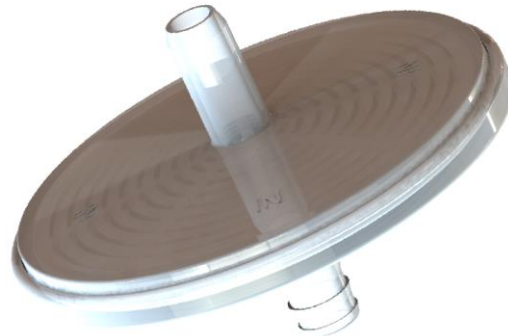


PRODUCT SPECIFICATION

Product P/N	2200/911	Mod. 984A Rev. 06
Description	90mm Suction Filter	

2200/911

**90mm Suction
Filter**



PRODUCT DESCRIPTION	<p>Inlet/Outlet Connectors: IN - 11mm hose plain, OUT - 11-15mm hose barbed. Approx. dimensions: 92mm diameter x 61.8mm height. Flow direction indicated by "IN" marking on filter face. Weight: 47gm (approx.). Unidirectional filter.</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 Rule 2 Annex IX 93/42 / EEC Rule 2 Annex VIII MDR 2017/745</p>
MATERIALS	<p>Filter media: <i>Hydrophobic PTFE 1.0µm</i> Frame/Housing Polymer: <i>Clear Styrene-Butadiene Copolymer (SBC)</i> Colour: <i>Transparent Clear</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	2200/911	Mod. 984A Rev. 06
Description	90mm Suction Filter	

PRODUCT CHARACTERISTICS	Appearance/Visual As shown on drawing.
	Physical/Mechanical Approx. dimensions: 92mm diameter x 61.8mm height. Weight: 47gm (approx.). Interfaces (ex: Input / Output connectors): IN - 11mm hose plain, OUT - 11-15mm hose barbed. Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Unidirectional Filter. Flow direction indicated by "IN" marking on filter face.
	Biological Pyrogenicity: <0.3 EU/ml Biocompatibility to ISO10993 Category – Surface device Contact – Skin Contact Duration - <24hrs
	Functional Air Flow Rate: Min. 54.4 l/min @ 1PSI (REP: 2184/20 with 20% Factor of Safety applied to Min.) Water Break Through Pressure: 0.8bar (600mmHG) Vacuum for 20s (REP: 2186/20) Filtration Efficiency: Filter Efficiency @ 30L/min using DEHS @0.3µm: Min.99.995% (REF: 2183/20 with Factor of Safety applied to Min.) Pressure Drop: N/A Internal Volume: N/A Operating Lifetime: Refer to Instructions for Use. Shelf Lifetime: 5 years from the date of manufacture. Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (Staphylococcus aureus @ 30L /minute) Ref.2200/02 REP: EXT846022-S01 Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (Bacteriophage @ 30L/ minute) Ref.2200/02 REP: EXT846021-S01 Cleanliness Device assembled within Class 8 Cleanroom.
INSTRUCTIONS / WARNINGS	Multi-language IFU available.
PRODUCT SHELF LIFE	5 years from the date of manufacture. Expiration date and date of manufacture are detailed on the product labelling.

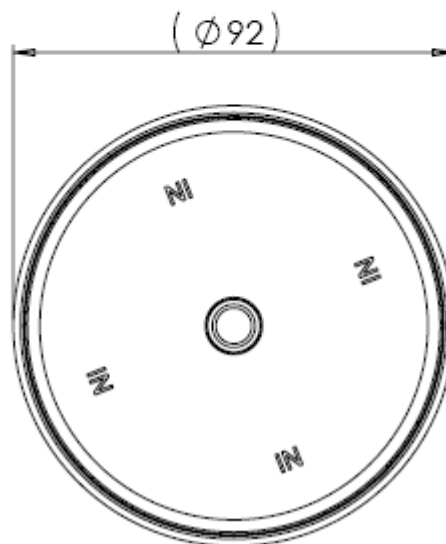
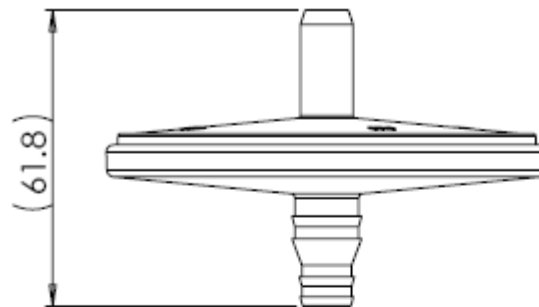
PRODUCT SPECIFICATION

Product P/N	2200/911	Mod. 984A
Description	90mm Suction Filter	Rev. 06

STERILIZATION	N/A
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required:</p> <ul style="list-style-type: none"> - CE mark - FDA <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 – Part 1: General requirements - ISO 15223-1.</i></p> <p><i>High Efficiency Air Filters – BS EN 1822.</i></p>
PACKAGING AND LABELING	<p>Packaging:</p> <ul style="list-style-type: none"> - Primary: 1 filter bagged in polybag 160x182mm White Front/Clear Back (10.051.0007.00.AA) - Secondary: 50 individually bagged filters in polybag 30"x40" (10.051.0010.00.AA) <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 packaged 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	<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>

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Product P/N	2200/911	Mod. 984A Rev. 06
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Approximate dimensions for reference only

ACCEPTABLE QUALITY LEVEL

AQL: with sampling Plan: 0.65 AQL to ISO 2859-1

VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Magnification: *Unaided eye at a distance of approximately 35-40cm.*
 Light type: *Lighting level must be reasonable for visual detection.*
 Timings: *Maximum inspection period per item is 25 seconds.*
For detailed defect list, refer to product control plan.

Acceptance Requirement		AQL	Sampling Plan
1	Black particle contamination	0.65	

PRODUCT SPECIFICATION

Product P/N	2200/911	Mod. 984A Rev. 06
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	2	Damaged/broken item	0.65	ISO 2859 Part 1 General Inspection Level 1
	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	
	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)
07/09/2021	2	IFU section amended on Mod.984.	Kinga Gawdzik - Engineering Support Technician 	Andrew Pearce – Quality Manager 

PRODUCT SPECIFICATION

Product P/N	2200/911	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.