

PRODUCT SPECIFICATION

Product P/N	2200/06	Mod. 984 Rev. 05
Description	Suction Filter	

2200/06

Suction Filter



PRODUCT DESCRIPTION SUMMARY	<p>Suction Filter Connectors- 5mm-9.8mm hose barbed both sides Flow direction indicated by IN marking on filter face 65mm diameter Weight 17g (approx.)</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 Fax: +44 (0) 1524 847800 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 6 Annex VIII 2017/745</p>
MATERIALS	<p>Filter media: <i>Hydrophobic PTFE 1.0um</i> Frame/Housing Polymer: <i>Clear Styrene-Butadiene Copolymer</i> Adhesive: N/A Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Biocompatibility according to ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> ROHS <input checked="" type="checkbox"/> BSE/TSE <input checked="" type="checkbox"/> DEHP plasticizer Free and latex free <input type="checkbox"/> Aging <input checked="" type="checkbox"/> REACH <input checked="" type="checkbox"/> Conflict minerals <p>Other:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:

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PRODUCT CHARACTERISTICS	<p>Appearance/Visual Aesthetic part: <input checked="" type="checkbox"/> Yes; <input type="checkbox"/> No Finishing: <input type="checkbox"/> Trim finishing mirror polished surfaces <input type="checkbox"/> Thin roughness surfaces <input type="checkbox"/> Gross roughness surface <input checked="" type="checkbox"/> As shown on drawing Presence of graphics/Artwork: <input checked="" type="checkbox"/> No; <input type="checkbox"/> Specify: Flash bears admitted: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>Smaller than 0.15mm</i> Injection gate vestige: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>Smaller than 0.15mm</i> Black spots admitted (size/area): <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>Refer to the defect list</i> Infiltration into insert admitted: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Other: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Physical/Mechanical Dimensions: <i>65mm diameter x 66mm length</i> Weight: <i>17gm (approx.)</i> Interfaces (ex: Input / Output connectors): <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>5mm-9.8mm barbed connectors on both sides</i> Operating temperature Range: <i>N/A</i> Storage temperature Range: <i>5 °C to 40 °C</i> Other: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>Mono-directional Filter – embossed "IN" determines the Liquid side of the filter</i></p> <p>Chemical Compatibility to solvents: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Resistance to weathering: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Other: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Biological Sterility: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Pyrogenicity: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i><0.25 Eu/ml</i> Haemolysis: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Toxicity: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p>
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Biocompatibility to ISO10993
Category – Surface medical device
Contact – Intact Skin
Contact Duration - <24hr

Functional
 Air Flow Rate:
 N/A Specify: Min 46l/min @ 5PSI
 Water Break Through Pressure:
 N/A Specify: 0.8bar (600mmHG) Vacuum (20s)
 Liquid Flow Rate:
 N/A Specify:
 Bubble Point Pressure:
 N/A Specify:
 Filtration Efficiency:
 N/A Specify:
Filter Efficiency @ 15L/min using DEHS@0.3µm: 99.9998% (Min-99.9990)
Rep reference: REP 0696_16
Filter Efficiency (ePTFE pore size): 1.0 micron
 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 - 99.99998%
(Staphylococcus aureus @ 30L /minute) (846022-S01)
Viral Filtration Efficiency in accordance with ASTM F2101-07: Min - 99.99998%
(Bacteriophage @ 30L/ minute) (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: Average – 80psi
 Leakage:
 N/A Specify: 27" water for 1 minute
 Other:
 N/A Specify:

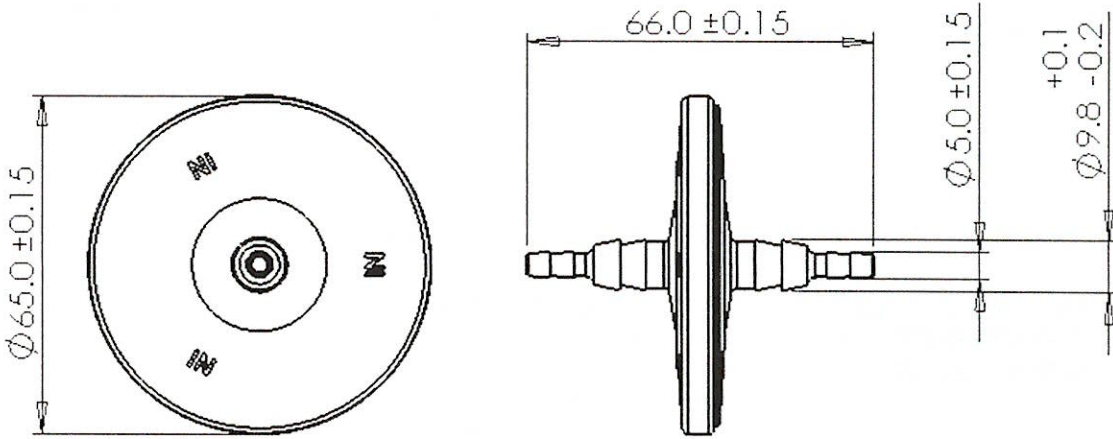
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INSTRUCTIONS / WARNINGS	IFU – <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Required: Specify Languages: <input checked="" type="checkbox"/> English <input type="checkbox"/> French <input type="checkbox"/> Italian <input type="checkbox"/> Spanish <input type="checkbox"/> Portuguese <input type="checkbox"/> German <input type="checkbox"/> Chinese <input type="checkbox"/> Japanese <input type="checkbox"/> Korean <input type="checkbox"/> Russian <input type="checkbox"/> Other (Specify):	
PRODUCT SHELF LIFE	5 years from the date of manufacture. <i>Expiration date and date of manufacture are detailed on the product</i>	
STERILIZATION	<input checked="" type="checkbox"/> Not required; <input type="checkbox"/> EtO; <input type="checkbox"/> Gamma; <input type="checkbox"/> Beta; <input type="checkbox"/> Steam; <input type="checkbox"/> e-beam	
APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: <input type="checkbox"/> CE mark <input type="checkbox"/> FDA <input type="checkbox"/> Canadian Health <input type="checkbox"/> Brazil ANVISA <input type="checkbox"/> Argentina ANMAT <input type="checkbox"/> NIOSH <input type="checkbox"/> Japan <input type="checkbox"/> Korea <input type="checkbox"/> China <input type="checkbox"/> Russia <input type="checkbox"/> Other (Specify):	
	Applicable Standards and Technical Regulations: <i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing</i> <i>Medical devices- Application of risk management to medical devices</i> <i>Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements</i>	ISO 10993-1 BS EN ISO 14971 ISO 15223-1
	Customer Specific Requirements: No	
	Is the Product a safety product? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Environment Impact: Have atmosphere emissions, liquid effluents, underground leachable been considered? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Energy released (heat, vibration): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
INTELLECTUAL PROPERTY AND FUNDING	Intellectual Property: Patents that have been granted or applied for that must be considered. <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Grants: Is the project (partially) funded by public institutions? <input type="checkbox"/> N/A <input type="checkbox"/> Specify:	
PACKAGING AND LABELING	Packaging <input checked="" type="checkbox"/> Primary; <input checked="" type="checkbox"/> Secondary: Labelling: <input checked="" type="checkbox"/> Standard; <input type="checkbox"/> Customer specific: UDI: <input type="checkbox"/> N/A; <input type="checkbox"/> No; <input checked="" type="checkbox"/> Yes (Specify):	

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	<p>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:</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. 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. 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>
ACCEPTABLE QUALITY LEVEL	<p><input checked="" type="checkbox"/> AQL: 0.65 with sampling Plan: ISO 2859 <input type="checkbox"/> PPM: smaller than <input type="checkbox"/> Other:</p>
DRAWING	<p>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.</p>  <p>The drawing shows two views of the suction filter. The left view is a top-down view of a circular disc with a central hole and three radial slots. The outer diameter is dimensioned as $\phi 65.0 \pm 0.15$. The right view is a side view showing the filter's profile, including a central shaft and a flange. The total length is dimensioned as 66.0 ± 0.15. The diameter of the central shaft is $\phi 5.0 \pm 0.15$. The diameter of the flange is $\phi 9.8$ with a tolerance of $+0.1$ and -0.2.</p>

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VISUAL REQUIREMENTS	<p><i>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</i></p>			
	Acceptance Requirement	AQL	Sampling Plan	
	1	Fibre Contamination - Embedded	0.65	ISO 2859 Part 1 General Inspection Level 1
	2	Fibre Contamination - Loose	0.65	
	3	Black particle contamination - loose (between 0.05mm ² and 0.08mm ²)	0.65	
	4	Black particle contamination - loose (between 0.08mm ² and 0.2mm ²)	0.65	
	5	Black particle contamination - loose (≥0.2mm ²)	0.65	
	6	Weld Fault	0.65	
	7	Faulty Scrim/Pad/Other Component	0.65	
	8	White Particle Contamination - embedded	0.65	
	9	Blocked Luer/Connector	0.65	
	10	Deformation/Distortion	0.65	
	11	Torn	0.65	
	12	Rough Surface or Edges	0.65	
	13	Incorrect raw materials used	0.65	
	14	Cracks	0.65	
	15	Pleat scratched/scuffed	0.65	
	16	Black particle contamination - embedded (≥0.3mm ²)	0.65	
	17	Black particle contamination - embedded (between 0.05mm ² and 0.3mm ²)	0.65	
	18	Weld marks	0.65	
	19	Damaged/Broken item	0.65	
	20	Dirty	0.65	
	21	Dimensions out of specification	0.65	
22	White particle contamination - loose	0.65		

GENERAL SAFETY & PERFORMANCE REQUIREMENTS	<p>Bulleted drawing reference: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Special characteristic: Special Characteristic # 01: Air flow rate at 5psi Special Characteristic # 02: Filter Efficiency @ 15L/min using DEHS @ 0.3µm Special Characteristic # 03: Bacterial Filtration Efficiency in accordance with US FDA(GMP) Viral Filtration Efficiency in accordance with US FDA(GMP) Special Characteristic # 04: Burst Pressure test</p>
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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)
12/04/2019	0	Updated to new Mod984 Rev 5	Roja Boorada - Design Engineer 	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.

