

PRODUCT SPECIFICATION

Product P/N	2200/60	Mod. 984A
Description	Suction Filter	Rev. 06

2200/60

Suction Filter



PRODUCT DESCRIPTION	Connectors - IN 11mm-15mm hose barb, OUT 18mm conical. Approx. dimensions 65mm diameter x 56mm height. Flow direction indicated by IN marking on filter face. Weight 17gm (approx.) Unidirectional 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	The hydrophobic filter protects surgical suction vacuum pump equipment from contamination.
CLASS OF THE PRODUCT	Non-classified device sold in bulk for further manufacturing.
MATERIALS	Filter media: <i>Hydrophobic PTFE 1.0µm</i> Frame/Housing Polymer: <i>Clear Styrene-Butadiene Copolymer</i> Colour: <i>Transparent Clear</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

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- Conflict minerals

PRODUCT CHARACTERISTICS

Appearance/Visual

As shown on drawing.

Physical/Mechanical

Approx. Dimensions: **65mm diameter x 56mm height.**

Weight: **17gm (approx.)**

Interfaces (ex: Input / Output connectors): **IN 11mm-15mm hose barb, OUT 18mm conical**

Operating temperature Range: **N/A**

Storage temperature Range: **5 °C to 40 °C**

Unidirectional Filter.

Flow direction indicated by IN marking on filter face.

Biological

Pyrogenicity: **<0.3 EU/ml**

Biocompatibility to ISO10993

Category – Surface device

Contact – Skin

Contact Duration - <24hrs

Functional

Air Flow Rate: **Min. 31.4 l/min @ 1PSI** (REP: 2195/20 with 20% Factor of Safety applied to Min.)

Water Break Through Pressure: **0.8bar (600mmHG) Vacuum for 20s** (REP: 2197/20)

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.)

Pressure Drop: **N/A**

Internal Volume: **N/A**

Operating Lifetime: **N/A**

Shelf Lifetime: **5 years from the date of manufacture.**

Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%

(*Staphylococcus aureus* @ 30L /minute) Ref.2200/02 REP: EXT846022-S01

Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%

(*Bacteriophage* @ 30L/ minute) Ref.2200/02 REP: EXT846021-S01

Cleanliness

Device assembled within Class 8 Cleanroom.

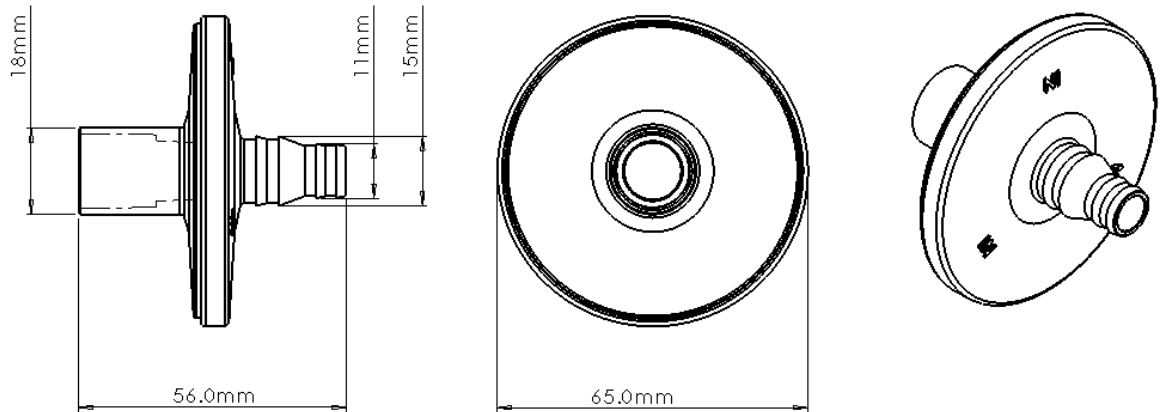
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	Testing Burst test: Min. 22.4psi (REP: 2196/20 with 20% Factor of Safety applied to Min.)
INSTRUCTIONS / WARNINGS	<i>No IFU required.</i>
PRODUCT SHELF LIFE	<i>5 years from the date of manufacture.</i>
STERILIZATION	<i>N/A</i>
APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: <i>N/A.</i> Applicable Standards and Technical Regulations: <i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i> <i>High Efficiency Air Filters – BS EN 1822.</i>
PACKAGING AND LABELING	<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> <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 <i>Different lots in one box are separately closed and separately labelled.</i> <i>Bulk products will be packaged in double PE bags</i>
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> <i>Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1.</i> <i>The Quality management system is in compliance with ISO 9001, ISO 13485.</i>
DRAWING	<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	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)
06/09/2021	1	Initial release.	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.