

# PRODUCT SPECIFICATION

Product P/N	2200/910KAUB042/0001	Mod. 984A
Description	90mm Suction Filter	Rev. 06

**2200/910**

**90mm Suction  
Filter**



<b>PRODUCT DESCRIPTION</b>	<p>Connectors - IN 11-15mm hose barbed, OUT 10mm conical</p> <p>Approx. dimensions 92mm diameter x 86mm height</p> <p>Flow direction indicated by IN marking on filter face</p> <p>Weight 47g (approx.)</p> <p>Unidirectional filter</p>
<b>MANUFACTURER NAME</b>	<p><b>GVS Filter Technology UK</b></p> <p>NFC House</p> <p>Vickers Industrial Estate</p> <p>Mellishaw Lane, Morecambe</p> <p>Lancashire LA3 3EN - United Kingdom</p> <p><b>Information</b></p> <p>Tel. +44 (0) 1524 847600</p> <p>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.
<b>MATERIALS</b>	<p><b>Filter media: <i>Hydrophobic PTFE 1.0µm</i></b></p> <p><b>Frame/Housing Polymer: <i>Clear Styrene-Butadiene Copolymer</i></b></p> <p><b>Colour: <i>Transparent Clear</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> </ul>


# PRODUCT SPECIFICATION

<b>Product P/N</b>	<b>2200/910KAUB042/0001</b>	<b>Mod. 984A</b>
<b>Description</b>	<b>90mm Suction Filter</b>	<b>Rev. 06</b>

	<ul style="list-style-type: none"> <li>- BSE/TSE</li> <li>- DEHP plasticizer Free and latex free</li> <li>- Aging</li> <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> Approx. Dimensions: <b>92mm diameter x 86mm height</b> Weight: <b>47g (approx.)</b> Interfaces (ex: Input / Output connectors): <b>IN 11-15mm hose barbed, OUT 10mm conical</b> Operating temperature Range: <b>N/A</b> Storage temperature Range: <b>5 °C to 40 °C</b> <b>Unidirectional Filter.</b> <b>Flow direction indicated by IN marking on filter face.</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. 54.4 l/min @ 1PSI</b> (REP: 2184/20 with 20% Factor of Safety applied to Min.)  Water Break Through Pressure: <b>0.8bar (600mmHG) Vacuum for 20s</b> (REP: 2186/20)  Filtration Efficiency: <b>Filter Efficiency @ 30L/min using DEHS@0.3µm: Min.99.995%</b> (REP: 2183/20 with Factor of Safety applied to Min.)  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>Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%</b> (<i>Staphylococcus aureus</i> @ 30L /minute) Ref.2200/02 REP: EXT846022-S01</p> <p><b>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999%</b> (<i>Bacteriophage</i> @ 30L/ minute) Ref.2200/02 REP: EXT846021-S01</p>

# PRODUCT SPECIFICATION

<b>Product P/N</b>	<b>2200/910KAUB042/0001</b>	<b>Mod. 984A</b>
<b>Description</b>	<b>90mm Suction Filter</b>	<b>Rev. 06</b>

	<p><b>Cleanliness</b> Device assembled within Class 8 Cleanroom.</p> <p><b>Testing</b> Burst test: <b>Min. 16.7psi</b> (REP: 2185/20 with 20% Factor of Safety applied to Min.)</p>
<b>INSTRUCTIONS / WARNINGS</b>	<i>IFU not required.</i>
<b>PRODUCT SHELF LIFE</b>	<p><i>5 years from the date of manufacture.</i></p> <p><i>Expiration date and date of manufacture are detailed on the product labelling.</i></p>
<b>STERILIZATION</b>	<i>N/A</i>
<b>APPLICABLE STANDARDS AND REGULATIONS</b>	<p><b>Product Certification required:</b></p> <p><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>  <i>High Efficiency Air Filters – BS EN 1822.</i></p>
<b>PACKAGING AND LABELING</b>	<p><b>Packaging:</b></p> <ul style="list-style-type: none"> <li>- Primary: Refer to individual part numbers</li> <li>- Secondary: Refer to individual part numbers</li> </ul> <p><b>Labelling:</b></p> <ul style="list-style-type: none"> <li>- Customer specific:</li> </ul> <p><b>Filter label:</b></p> 

# PRODUCT SPECIFICATION

<b>Product P/N</b>	<b>2200/910KAUB042/0001</b>	<b>Mod. 984A</b>
<b>Description</b>	<b>90mm Suction Filter</b>	<b>Rev. 06</b>

## Bag artwork:



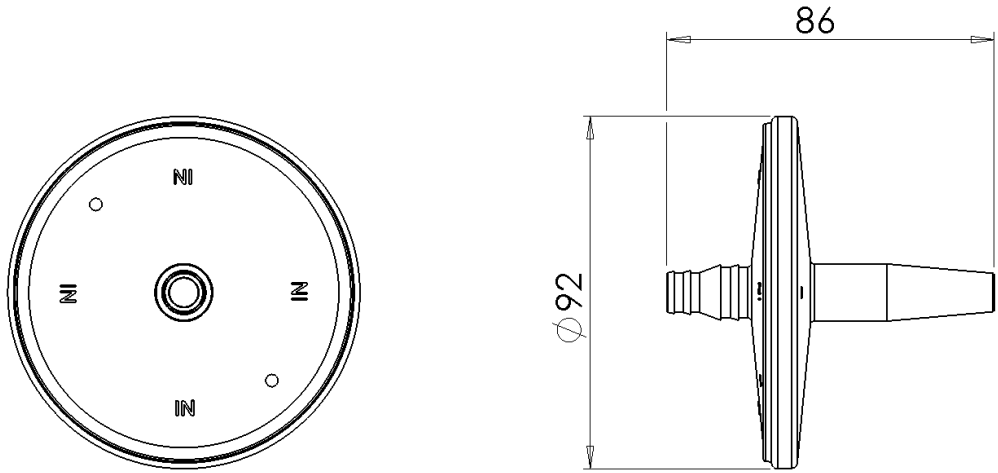
Number of pcs per bag is determined by the sales order.  
The first barcode label is applied to the outside of the bags.  
The second barcode label is applied onto the outside of the box.  
Each bag is labelled with the following traceability information:

- ✓ Quantity
- ✓ Product description
- ✓ Product Date
- ✓ Lot Number (OL and 5-digit batch number to trace back to raw materials used)
- ✓ Operator Code

Different lots in one box are separately closed and separately labelled.

# PRODUCT SPECIFICATION

<b>Product P/N</b>	<b>2200/910KAUB042/0001</b>	<b>Mod. 984A</b>
<b>Description</b>	<b>90mm Suction Filter</b>	<b>Rev. 06</b>

<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.</p> <p>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>																
<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> <div style="text-align: center;">  <p>Approximate dimensions for reference only</p> </div>																
<b>ACCEPTABLE QUALITY LEVEL</b>	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1																
<b>VISUAL REQUIREMENTS</b>	<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></p> <p>Light type: <i>Lighting level must be reasonable for visual detection.</i></p> <p>Timings: <i>Maximum inspection period per item is 25 seconds.</i></p> <p><i>For detailed defect list, refer to product control plan.</i></p> <table border="1"> <thead> <tr> <th></th><th>Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr> </thead> <tbody> <tr> <td>1</td><td>Black particle contamination</td><td>0.65</td><td rowspan="3">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> </tbody> </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
	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															

# PRODUCT SPECIFICATION

Product P/N	2200/910KAUB042/0001	Mod. 984A
Description	90mm Suction Filter	Rev. 06

	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	
	11	Weld fault	0.65	
	12	Weld marks	0.65	

## GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

**Special characteristic:** Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.

**Special Characteristic # 01:** Air Flow rate at 1psi.

**Special Characteristic # 02:** Filter Efficiency @ 30L/min using DEHS @ 0.3µm in accordance with High Efficiency Air Filters – BS EN 1822.

**Special Characteristic # 03:** Bacterial Filtration Efficiency in accordance with ASTM F2101-07  
Viral Filtration Efficiency in accordance with ASTM F2101-07.

**Special Characteristic # 04:** Burst Pressure.

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 

# PRODUCT SPECIFICATION

Product P/N	2200/910KAUB042/0001	Mod. 984A
Description	90mm Suction Filter	Rev. 06

## 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.