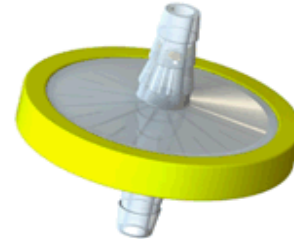


PRODUCT SPECIFICATION

Product P/N	2000/53	Mod. 984A Rev. 06
Description	Suction Filter	

2000/53

Suction Filter



PRODUCT DESCRIPTION	<p>Inlet/Outlet Connectors: 8mm-11mm hose barbed both sides, machine side indicated by markings on outer ring.</p> <p>Flow direction indicated by an arrow on the yellow overmould ring of the filter.</p> <p>Approximate dimensions: 54mm diameter x 51mm height.</p> <p>Unidirectional filter.</p> <p>Weight: 11g (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 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</p> <p>Rule 2 Annex IX 93/42 / EEC</p> <p>Rule 2 Annex VIII MDR 2017/745</p>
MATERIALS	<p>Filter media: <i>Hydrophobic PTFE 1.0µm</i></p> <p>Frame/Housing Polymer: <i>Transparent Clear Polypropylene Homopolymer (PP)</i> <i>Yellow Polypropylene homopolymer (PP)</i></p> <p>Colour: <i>Transparent Clear with Yellow overmould ring</i></p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> - Biocompatibility according ISO 10993-1 - ROHS - BSE/TSE - DEHP plasticizer Free and latex free - Aging - REACH - Conflict minerals

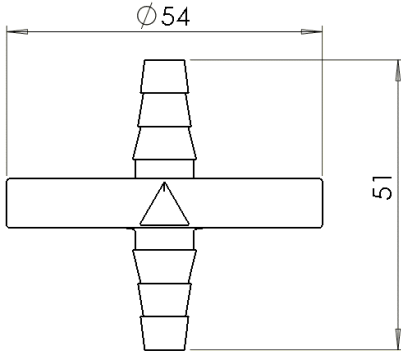
PRODUCT SPECIFICATION

Product P/N	2000/53	Mod. 984A
Description	Suction Filter	Rev. 06

PRODUCT CHARACTERISTICS	Appearance/Visual As shown on drawing.	
	Physical/Mechanical <i>Approximate dimensions: 54mm diameter x 51mm height.</i> <i>Weight: 11g (approx.).</i> Interfaces (ex: Input / Output connectors): 8mm-11mm barbed connector on both sides Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Unidirectional Filter. Machine side indicated by markings on outer ring. Flow direction indicated by an arrow on the yellow overmould ring of the filter.	
	Biological Pyrogenicity: <0.3 EU/ml Biocompatibility to ISO10993 Category – Surface device Contact – Skin Contact Duration - <24hrs	
	Functional Air Flow Rate: Min. 68.5l/min at 5PSI (REP: 1798/19 with 20% Factor of safety) Water Break Through Pressure: Min. 20 seconds at 600mmHg vacuum (REP: 1797/19) Filtration Efficiency: <i>Filter Efficiency @ 15L/min using DEHS@0.3µm: Min. 99.99%</i> (REP: 1796/19 with Factor of safety) Pressure Drop: N/A Internal Volume: N/A Operating Lifetime: N/A Shelf Lifetime: 5 years from the date of manufacture.	
	Cleanliness Device assembled within Clean Manufacturing Environment.	
	Testing Leakage: Vacuum Test @600mmHG.	
	INSTRUCTIONS / WARNINGS	<i>Multi-language IFU available.</i>
	PRODUCT SHELF LIFE	<i>5 years from the date of manufacture.</i> <i>Expiration date and date of manufacture are detailed on the product labelling.</i>
	STERILIZATION	N/A
	APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: <ul style="list-style-type: none">- CE mark- FDA

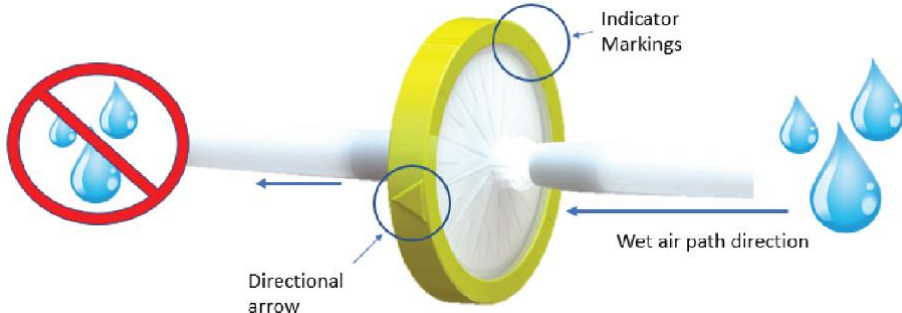
PRODUCT SPECIFICATION

Product P/N	2000/53	Mod. 984A Rev. 06
Description	Suction Filter	

	<p>Applicable Standards and Technical Regulations:</p> <p><i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i></p> <p><i>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</i></p> <p><i>Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1.</i></p> <p><i>High Efficiency Air Filters – BS EN 1822.</i></p>
PACKAGING AND LABELING	<p><i>Number of pcs per bag is determined by the sales order.</i></p> <p><i>The first barcode label is applied to the outside of the bags.</i></p> <p><i>The second barcode label is applied onto the outside of the box.</i></p> <p><i>Each bag is labelled with the following traceability information:</i></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><i>Different lots in one box are separately closed and separately labelled.</i></p> <p><i>Bulk products will be packed in double PE bags.</i></p>
CERTIFICATE OF COMPLIANCE	<p><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></p> <p><i>Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1.</i></p> <p><i>The Quality management system is in compliance with ISO 9001, ISO 13485.</i></p>
DRAWING	<p><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></p> <div style="text-align: center;">  </div> <div style="border: 1px solid black; padding: 5px; margin-left: auto; margin-right: auto;"> <p>Approximate dimensions for reference only</p> </div>

PRODUCT SPECIFICATION

Product P/N	2000/53	Mod. 984A
Description	Suction Filter	Rev. 06

	 <p>The diagram illustrates a suction filter assembly. It features a central white cylindrical body with a yellow ring at each end. A blue arrow labeled "Wet air path direction" points from right to left through the filter. A red circle with a diagonal line and three blue water droplets is on the left, indicating a prohibition against liquid. A blue arrow labeled "Directional arrow" points from the yellow ring towards the left. Two blue circles on the yellow ring are labeled "Indicator Markings".</p>																																			
ACCEPTABLE QUALITY LEVEL	AQL: 0.65 with sampling Plan: ISO2859.																																			
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions:</p> <p>Magnification: <i>Unaided eye at a distance of approximately 35-40cm.</i> Light type: <i>Lighting level must be reasonable for visual detection.</i> Timings: <i>Maximum inspection period per item is 25 seconds.</i> <i>For detailed defect list, refer to product control plan.</i></p> <table><tr><th colspan="2">Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Black particle contamination</td><td>0.65</td><td rowspan="10">ISO 2859 Part 1 General Inspection Level 1</td></tr><tr><td>2</td><td>Damaged/broken item</td><td>0.65</td></tr><tr><td>3</td><td>Blocked connector/luer</td><td>0.65</td></tr><tr><td>4</td><td>Short fill moulding</td><td>0.65</td></tr><tr><td>5</td><td>Rough surface or edges</td><td>0.65</td></tr><tr><td>6</td><td>Pronounced injection gate</td><td>0.65</td></tr><tr><td>7</td><td>Deformation/distortion</td><td>0.65</td></tr><tr><td>8</td><td>Crack</td><td>0.65</td></tr><tr><td>9</td><td>Oil/grease</td><td>0.65</td></tr><tr><td>10</td><td>Wrong colour</td><td>0.65</td></tr></table>	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	10	Wrong colour	0.65
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GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	<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 @ 15L/min using DEHS @ 0.3µm.</i></p>																																			

PRODUCT SPECIFICATION

Product P/N	2000/53	Mod. 984A Rev. 06
Description	Suction Filter	

	Special Characteristic # 03: <i>Vacuum Test @ 600mmHg.</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	Flow direction information added.	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.