

Product P/N	4100/725BAUB020/0001	Mod. 984 Rev. 05
Description	Oxygen Concentrator Filter	

4100/725

Oxygen Concentrator Filter



PRODUCT DESCRIPTION	<p>Oxygen Concentrator Filter Inlet / Outlet Connectors: 22mm Male connector Approx. Dimensions: 115.2mm length x 60.9mm width x 64.4mm height Weight: 62gm (approx.) Unidirectional Filter</p> <p>Similar existing product: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: for example: 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, Black 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: Bronze</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</p>

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	<input checked="" type="checkbox"/> ROHS <input checked="" type="checkbox"/> BSE/TSE <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 64.4mm height Weight: 62gm (approx.) Interfaces (ex: Input / Output connectors): <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: 22mm Male connector 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:</p>

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	<p>Other: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Biological Sterility: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Pyrogenicity: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Haemolysis: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Toxicity: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Biocompatibility to ISO10993 Category – Surface device Contact – Intact Skin Contact Duration - <24hr</p> <p>Functional Air Flow Rate: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: 30l/min, 60l/min, 90l/min Water Break Through Pressure: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Liquid Flow Rate: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Bubble Point Pressure: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Filtration Efficiency: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>Filter Efficiency @ 30L/min using TSI 8130: Min. 99.2% (REP: 1826/19)</i> Pressure Drop: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: <i>Flow Resistance @ 30L/min in accordance with EN ISO 9360-1: Max. 551Pa</i> <i>Flow Resistance @ 60L/min in accordance with EN ISO 9360-1: Max. 1756Pa</i> <i>Flow Resistance @ 90L/min in accordance with EN ISO 9360-1: Max. 3533Pa</i> (REP: 1915/19) Internal Volume: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Operating Lifetime: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Refer to Instructions for Use. Shelf Lifetime: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: 5 years from the date of manufacture. Other:</p>
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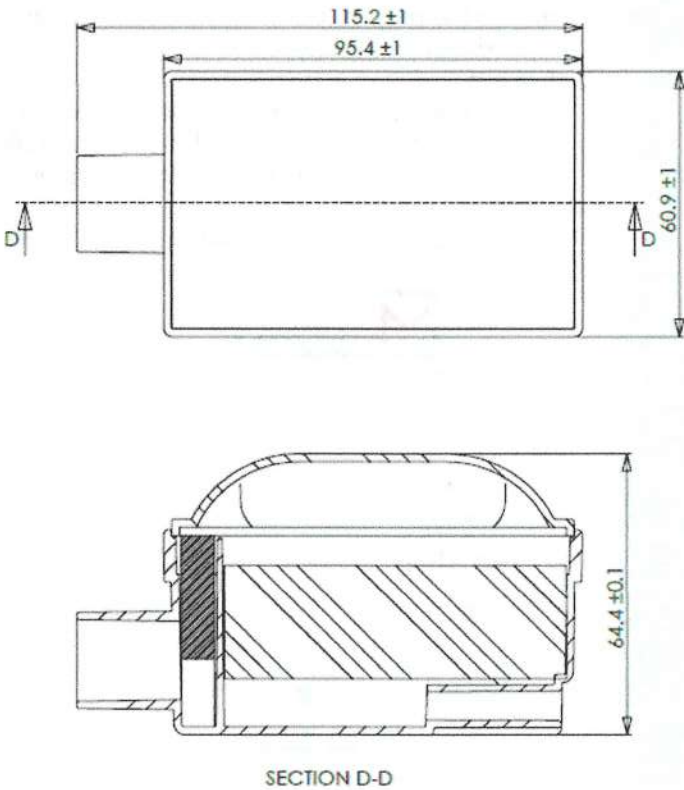
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	<input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Cleanliness Part cleanliness: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Clean-room Production required: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Class 8. Testing Insert embedding Test: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Burst test: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Leakage: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify: Other: <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:
INSTRUCTIONS / WARNINGS	IFU <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Required: Specify Languages: <input checked="" 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"/> <input type="checkbox"/> Chinese <input type="checkbox"/> Japanese <input type="checkbox"/> Korean <input type="checkbox"/> Russian <input type="checkbox"/> Other (Specify):
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	<input checked="" 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
APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: <input checked="" type="checkbox"/> CE mark <input checked="" 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): 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>





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	<p>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
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>SECTION D-D</p> </div>
ACCEPTABLE QUALITY LEVEL	<p>☑ AQL: with sampling Plan: 0.65 AQL to ISO 2859-1 ☐ PPM: ☐ Other:</p>
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions:</p>

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	<p><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> <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: 1 filter packed and sealed in polybag <input checked="" type="checkbox"/> Secondary: 125 individually bagged filters packed into the carton 577mm x 385mm x 320mm (10.047.0076.00.AB)</p> <p>Labelling: <input type="checkbox"/> Standard; <input checked="" type="checkbox"/> Customer specific: On Primary Packaging</p> <p>Distributed in Spain by:</p> <div style="text-align: center;">  <p>MARTIN VECINO, S.L. Polig. Ind. Cobo Calleja C/Leon Nº80 C.P. : 28940 Fuenlabrada (Madrid) -Spain- Tlf. +34 916424471 - Fax: +34 916423055 C.I.F. B81316101 @: info@martinvecino-sl.com</p> </div> <p>PRODUCT ABCDEFGHIJKLMNOPRS CATNO ABCDEFGHIJK LOT NO 0L-XXXXXXX/XX  YYYY-MM-DD</p> <div style="text-align: center;">  </div> <p>Manufactured by:</p> <div style="text-align: center;">  <p>Vickers Industrial Estate, Mellishaw Lane, Morecambe, Lancashire, LA3 3EN, UK Tel. +44 1524 847600, Fax. +44 1524 847800</p> </div> <p>UDI: <input checked="" type="checkbox"/> N/A; <input type="checkbox"/> No; <input type="checkbox"/> Yes (Specify):</p> <p><i>Number of pcs per bag is determined by the sales order. The first barcode label is applied to the outside of the bags.</i></p>

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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	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	<p>Special characteristic: <i>Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</i></p> <p>Special Characteristic # 01:</p> <p><i>Flow Resistance @ 30L/min in accordance with EN ISO 9360-1</i></p> <p><i>Flow Resistance @ 60L/min in accordance with EN ISO 9360-1</i></p> <p><i>Flow Resistance @ 90L/min in accordance with EN ISO 9360-1</i></p> <p>Special Characteristic # 02: <i>Filter Efficiency @ 30L/min using TSI 8130 in accordance with EN 13274-7.</i></p>
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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)
17/12/2019	1	First Issue	Kinga Gawdzik – Engineering Support Technician 	Andrew Pearce – Quality Manager 

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.