

# PRODUCT SPECIFICATION

Product P/N	2000/10	Mod. 984A Rev. 06
Description	Gardner Suction Filter	

**2000/10**

## Gardner Suction Filter



<b>PRODUCT DESCRIPTION</b>	<p>Inlet/Outlet Connectors: Stepped Barb (Hose side) and 1/8th NPT Thread (Machine side). Hydrophobic on barbed connector side. Approximate dimensions: 54mm diameter x 50.2mm height. Unidirectional filter. Weight: 11.6g (approx.)</p>
<b>MANUFACTURER NAME</b>	<p><b>GVS Filter Technology UK</b> NFC House Vickers Industrial Estate Mellishaw Lane, Morecambe Lancashire LA3 3EN - United Kingdom</p> <p><b>Information</b> 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 product provided in bulk packs for further manufacturing.
<b>MATERIALS</b>	<p><b>Filter media:</b> <i>Hydrophobic PTFE 1.0µm</i></p> <p><b>Frame/Housing Polymer:</b> <i>Transparent Clear Polypropylene Homopolymer (PP)</i> <i>White Polypropylene homopolymer (PP)</i></p> <p><b>Colour:</b> <i>Transparent Clear with White overmould ring</i></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> <li>- REACH</li> <li>- Conflict minerals</li> </ul>

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PRODUCT CHARACTERISTICS	<b>Appearance/Visual</b> As shown on drawing.	
	<b>Physical/Mechanical</b> Approximate dimensions: <b>54mm diameter x 50.2mm height.</b> Weight: <b>11.6g (approx.)</b> Interfaces (ex: Input / Output connectors): <b>Stepped Barb (Hose side) and 1/8th NPT Thread (Machine side)</b>  Operating temperature Range: <b>N/A</b> Storage temperature Range: <b>5 °C to 40 °C</b> <b>Unidirectional Filter.</b>	
	<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>	
	<b>Functional</b> Air Flow Rate: <b>Min. 68.5l/min at 5PSI</b> (Ref.2000/53 REP: 1798/19 with 20% Factor of safety)  Water Break Through Pressure: <b>Min. 20 seconds at 600mmHg vacuum</b> (REP: 1110/17)  Filtration Efficiency: <i>Filter Efficiency @ 15L/min using DEHS@0.3µm: <b>Min. 99.99%</b> (REP: 1077/17 with Factor of safety)</i>  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>	
	<b>Cleanliness</b> Device assembled within Clean Manufacturing Environment.	
	<b>Testing</b> Leakage: <b>Vacuum Test @600mmHG.</b>	
	<b>INSTRUCTIONS / WARNINGS</b>	No IFU required.
	<b>PRODUCT SHELF LIFE</b>	5 years from the date of manufacture.
	<b>STERILIZATION</b>	N/A
	<b>APPLICABLE STANDARDS AND REGULATIONS</b>	<b>Product Certification required:</b> N/A <b>Applicable Standards and Technical Regulations:</b> Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.  High Efficiency Air Filters – BS EN 1822

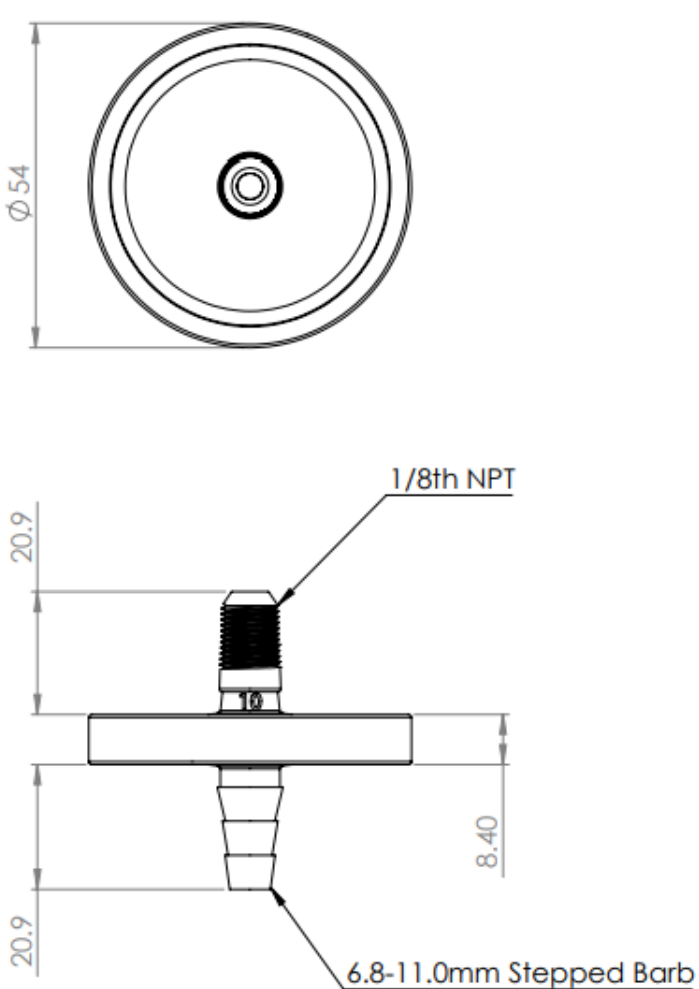
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<b>PACKAGING AND LABELING</b>	<p>Number of pcs per bag is determined by the sales order.  The first barcode label is applied to the outside of the bags.  The second barcode label is applied onto the outside of the box.  Each bag is labelled with the following traceability information:</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>Different lots in one box are separately closed and separately labelled.  Bulk products will be packed in double PE bags.</p>
<b>CERTIFICATE OF COMPLIANCE</b>	<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.  The Quality management system is in compliance with ISO 9001, ISO 13485.</p>
<b>DRAWING</b>	<p>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.</p>

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	<p>Approximate dimensions for reference only</p>  <p>The drawing shows two views of the Gardner Suction Filter. The top view is a circular flange with a diameter of 54 mm (Ø 54). The side view shows a central threaded port with a 1/8th NPT connection. The total height of the filter is 20.9 mm. The central port has a diameter of 10 mm. The bottom of the filter features a stepped barbed fitting with a diameter range of 6.8-11.0 mm. The distance from the bottom of the filter to the center of the port is 8.40 mm.</p>
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>

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	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	
GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	<b>Special characteristic:</b> <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i>			
	<b>Special Characteristic # 01:</b> <i>Air Flow rate at 5psi.</i>			
	<b>Special Characteristic # 02:</b> <i>Filter Efficiency @ 15L/min using DEHS @ 0.3µm.</i>			
	<b>Special Characteristic # 03:</b> <i>Vacuum Test @ 600mmHg.</i>			
	Acceptance Requirement		AQL	Sampling Plan
1	Leak Test	14 PSI Vacuum	0.65	ISO 2859 Part 1 Special Inspection Level 3
2	Thread Check	1/8 <sup>th</sup> NPT	0.65	ISO 2859 Part 1 Special Inspection Level 3
3	Barbed Connector Check	10.90 +/-0.15mm	0.65	ISO 2859 Part 1 Special Inspection Level 3

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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)
03/09/2021	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.