / WARNINGS</b> Multi-language IFU available.</p>
	<p><b>PRODUCT SHELF LIFE</b> 5 years from the date of manufacture. Expiration date and date of manufacture are detailed on the product labelling.</p>

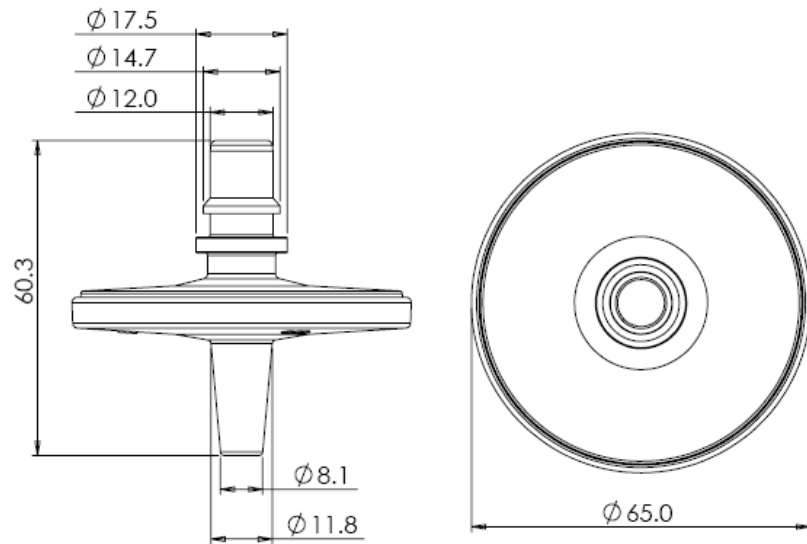
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<b>STERILIZATION</b>	N/A
<b>APPLICABLE STANDARDS AND REGULATIONS</b>	<p><b>Product Certification required:</b></p> <ul style="list-style-type: none"> <li>- CE mark</li> <li>- FDA</li> </ul> <p><b>Applicable Standards and Technical Regulations:</b></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 – Part 1: 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 packaged in double PE bags</i></p>
<b>CERTIFICATE OF COMPLIANCE</b>	<p><i>With each shipment, GVS UK Customer Service will send the CoC 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>	<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>

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Approximate dimensions for reference only

## ACCEPTABLE QUALITY LEVEL

AQL: with sampling Plan: 0.65 AQL to ISO 2859-1

## 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	

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	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 1psi.</i>			
	<b>Special Characteristic # 02:</b> <i>Filter Efficiency @ 30L/min using DEHS @ 0.3µm in accordance with High Efficiency Air Filters – BS EN 1822.</i>			
	<b>Special Characteristic # 03:</b> <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07, Viral Filtration Efficiency in accordance with ASTM F2101-07.</i>			
	<b>Special Characteristic # 04:</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.				

## REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
07/09/2021	2	IFU section amended on Mod.984.	Kinga Gawdzik - Engineering Support Technician 	Andrew Pearce – Quality Manager 

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## 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.*