

PRODUCT SPECIFICATION

Product P/N	2200/16	Mod. 984
Description	Suction Filter	Rev. 05

2200/16 Suction Filter



PRODUCT DESCRIPTION SUMMARY	Suction Filter Connectors – 11mm to 15mm hose barbed both sides Flow direction indicated by IN marking on filter face Dimensions: 65mm diameter x 56mm length (Approx.) Weight 17g (approx.)
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 Fax: +44 (0) 1524 847800 e-mail: gvsuk@gvs.com
INTENDED USE / APPLICATION	The hydrophobic filter protects surgical suction vacuum pump equipment from contamination.
CLASS OF THE PRODUCT	Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC Rule 6 Annex VIII 2017/745
MATERIALS	Filter media: Hydrophobic PTFE 1.0um Frame/Housing Polymer: Clear Styrene-Butadiene Copolymer Regulatory Documentation Required: ☒ Biocompatibility according ISO 10993-1 ☐ IMDS ☒ ROHS ☒ BSE/TSE ☒ DEHP plasticizer Free and latex free ☐ Aging ☒ REACH ☒ Conflict minerals Other: ☒ N/A ☐ Specify:

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PRODUCT CHARACTERISTICS

Appearance/Visual

Aesthetic part:

☒ Yes; ☐ No

Finishing:

☐ Trim finishing mirror polished surfaces

☐ Thin roughness surfaces

☐ Gross roughness surface

☒ As shown on drawing

Presence of graphics/Artwork:

☒ No; ☐ Specify:

Flash bears admitted:

☐ N/A ☒ Specify: *Smaller than 0.15mm*

Injection gate vestige:

☐ N/A ☒ Specify: *Smaller than 0.15mm*

Black spots admitted (size/area):

☐ N/A ☒ Specify: *Refer to the defect list*

Infiltration into insert admitted:

☒ N/A ☐ Specify:

Other:

☒ N/A ☐ Specify:

Physical/Mechanical

Dimensions: **65mm diameter x 56mm length (approx.)**

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

Interfaces (ex: Input / Output connectors):

☐ N/A ☒ Specify: **Hose barb OD 11mm and ID 7.9mm (approx.) connectors on both sides**

Operating temperature Range: *N/A*

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

Other:

☐ N/A ☒ Specify: **Mono-directional filter**

Flow direction indicated by IN marking on filter face

Chemical

Compatibility to solvents:

☒ N/A ☐ Specify:

Resistance to weathering:

☒ N/A ☐ Specify:

Other:

☒ N/A ☐ Specify:

Biological

Sterility:

☒ N/A ☐ Specify:

Pyrogenicity:

☐ N/A ☒ Specify: **<0.25 Eu/ml**

Haemolysis:

☒ N/A ☐ Specify:

Toxicity:

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☐ N/A ☐ Specify:

Biocompatibility to ISO10993

Category – **Surface medical device**

Contact – **Intact Skin**

Contact Duration - **<24hr**

Functional

Air Flow Rate:

☐ N/A ☐ Specify: **Min 37.3 l/min @ 5PSI** (REP 0613/15 with 20% Factor of Safety)

Water Break Through Pressure:

☐ N/A ☐ Specify: **0.8bar (600mmHG) Vacuum for 20s** (REP 0621/15)

Liquid Flow Rate:

☐ N/A ☐ Specify:

Bubble Point Pressure:

☐ N/A ☐ Specify:

Filtration Efficiency:

☐ N/A ☐ Specify:

Filter Efficiency @ 30L/min using DEHS@0.3µm: **Min. 99.99%** (REP 0696/16 with Factor of Safety)

Pressure Drop:

☐ N/A ☐ Specify:

Dead Volume:

☐ N/A ☐ Specify:

Operating Lifetime:

☐ N/A ☐ Specify:

Shelf Lifetime:

☐ N/A ☐ Specify: **5 years from the date of manufacture.**

Other:

☐ N/A ☐ Specify:

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

(Staphylococcus aureus @ 30L /minute) Lab 846022-S01

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

(Bacteriophage @ 30L/ minute) Lab 846021-S01

Cleanliness

Part cleanliness:

☐ N/A ☐ Specify:

Clean-room Production required:

☐ N/A ☐ Specify: **Class 8**

Testing

Insert embedding Test:

☐ N/A ☐ Specify:

Burst test:

☐ N/A ☐ Specify: **Min. 32psi** (REP 0617/15 with 20% Factor of Safety applied to Minimum)

Leakage:

☐ N/A ☐ Specify:

Other:

☐ N/A ☐ Specify:

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INSTRUCTIONS / WARNINGS	IFU – ☐ N/A ☒ Required: Specify Languages: ☒ English ☒ French ☒ Italian ☒ Spanish ☒ Portuguese ☒ German ☐ Chinese ☐ Japanese ☐ Korean ☐ Russian ☐ Other (Specify): Dutch, Swedish, Danish, Norwegian, Finnish, Polish
PRODUCT SHELF LIFE	5 years from the date of manufacture. Expiration date and date of manufacture are detailed on the product
STERILIZATION	☒ Not required; ☐ EtO; ☐ Gamma; ☐ Beta; ☐ Steam; ☐ e-beam
APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: ☒ CE mark ☒ FDA ☐ Canadian Health ☐ Brazil ANVISA ☐ Argentina ANMAT ☐ NIOSH ☐ Japan ☐ Korea ☐ China ☐ Russia ☐ Other (Specify): <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 – Part 1: General requirements - ISO 15223-1</i> Customer Specific Requirements: No Is the Product a safety product? ☐ Yes ☒ No Environment Impact: Have atmosphere emissions, liquid effluents, underground leachables been considered? ☒ Yes ☐ No Energy released (heat, vibration): ☐ Yes ☒ No
INTELLECTUAL PROPERTY AND FUNDING	Intellectual Property: Patents that have been granted or applied for that must be considered. ☐ N/A ☐ Specify: Grants: Is the project (partially) funded by public institutions? ☐ N/A ☐ Specify:
PACKAGING AND LABELING	Packaging ☒ Primary: Refer to individual Part Numbers ☒ Secondary: Refer to individual Part Numbers Labelling: ☒ Standard; ☒ Customer specific: Refer to customer specific artwork and labelling UDI: ☐ N/A; ☐ No; ☒ Yes (Specify):

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Number of pcs per bag is determined by the Sales order.
The first bar-code label is outside the bags.
The second bar-code label is stuck outside the box.
Each bag is labelled with the following traceability information:

- ✓ Quantity
- ✓ Product Description
- ✓ Product Date
- ✓ Lot Number (OL and 5 digit batch number to trace back to raw materials used)
- ✓ Operator Code

Different lots in one box are separately closed and separately labelled.
Bulk products will be packaged in double PE bags.

CERTIFICATE OF COMPLIANCE

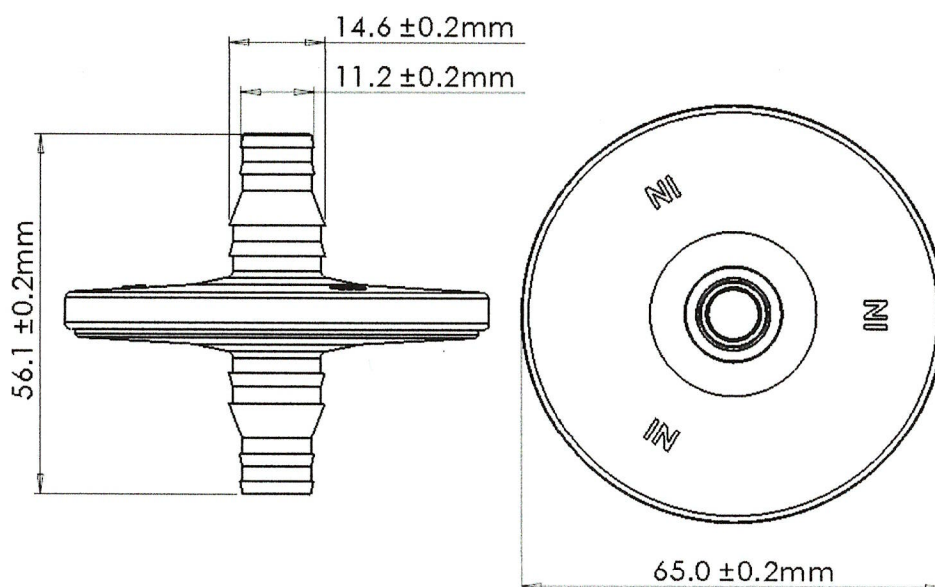
With each shipment, GVS UK Customer Service will send the CoFC to the Customer, based on the lot numbers and date of manufacture.
Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1.
The Quality management system is in compliance with ISO 9001, ISO 13485.

ACCEPTABLE QUALITY LEVEL

☑ AQL: 0.65 with sampling Plan: ISO 2859
☐ PPM: smaller than
☐ Other:

DRAWING

The attached drawing is part of this material specification and must not be duplicated or made accessible to a third party without prior written permission from GVS Filter Technology UK Ltd.



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VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under the conditions below:
Magnification: Unaided eye at a distance of approximately 35-40cm.
Illumination: Lighting level must be reasonable for visual detection i.e. 1000Lux
Timings: Maximum inspection period per item 25s

Acceptance Requirement		AQL	Sampling Plan
1	Black particle contamination - loose ($\geq 0.2\text{mm}^2$)	0.65	ISO 2859 Part 1 General Inspection Level 1
2	Surface damage	0.65	
3	Blocked connector / luer	0.65	
4	Weld marks	0.65	
5	Short fill moulding (functional)	0.65	
6	Short fill moulding (non-functional)	0.65	
7	Rough surface or edges	0.65	
8	Pronounced injection gate	0.65	
9	Bubble in moulding (max 3 air bubbles)	0.65	
10	Deformation / Distortion	0.65	
11	Crack	0.65	
12	Wrong colour	0.65	
13	Flash	0.65	
14	Weld fault	0.65	
15	Oil / grease	0.65	
16	Flow marks / marbling	0.65	
17	Wrong artwork / printing	0.65	
18	Incomplete or missing membrane	0.65	

GENERAL SAFETY & PERFORMANCE REQUIREMENTS

Bullethead drawing reference:

☒ N/A ☐ Specify:

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 @ 30L/min using DEHS @ 0.3 μm

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

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)
24/10/2019	1	Product characteristics updated	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.