

PRODUCT SPECIFICATION

Product P/N	2200/49	Mod. 984A Rev. 06
Description	Insufflation Filter	

2200/49

Insufflation Filter



PRODUCT DESCRIPTION	<p>Inlet/Outlet Connectors: IN - OD 8mm (approx.) hose barbed and ID 3.6mm (approx.), OUT - OD 15 mm Male ISO and ID 12.7mm (approx.).</p> <p>Bidirectional filter.</p> <p>Approx. dimensions: 65mm diameter x 55.9mm height.</p> <p>Weight: 17g (approx.).</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	To be used in conjunction with insufflators for intra-abdominal insufflation.
CLASS OF THE PRODUCT	Non-classified product provided in bulk packs for further manufacturing.
MATERIALS	<p>Filter media: <i>Hydrophobic Glass Microfibre Media</i></p> <p>Frame/Housing Polymer: <i>Clear Styrene-Butadiene Copolymer (SBC)</i></p> <p>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

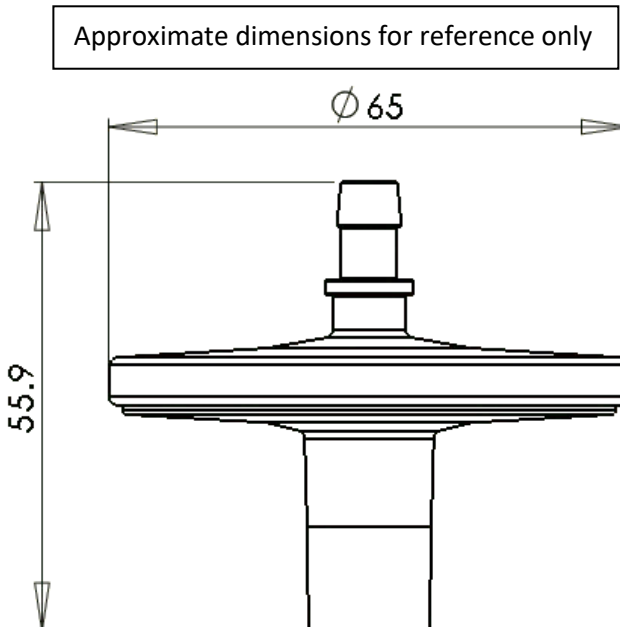
PRODUCT SPECIFICATION

Product P/N	2200/49	Mod. 984A Rev. 06
Description	Insufflation Filter	

PRODUCT CHARACTERISTICS	Appearance/Visual As shown on drawing.
	Physical/Mechanical Dimensions (Approx.): 65mm diameter x 55.9mm height. Weight: 17gm (approx.). Interfaces (ex: Input / Output connectors): IN - OD 8mm (approx.) hose barbed and ID 3.6mm (approx.), OUT - OD 15 mm Male ISO and ID 12.7mm (approx.) Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Bidirectional Filter
	Biological Pyrogenicity: <0.3 Eu/ml Biocompatibility to ISO10993 Category – Surface device Contact – Skin Contact Duration - <24hrs
	Functional Air Flow Rate: Min.73.6 l/min at 5PSI (Ref.2200/48, REP 1215/17 with 20% Factor of Safety applied to Min.) Filtration Efficiency: Filter Efficiency @ 15L/min using DEHS @0.3µm: Min.98.3% (REP: 1874/19 with Factor of Safety) Pressure Drop: N/A Internal Volume: N/A Operating Lifetime: Refer to Instructions for Use. Shelf Lifetime: 5 years from the date of manufacture.
	Cleanliness Device assembled within Class 8 Cleanroom.
	Testing Burst test: Min. 21.9 psi (REP 1855/19 with 20% Factor of Safety) Leakage: Static Head Test 27" H2O for 1minute (REP 1856/19)
INSTRUCTIONS / WARNINGS	N/A
PRODUCT SHELF LIFE	5 years from the date of manufacture. <i>Expiration date and date of manufacture are detailed on the product labelling.</i>
STERILIZATION	N/A
APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: N/A

PRODUCT SPECIFICATION

Product P/N	2200/49	Mod. 984A Rev. 06
Description	Insufflation Filter	

	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>
PACKAGING AND LABELING	<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 packed 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> <div style="text-align: center;"> <p>Approximate dimensions for reference only</p>  <p>The drawing shows a cross-section of a cylindrical filter. The top flange has a diameter of 65. The total height of the filter assembly is 55.9. The filter has a central inlet/outlet port.</p> </div>
ACCEPTABLE QUALITY LEVEL	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1

PRODUCT SPECIFICATION

Product P/N	2200/49	Mod. 984A Rev. 06
Description	Insufflation Filter	

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	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.

PRODUCT SPECIFICATION

Product P/N	2200/49	Mod. 984A Rev. 06
Description	Insufflation Filter	

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE)	APPROVED BY: (NAME/FUNCTION/SIGNATURE)
23/08/2021	4	Product certification corrected.	Kinga Gawdzik – Engineering Support Technician 	Andrew Pearce – Quality Manager 

PRODUCT SPECIFICATION

Product P/N	2200/49	Mod. 984A Rev. 06
Description	Insufflation Filter	

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.