

PRODUCT SPECIFICATION

Product P/N	4100/25	Mod. 984 Rev. 05
Description	Oxygen Concentrator Filter	

4100/25

Oxygen Concentrator Filter



PRODUCT DESCRIPTION	<p>Inlet / Outlet Connectors: 22mm Male/18.8mm i/d. Approx. Dimensions: 115.2mm length x 60.9mm width x 62.4mm height Weight: 62gm (approx.) Unidirectional Filter</p> <p>Similar existing product: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: 4100 series filters.</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	Pre-filter for use within oxygen concentrator machines, to filter the air entering the device.
CLASS OF THE PRODUCT	<p>Disposable medical device - Class 1 Annex V 93/42/EEC Rule 1 Annex VIII MDR 2017/745</p>
MATERIALS	<p>Filter media: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Glass Microfibre Media and White Polyurethane foam</p> <p>Frame/Housing Polymer: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Bronze Tinted Acrylonitrile Butadiene Styrene (ABS)</p> <p>Colour: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Brown</p> <p>Other insert(s): <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Adhesive: Polyolefin Hot Melt Adhesive</p> <p>Regulatory Documentation Required: <input checked="" type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> ROHS <input checked="" type="checkbox"/> BSE/TSE</p>

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	<input checked="" type="checkbox"/> DEHP plasticizer Free and latex free <input checked="" type="checkbox"/> Aging <input checked="" type="checkbox"/> REACH <input checked="" type="checkbox"/> Conflict minerals Other: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:
PRODUCT CHARACTERISTICS	<p>Appearance/Visual Aesthetic part: <input checked="" type="checkbox"/> Yes; <input type="checkbox"/> No Finishing: <input type="checkbox"/> Trim finishing mirror polished surfaces <input type="checkbox"/> Thin roughness surfaces <input type="checkbox"/> Gross roughness surface <input checked="" type="checkbox"/> As shown on drawing Presence of graphics/Artwork: <input checked="" type="checkbox"/> No; <input type="checkbox"/> Specify: Flash bears admitted: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Refer to the control plan. Injection gate vestige: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Refer to the control plan. Black spots admitted (size/area): <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Refer to the control plan. Infiltration into insert admitted: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Other: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Physical/Mechanical Dimensions (Approx.): 115.2mm length x 60.9mm width x 62.4mm height Weight: 62gm (approx.) Interfaces (ex: Input / Output connectors): <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: 22mm Male/18.8mm i/d Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Other: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Unidirectional Filter</p> <p>Chemical Compatibility to solvents: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Resistance to weathering: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Other: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p>

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Biological

Sterility:

N/A Specify:

Pyrogenicity:

N/A Specify:

Haemolysis:

N/A Specify:

Toxicity:

N/A Specify:

Category – Surface device

Contact – Intact Skin

Contact Duration - <24hr

Functional

Air Flow Rate:

N/A Specify: 30l/min, 60l/min, 90l/min

Water Break Through Pressure:

N/A Specify:

Liquid Flow Rate:

N/A Specify:

Bubble Point Pressure:

N/A Specify:

Filtration Efficiency:

N/A Specify:

Filter Efficiency @ 30L/min using TSI 8130: *Min. 99.8%* (REP 1921/19 with safety factor added)

Pressure Drop:

N/A Specify:

Flow Resistance @ 30L/min in accordance with EN ISO 9360-1: *Max. 7.3Pa*

Flow Resistance @ 60L/min in accordance with EN ISO 9360-1: *Max. 20.9Pa*

Flow Resistance @ 90L/min in accordance with EN ISO 9360-1: *Max. 40Pa*

(REP 1920/19 with 10% safety factor added)

Internal Volume:

N/A Specify:

Operating Lifetime:

N/A Specify: **Refer to Instructions for Use.**

Shelf Lifetime:

N/A Specify: **5 years from the date of manufacture.**

Other:

N/A Specify:

Bacterial Filtration Efficiency in accordance with ASTM F2101-07: *Min. 99.9%*

(*Staphylococcus aureus @ 30L /minute*) Lab 846022-S01

Viral Filtration Efficiency in accordance with ASTM F2101-07: *Min. 99.999%*

(*Bacteriophage @ 30L/ minute*) Lab 846021-S01














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	<p>Cleanliness Part cleanliness: <input type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Clean-room Production required: <input type="checkbox"/> N/A <input type="checkbox"/> Specify: Class 8.</p> <p>Testing Insert embedding Test: <input type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Burst test: <input type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Leakage: <input type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Other: <input type="checkbox"/> N/A <input type="checkbox"/> Specify:</p>
INSTRUCTIONS / WARNINGS	<p>IFU <input type="checkbox"/> N/A <input type="checkbox"/> Required: Specify Languages: <input type="checkbox"/> English <input type="checkbox"/> French <input type="checkbox"/> Italian <input type="checkbox"/> Spanish <input type="checkbox"/> Portuguese <input type="checkbox"/> German <input type="checkbox"/> Chinese <input type="checkbox"/> Japanese <input type="checkbox"/> Korean <input type="checkbox"/> Russian <input type="checkbox"/> Other (Specify):</p>
PRODUCT SHELF LIFE	<p>5 years from the date of manufacture. <i>Expiration date and date of manufacture are detailed on the product labelling.</i></p>
STERILIZATION	<p><input type="checkbox"/> Not required; <input type="checkbox"/> EtO; <input type="checkbox"/> Gamma; <input type="checkbox"/> Beta; <input type="checkbox"/> Steam; <input type="checkbox"/> e-beam</p>
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required: <input type="checkbox"/> CE mark <input type="checkbox"/> FDA <input type="checkbox"/> Canadian Health <input type="checkbox"/> Brazil ANVISA <input type="checkbox"/> Argentina ANMAT <input type="checkbox"/> NIOSH <input type="checkbox"/> Japan <input type="checkbox"/> Korea <input type="checkbox"/> China <input type="checkbox"/> Russia <input type="checkbox"/> Other (Specify):</p> <p>Applicable Standards and Technical Regulations: <i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i> <i>Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration - BS EN 13274-7.</i> <i>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</i> <i>Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1.</i></p> <p>Customer Specific Requirements: No</p>

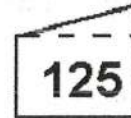
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	<p>Is the Product a safety product? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>Environment Impact: Have atmosphere emissions, liquid effluents, underground leachables been considered? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Energy released (heat, vibration): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>
INTELLECTUAL PROPERTY AND FUNDING	<p>Intellectual Property: Patents that have been granted or applied for that must be considered. <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Grants: Is the project (partially) funded by public institutions? <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p>
PACKAGING AND LABELING	<p>Packaging <input checked="" type="checkbox"/> Primary: Refer to individual Part Numbers. <input checked="" type="checkbox"/> Secondary: Refer to individual Part Numbers.</p> <p>Labelling: <input checked="" type="checkbox"/> Standard; <input type="checkbox"/> Customer specific:</p> <p style="text-align: center;">Primary packaging label</p> <div style="text-align: center;">  </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;">          </div> <div style="width: 65%;"> <p style="text-align: center;">Item Description</p> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; margin-bottom: 5px;"> REF XXXX/XXABCD001/0001 </div> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; margin-bottom: 5px;"> LOT OL-XXXX/XXXXX/21 </div> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; margin-bottom: 5px;">  YYYY-MM-DD </div> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; margin-bottom: 5px;">  YYYY-MM-DD </div> <div style="margin-top: 20px;">  <p>GVS Filter Technology UK Ltd Morecambe, Lancashire, UK LA3 3EN www.gvs.com</p> </div> <div style="border: 1px solid black; padding: 2px; margin-top: 10px; display: flex; align-items: center;"> <div style="font-weight: bold; font-size: small;">EC REP</div> <div style="font-size: x-small; margin-left: 5px;"> GVS S.p.A. - www.gvs.com Via Roma, 50 - 40059 Zola Predosa ITALY </div> <div style="margin-left: auto; font-size: x-small;">Re v 05A</div> </div> </div> </div>

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Box label



Item description



REF XXXX/XXABCD001/0001



LOT OL-XXXX/XXXXX/21



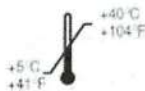
Factory Date YYYY-MM-DD



Expiry Date YYYY-MM-DD



GVS Filter Technology UK Ltd
Morecambe, Lancashire, UK LA3 3EN
www.gvs.com Rev 09A



EC REP GVS S.p.A. - www.gvs.com
Via Roma, 50 - 40069 Zola Predosa ITALY



12345678

UDI:

N/A; No; Yes (Specify):

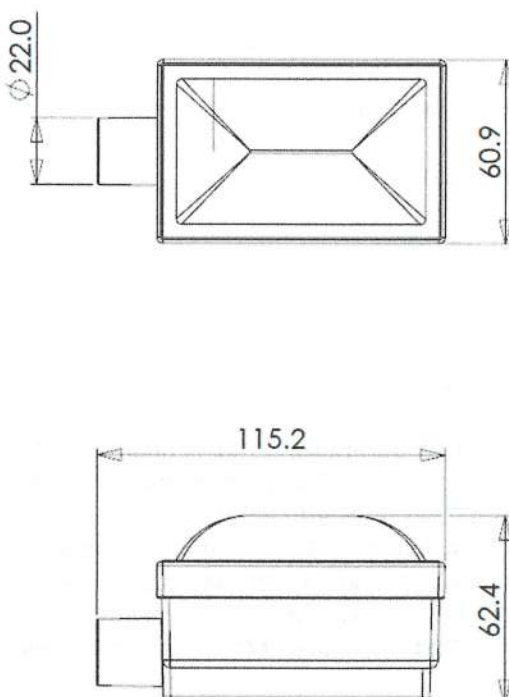
Number of pcs per bag is determined by the sales order.
The first barcode label is applied to the outside of the bags.
The second barcode label is applied onto the outside of the box.
Each bag is labelled with the following traceability information:

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

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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>
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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> 
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ACCEPTABLE QUALITY LEVEL	<input checked="" type="checkbox"/> AQL: with sampling Plan: 0.65 AQL to ISO 2859-1 <input type="checkbox"/> PPM: <input type="checkbox"/> Other:
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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>
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Acceptance Requirement		AQL	Sampling Plan
1	Black particle contamination	0.65	

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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	Weld marks	0.65	
	5	Short fill moulding	0.65	
	6	Rough surface or edges	0.65	
	7	Pronounced injection gate	0.65	
	8	Deformation/distortion	0.65	
	9	Crack	0.65	
	10	Oil/grease	0.65	
	11	Wrong colour	0.65	
	12	Weld fault	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:
*Flow Resistance @ 30L/min in accordance with EN ISO 9360-1
 Flow Resistance @ 60L/min in accordance with EN ISO 9360-1
 Flow Resistance @ 90L/min in accordance with EN ISO 9360-1*

Special Characteristic # 02: *Filter Efficiency @ 30L/min using TSI 8130 in accordance with EN 13274-7.*

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

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)
28/01/2020	1	Updated to new Mod.984 Rev.05	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.

