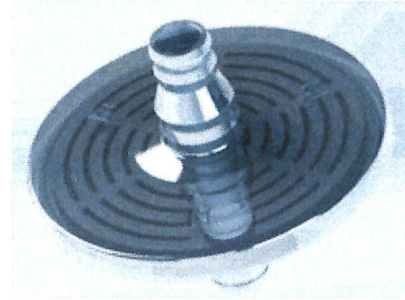


PRODUCT SPECIFICATION

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

2200/16 Suction Filter



PRODUCT DESCRIPTION SUMMARY	<p>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.)</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	Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC Rule 6 Annex VIII 2017/745
MATERIALS	<p>Filter media: Hydrophobic PTFE 1.0um Frame/Housing Polymer: Clear Styrene-Butadiene Copolymer</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Biocompatibility according 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:

PRODUCT SPECIFICATION

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

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:

PRODUCT SPECIFICATION

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

	<p><input type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Biocompatibility to ISO10993 <i>Category – Surface medical device</i> <i>Contact – Intact Skin</i> <i>Contact Duration - <24hr</i></p> <p>Functional Air Flow Rate: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Min 37.3 l/min @ 5PSI (REP 0613/15 with 20% Factor of Safety) Water Break Through Pressure: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: 0.8bar (600mmHG) Vacuum for 20s (REP 0621/15) Liquid Flow Rate: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Bubble Point Pressure: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Filtration Efficiency: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>Filter Efficiency @ 30L/min using DEHS@0.3µm: Min. 99.99%</i> (REP 0696/16 with Factor of Safety) Pressure Drop: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Dead Volume: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Operating Lifetime: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Shelf Lifetime: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: 5 years from the date of manufacture. Other: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min - 99.999%</i> <i>(Staphylococcus aureus @ 30L /minute) Lab 846022-S01</i> <i>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min - 99.999%</i> <i>(Bacteriophage @ 30L/ minute) Lab 846021-S01</i></p> <p>Cleanliness Part cleanliness: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Clean-room Production required: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Class 8</p> <p>Testing Insert embedding Test: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Burst test: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Min. 32psi (REP 0617/15 with 20% Factor of Safety applied to Minimum) Leakage: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Other: <input type="checkbox"/> N/A <input type="checkbox"/> Specify:</p>
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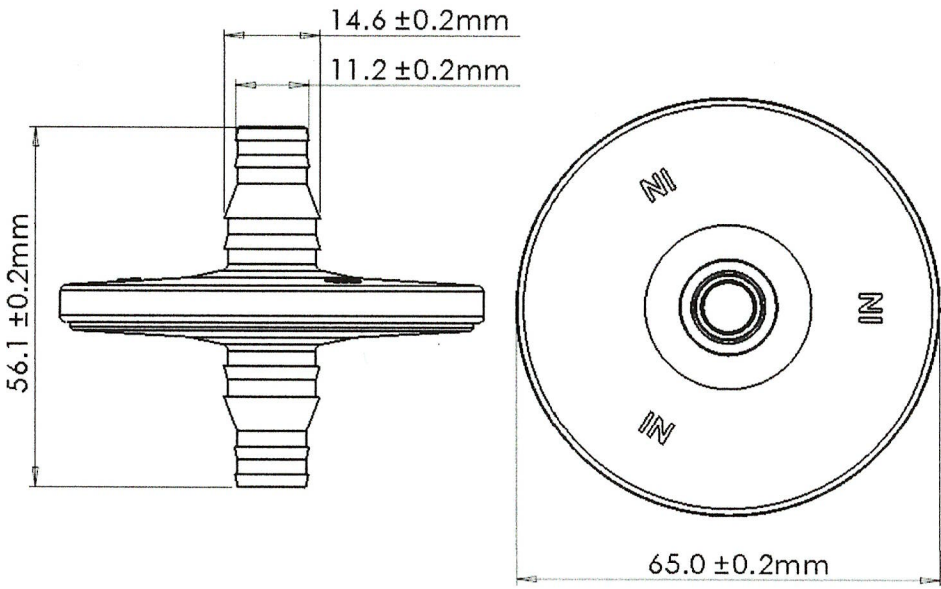
PRODUCT SPECIFICATION

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

INSTRUCTIONS / WARNINGS	<p>IFU – <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Required: Specify Languages: <input checked="" type="checkbox"/> English <input checked="" type="checkbox"/> French <input checked="" type="checkbox"/> Italian <input checked="" type="checkbox"/> Spanish <input checked="" type="checkbox"/> Portuguese <input checked="" type="checkbox"/> German <input type="checkbox"/> Chinese <input type="checkbox"/> Japanese <input type="checkbox"/> Korean <input type="checkbox"/> Russian <input type="checkbox"/> Other (Specify): Dutch, Swedish, Danish, Norwegian, Finnish, Polish</p>
PRODUCT SHELF LIFE	<p>5 years from the date of manufacture. Expiration date and date of manufacture are detailed on the product</p>
STERILIZATION	<p><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</p>
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required: <input checked="" type="checkbox"/> CE mark <input checked="" 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):</p> <p><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</p> <p>Is the Product a safety product? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Environment Impact: Have atmosphere emissions, liquid effluents, underground leachables been considered? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Energy released (heat, vibration): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
INTELLECTUAL PROPERTY AND FUNDING	<p>Intellectual Property: Patents that have been granted or applied for that must be considered. <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Grants: Is the project (partially) funded by public institutions? <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p>
PACKAGING AND LABELING	<p>Packaging <input checked="" type="checkbox"/> Primary: Refer to individual Part Numbers <input checked="" type="checkbox"/> Secondary: Refer to individual Part Numbers</p> <p>Labelling: <input checked="" type="checkbox"/> Standard; <input checked="" type="checkbox"/> Customer specific: Refer to customer specific artwork and labelling</p> <p>UDI: <input type="checkbox"/> N/A; <input type="checkbox"/> No; <input checked="" type="checkbox"/> Yes (Specify):</p>

PRODUCT SPECIFICATION

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

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

PRODUCT SPECIFICATION

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

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	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	<p>Bullethead drawing reference: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Special characteristic: <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i></p> <p>Special Characteristic # 01: <i>Air Flow rate at 5psi</i></p> <p>Special Characteristic # 02: <i>Filter Efficiency @ 30L/min using DEHS @ 0.3μm</i></p> <p>Special Characteristic # 03: <i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07 Viral Filtration Efficiency in accordance with ASTM F2101-07</i></p> <p>Special Characteristic # 04: <i>Burst Pressure</i></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.

PRODUCT SPECIFICATION

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

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.