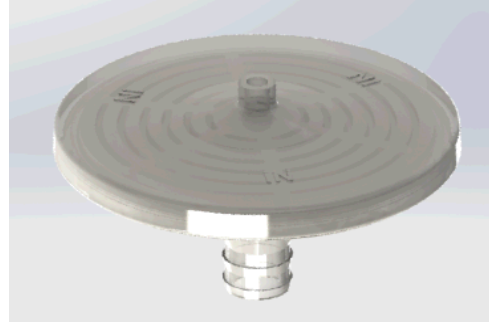


PRODUCT SPECIFICATION

Product P/N	2200/66GAUA051/0001	Mod. 984A
Description	Insufflation Filter	Rev. 06

2200/66

Insufflation Filter



PRODUCT DESCRIPTION	Connectors – IN ID3.5mm OD6mm 4mm straight, OUT 11-15mm hose barbed Approx. dimensions 65mm diameter x 38.7mm height Bidirectional filter Weight 17gm (approx.)
MANUFACTURER NAME	GVS Filter Technology UK NFC House Vickers Industrial Estate Mellishaw Lane, Morecambe Lancashire LA3 3EN - United Kingdom Information Tel. +44 (0) 1524 847600 e-mail: gvsuk@gvs.com
INTENDED USE / APPLICATION	To be used in conjunction with insufflators for intra-abdominal insufflation.
CLASS OF THE PRODUCT	Non-classified device.
MATERIALS	Filter media: <i>Hydrophobic Glass Microfibre Media</i> Frame/Housing Polymer: <i>Clear Styrene-Butadiene Copolymer</i> Colour: <i>Transparent Clear</i> Regulatory Documentation Required: <ul style="list-style-type: none"> - Biocompatibility according ISO 10993-1 - ROHS - BSE/TSE - DEHP plasticizer Free and latex free - Aging






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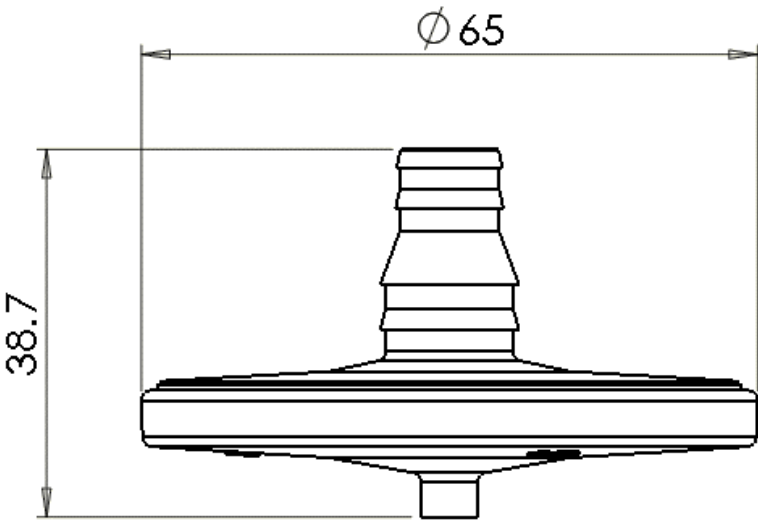
	<ul style="list-style-type: none"> - REACH - Conflict minerals
PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <p>Physical/Mechanical Approx. Dimensions: 65mm diameter x 38.7mm height Weight: 17gm (approx.)</p> <p>Interfaces (ex: Input / Output connectors): IN ID3.5mm OD6mm 4mm straight, OUT 11-15mm hose barbed</p> <p>Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Bidirectional Filter</p> <p>Biological Pyrogenicity: <0.3 EU/ml Biocompatibility to ISO10993 Category – Surface device Contact – Skin Contact Duration - <24hr</p> <p>Functional Air Flow Rate: Min. 28.4l/min @ 5PSI (Ref.2200/05, REP 0614/15 with 20% Factor of Safety applied to Min.)</p> <p>Filtration Efficiency: Filter Efficiency @ 15L/min using DEHS@0.3µm: Min.99.8% (REP 1218/17 with Factor of Safety)</p> <p>Pressure Drop: N/A Internal Volume: N/A Operating Lifetime: N/A Shelf Lifetime: 5 years from the date of manufacture.</p> <p>Cleanliness Device assembled within Class 8 Cleanroom.</p> <p>Testing Burst test: Min.15.7psi (Ref.2200/05, REP 0618/15 with 20% Factor of Safety applied to Min.) Leakage: Static Head Test 27" of water for 1 minute (Ref.2200/05, REP: 0622/15)</p>

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Product P/N	2200/66GAUA051/0001	Mod. 984A
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INSTRUCTIONS / WARNINGS	<i>IFU not required.</i>
PRODUCT SHELF LIFE	<i>5 years from the date of manufacture.</i>
STERILIZATION	<i>N/A</i>
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required:</p> <p><i>N/A.</i></p> <p>Applicable Standards and Technical Regulations: <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>
PACKAGING AND LABELING	<p>Packaging:</p> <ul style="list-style-type: none"> - Primary: Refer to individual part numbers - Secondary: Refer to individual part numbers <p>Labelling: Customer specific: on Primary packaging</p> <p>Soluscope SAS 100 rue du FAUGE ZI LES PALUDS 13400 AUBAGNE, FRANCE Tel. +33(0)4 91 83 21 22 Fax. +33(0)4 91 83 21 10</p> <p>Product : 0,2 µm air filter hepa class 13</p> <p>REF A-093</p> <p>LOT NO XXXXXXXX</p> <p> DDMMYY</p> <p> MM/YYYY</p>  <p> </p>

PRODUCT SPECIFICATION

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	<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"> ✓ Quantity ✓ Product description ✓ Product Date ✓ Lot Number (OL and 5-digit batch number to trace back to raw materials used) ✓ Operator Code <p>Different lots in one box are separately closed and separately labelled. Bulk products will be packaged in double PE bags</p>	
CERTIFICATE OF COMPLIANCE	<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.</p> <p>The Quality management system is in compliance with ISO 9001, ISO 13485.</p>	
DRAWING	<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>  <p style="text-align: center;">Approximate dimensions for reference only</p>	
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:	

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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	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	
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 5psi*

Special Characteristic # 02: *Filter Efficiency @ 15L/min using DEHS @ 0.3µm in accordance with High Efficiency Air Filters – BS EN 1822.*

Special Characteristic # 03: *Burst Pressure*

Special Characteristic # 04: *27" water leak test – Static head test*

This material specification describes the properties of product above indicated. This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
06/09/2021	2	Classification of the product updated.	Kinga Gawdzik - Engineering Support Technician 	Andrew Pearce – Quality Manager 

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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.