

# PRODUCT SPECIFICATION

Product P/N	2000/54	Mod. 984A Rev. 06
Description	Suction Filter	

**2000/54**

**Suction Filter**



<b>PRODUCT DESCRIPTION</b>	<p>Inlet/Outlet Connectors: 8mm-8mm hose barbed both sides, machine side indicated by markings on outer ring.</p> <p>Approximate dimensions: 54mm diameter x 54mm height.</p> <p>Unidirectional filter.</p> <p>Weight: 11g (approx.)</p>
<b>MANUFACTURER NAME</b>	<p><b>GVS Filter Technology UK</b></p> <p>NFC House Vickers Industrial Estate Mellishaw Lane, Morecambe Lancashire LA3 3EN - United Kingdom</p> <p><b>Information</b></p> <p>Tel. +44 (0) 1524 847600 e-mail: gvsuk@gvs.com</p>
<b>INTENDED USE / APPLICATION</b>	The hydrophobic filter protects surgical suction vacuum pump equipment from contamination.
<b>CLASS OF THE PRODUCT</b>	Non-classified device sold in bulk for further manufacturing.
<b>MATERIALS</b>	<p><b>Filter media: <i>Hydrophobic PTFE 1.0µm</i></b></p> <p><b>Frame/Housing Polymer: <i>Transparent Clear Polypropylene Homopolymer (PP)</i> <i>Yellow Polypropylene homopolymer (PP)</i></b></p> <p><b>Colour: <i>Transparent Clear with Yellow overmould ring</i></b></p> <p><b>Regulatory Documentation Required:</b></p> <ul style="list-style-type: none"> <li>- Biocompatibility according ISO 10993-1</li> <li>- ROHS</li> <li>- BSE/TSE</li> <li>- DEHP plasticizer Free and latex free</li> <li>- Aging</li> </ul>

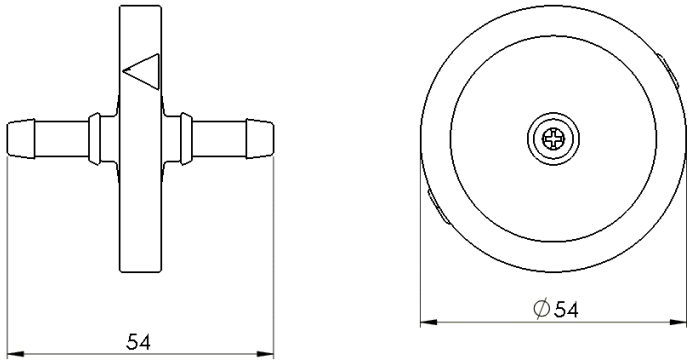
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	<ul style="list-style-type: none"> <li>- REACH</li> <li>- Conflict minerals</li> </ul>
<b>PRODUCT CHARACTERISTICS</b>	<p><b>Appearance/Visual</b> As shown on drawing.</p> <p><b>Physical/Mechanical</b> Approximate dimensions: <b>54mm diameter x 54mm height.</b> Weight: <b>11g (approx.)</b> Interfaces (ex: Input / Output connectors): <b>8mm barbed connector on both sides</b> Operating temperature Range: <b>N/A</b> Storage temperature Range: <b>5 °C to 40 °C</b> <b>Unidirectional Filter.</b> <b>Machine side indicated by markings on outer ring.</b></p> <p><b>Biological</b> Pyrogenicity: <b>&lt;0.3 EU/ml</b> <b>Biocompatibility to ISO10993</b> <b>Category – Surface device</b> <b>Contact – Skin</b> <b>Contact Duration - &lt;24hrs</b></p> <p><b>Functional</b> Air Flow Rate: <b>Min. 62.8l/min at 5PSI</b> (REP: 1864/19 with 20% Factor of safety)  Water Break Through Pressure: <b>Min. 20 seconds at 600mmHg vacuum</b> (REP: 1867/19)  Filtration Efficiency: <i>Filter Efficiency @ 15L/min using DEHS@0.3µm: <b>Min. 99.99%</b></i> (REP: 1863/19 with Factor of safety)  Pressure Drop: <b>N/A</b> Internal Volume: <b>N/A</b> Operating Lifetime: <b>N/A</b> Shelf Lifetime: <b>5 years from the date of manufacture.</b></p> <p><b>Cleanliness</b> Device assembled within Clean Manufacturing Environment.</p> <p><b>Testing</b> Burst test: <b>Min. 80 psi</b> (REP: 1609/18 with Factor of safety) Leakage: <b>Vacuum Test @600mmHg</b></p>
<b>INSTRUCTIONS / WARNINGS</b>	No IFU required.

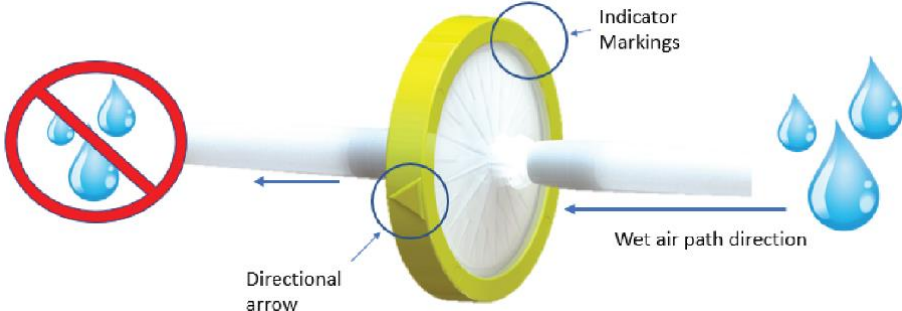
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<b>PRODUCT SHELF LIFE</b>	<i>5 years from the date of manufacture.</i>
<b>STERILIZATION</b>	<i>N/A</i>
<b>APPLICABLE STANDARDS AND REGULATIONS</b>	<p><b>Product Certification required:</b> <i>N/A.</i></p> <p><b>Applicable Standards and Technical Regulations:</b> <i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i></p> <p><i>High Efficiency Air Filters – BS EN 1822.</i></p>
<b>PACKAGING AND LABELING</b>	<p><b>Packaging</b></p> <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"> <li>✓ Quantity</li> <li>✓ Product description</li> <li>✓ Product Date</li> <li>✓ Lot Number (OL and 5-digit batch number to trace back to raw materials used)</li> <li>✓ Operator Code</li> </ul> <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>
<b>CERTIFICATE OF COMPLIANCE</b>	<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>
<b>DRAWING</b>	<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="border: 1px solid black; padding: 5px; text-align: center; margin: 10px auto; width: fit-content;"> Approximate dimensions for reference only </div> <div style="text-align: center; margin-top: 20px;">  </div>

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ACCEPTABLE QUALITY LEVEL	AQL: 0.65 with sampling Plan: ISO2859.																																			
VISUAL REQUIREMENTS	<p><b>Visual acceptance requirements apply when inspected under below conditions:</b></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><b>Special characteristic:</b> <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i></p> <p><b>Special Characteristic # 01:</b> <i>Air Flow rate at 5psi.</i></p>																																			

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<p><b>Special Characteristic # 02:</b> <i>Filter Efficiency @ 15L/min using DEHS @ 0.3µm.</i></p> <p><b>Special Characteristic # 03:</b> <i>Vacuum Test @ 600mmHg.</i></p> <p><b>Special Characteristic # 04:</b> <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.

## 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 

## 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.



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