

PRODUCT SPECIFICATION

Product P/N	2200/55	Mod. 984A Rev. 06
Description	Suction Atmos Filter	

2200/55

**Suction Atmos
Filter**



PRODUCT DESCRIPTION	<p>Inlet/Outlet Connectors: IN - 8.6mm hose plain, OUT - 12mm hose straight. Approx. dimensions: 65mm diameter x 42.2mm height. Flow direction indicated by "IN" marking on filter face. Weight: 17gm (approx.). Unidirectional filter.</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	The hydrophobic filter protects surgical suction vacuum pump equipment from contamination.
CLASS OF THE PRODUCT	<p>Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC Rule 2 Annex VIII MDR 2017/745</p>
MATERIALS	<p>Filter media: <i>Hydrophobic PTFE 1.0µm</i></p> <p>Frame/Housing Polymer: <i>Clear Styrene-Butadiene Copolymer (SBC)</i></p> <p>Colour: <i>Transparent Clear</i></p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> - Biocompatibility according to ISO 10993-1 - ROHS - BSE/TSE - DEHP plasticizer Free and latex free - Aging - REACH - Conflict minerals

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PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <p>Physical/Mechanical Approx. dimensions: 65mm diameter x 42.2mm height. Weight: 17gm (approx.).</p> <p>Interfaces (ex: Input / Output connectors): IN - 8.6mm hose plain, OUT - 12mm hose straight Connectors.</p> <p>Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Unidirectional Filter. Flow direction indicated by "IN" marking on filter face.</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. 29 l/min @ 1PSI (REP: 2192/20 with 20% Factor of Safety applied to Min.) Water Break Through Pressure: 0.8bar (600mmHG) Vacuum for 20s (REP: 2194/20)</p> <p>Filtration Efficiency: Filter Efficiency @ 30L/min using DEHS @0.3µm: Min.99.99% (Ref.2200/02 REP: 0696/16 with Factor of Safety applied to Min.)</p> <p>Pressure Drop: N/A Internal Volume: N/A Operating Lifetime: Refer to Instructions for Use. 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 /minute) Ref.2200/02 REP: EXT846022-S01</p> <p>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (<i>Bacteriophage</i> @ 30L/ minute) Ref.2200/02 REP: EXT846021-S01</p> <p>Cleanliness Device assembled within Class 8 Cleanroom.</p> <p>Testing Burst test: Min. 37.1psi (REP: 2193/20 with 20% Factor of Safety applied to Min.)</p>
	<p>INSTRUCTIONS / WARNINGS Multi-language IFU available.</p>

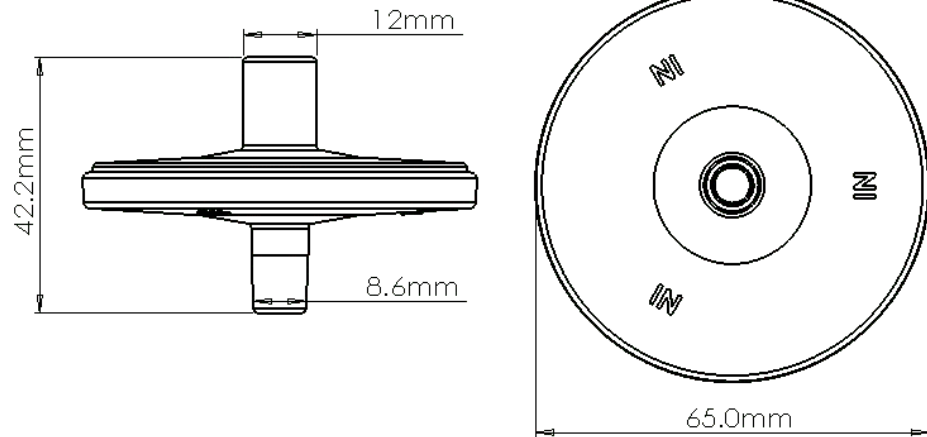
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PRODUCT SHELF LIFE	<p>5 years from the date of manufacture.</p> <p>Expiration date and date of manufacture are detailed on the product labelling.</p>
STERILIZATION	N/A
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required:</p> <ul style="list-style-type: none"> - CE mark - FDA <p>Applicable Standards and Technical Regulations:</p> <p>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</p> <p>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</p> <p>Medical devices – symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements - ISO 15223-1.</p> <p>High Efficiency Air Filters – BS EN 1822.</p>
PACKAGING AND LABELING	<p>Number of pcs per bag is determined by the sales order.</p> <p>The first barcode label is applied to the outside of the bags.</p> <p>The second barcode label is applied onto the outside of the box.</p> <p>Each bag is labelled with the following traceability information:</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>Different lots in one box are separately closed and separately labelled.</p> <p>Bulk products will be packaged in double PE bags</p>
CERTIFICATE OF COMPLIANCE	<p>With each shipment, GVS UK Customer Service will send the CofC to the Customer, based on the lot numbers and date of manufacture.</p> <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>

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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	
9	Oil/grease	0.65	

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	10	Wrong colour	0.65	
	11	Weld fault	0.65	
	12	Weld marks	0.65	
GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	Special characteristic: <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i>			
	Special Characteristic # 01: <i>Air Flow rate at 1psi.</i>			
	Special Characteristic # 02: <i>Filter Efficiency @ 30L/min using DEHS @ 0.3µm in accordance with High Efficiency Air Filters – BS EN 1822.</i>			
	Special Characteristic # 03: <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07 Viral Filtration Efficiency in accordance with ASTM F2101-07.</i>			
	Special Characteristic # 04: <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.