

PRODUCT SPECIFICATION

Product P/N	2200/33	Mod. 984A Rev. 06
Description	Insufflation Filter	

2200/33

Insufflation Filter



PRODUCT DESCRIPTION	<p>Inlet/Outlet Connectors:</p> <ul style="list-style-type: none"> -IN: OD 11mm (approx.) hose barbed and ID 7.9mm (approx.), - OUT: OD 15mm Male ISO and ID 12.7mm (approx.). <p>Approx. dimensions: 65mm diameter x 58.9mm height. Bidirectional filter. Weight 17gm (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	<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 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

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	- Conflict minerals
PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <p>Physical/Mechanical Approx. Dimensions: 65mm diameter x 58.9mm height. Weight: 17gm (approx.).</p> <p>Interfaces (ex: Input / Output connectors): - IN: OD 11mm (approx.) hose barbed and ID 7.9mm (approx.), - OUT: OD 15mm Male ISO and ID 12.7mm (approx.).</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 - <24hrs</p> <p>Functional Air Flow Rate: Min. 50 l/min @ 1PSI (REP: 1854/19 with 20% Factor of Safety applied to Min.)</p> <p>Filtration Efficiency: Filter Efficiency @ 15L/min using DEHS @0.3µm: Min. 98.3% (REP: 1874/19 with Factor of Safety)</p> <p>Pressure Drop: N/A Internal Volume: N/A</p> <p>Operating Lifetime: Refer to Instructions for Use.</p> <p>Shelf Lifetime: 5 years from the date of manufacture.</p> <p>Cleanliness Device assembled within Class 8 Cleanroom.</p> <p>Testing Burst test: Min. 21.9 psi (REP: 1855/19 with 20% Factor of Safety) Leakage: Static Head Test 27" H₂O for 1 minute (REP: 1856/19)</p>
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.
STERILIZATION	N/A

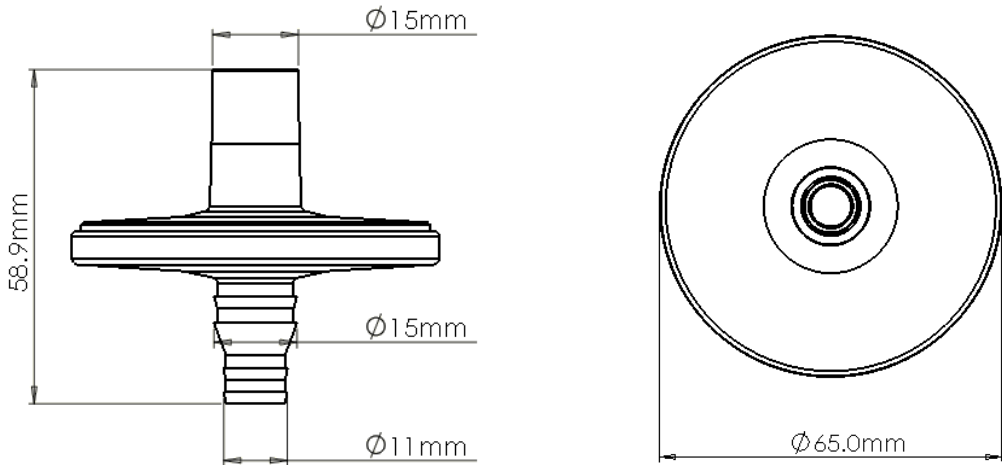
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APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required:</p> <ul style="list-style-type: none"> - CE mark - FDA <p>Applicable Standards and Technical Regulations:</p> <p><i>Biological evaluation of Medical Devices - Part 1: Evaluation 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><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	<p><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></p>

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	<p>Approximate dimensions for reference only</p>  <p>The drawing shows two views of the filter. The side view on the left indicates a total height of 58.9mm. It features a central stem with a top diameter of Ø15mm, a wider middle section, and a bottom section with a diameter of Ø11mm. The top view on the right shows a circular disc with an outer diameter of Ø65.0mm and a central hole with a diameter of Ø15mm.</p>																															
ACCEPTABLE QUALITY LEVEL	AQL: with sampling Plan: 0.65 AQL to ISO 2859-1																															
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions:</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> <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="8">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> <tr> <td>4</td><td>Short fill moulding</td><td>0.65</td></tr> <tr> <td>5</td><td>Rough surface or edges</td><td>0.65</td></tr> <tr> <td>6</td><td>Pronounced injection gate</td><td>0.65</td></tr> <tr> <td>7</td><td>Deformation/distortion</td><td>0.65</td></tr> <tr> <td>8</td><td>Crack</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	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
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	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: <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i>			
	Special Characteristic # 01: <i>Air Flow rate at 1psi</i>			
	Special Characteristic # 02: <i>Filter Efficiency @ 15L/min using DEHS @ 0.3µm in accordance with High Efficiency Air Filters – BS EN 1822.</i>			
	Special Characteristic # 03: <i>Burst Pressure</i>			
	Special Characteristic # 04: <i>27” water leak test – Static head test</i>			
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)
09/09/2021	2	Image of the filter amended.	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.