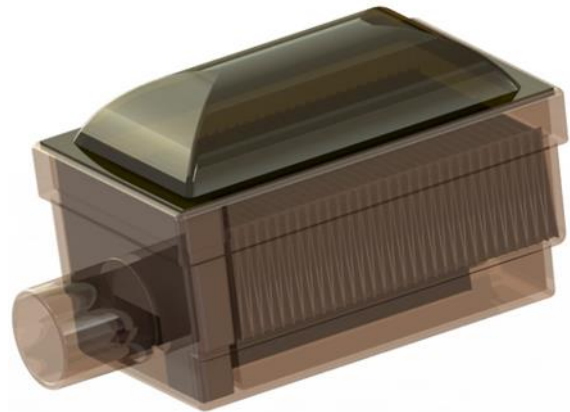


PRODUCT SPECIFICATION

Product P/N	4100/92	Mod. 984A Rev. 06
Description	Oxygen Concentrator Filter	

4100/92

**Oxygen Concentrator
Filter**



PRODUCT DESCRIPTION	Inlet / Outlet Connectors: 22mm Male connector. Approx. dimensions: 115.2mm length x 60.9mm width x 64.4mm height. Weight: 62gm (approx.). Unidirectional Filter.
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	Pre-filter for use within oxygen concentrator machines, to filter the air entering the device.
CLASS OF THE PRODUCT	Disposable medical device - Class I Rule 1 Annex VIII MDR 2017/745
MATERIALS	Filter media: <i>Glass Microfibre Media, White Polyurethane foam (PU)</i> Frame/Housing Polymer: <i>Bronze Tinted Acrylonitrile Butadiene Styrene (ABS)</i> Colour: <i>Bronze</i> Other insert(s): <i>Polyolefin Hot Melt Adhesive</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 - REACH - Conflict minerals
PRODUCT CHARACTERISTICS	Appearance/Visual As shown on drawing.

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	<p>Physical/Mechanical Approx. dimensions: 115.2mm length x 60.9mm width x 64.4mm height. Weight: 62gm (approx.) Interfaces (ex: Input / Output connectors): 22mm Male connector Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Unidirectional 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: 30l/min, 60l/min, 90l/min</p> <p>Filtration Efficiency: <i>NaCl Filter Efficiency @ 30L/min using TSI 8130: Min. 99.94% (REP: 2013/20 with Factor of Safety applied to Min.)</i></p> <p>Pressure Drop: <i>Flow Resistance @ 30L/min in accordance with EN ISO 9360-1: Max. 334Pa</i> <i>Flow Resistance @ 60L/min in accordance with EN ISO 9360-1: Max. 1169Pa</i> <i>Flow Resistance @ 90L/min in accordance with EN ISO 9360-1: Max. 2398Pa</i> (REP: 2014/20 with 10% Safety Margin applied to Max.)</p> <p>Internal Volume: <i>N/A</i> Operating Lifetime: Refer to Instructions for Use. Shelf Lifetime: 5 years from the date of manufacture.</p> <p>Cleanliness Device assembled within Class 8 Cleanroom.</p> <p>Testing <i>N/A</i></p>
INSTRUCTIONS / WARNINGS	<i>Multi-language IFU available.</i>
PRODUCT SHELF LIFE	<i>5 years from the date of manufacture.</i> <i>Expiration date and date of manufacture are detailed on the product labelling.</i>
STERILIZATION	<i>N/A</i>
APPLICABLE STANDARDS AND REGULATIONS	Product Certification required: <ul style="list-style-type: none"> - CE mark - FDA

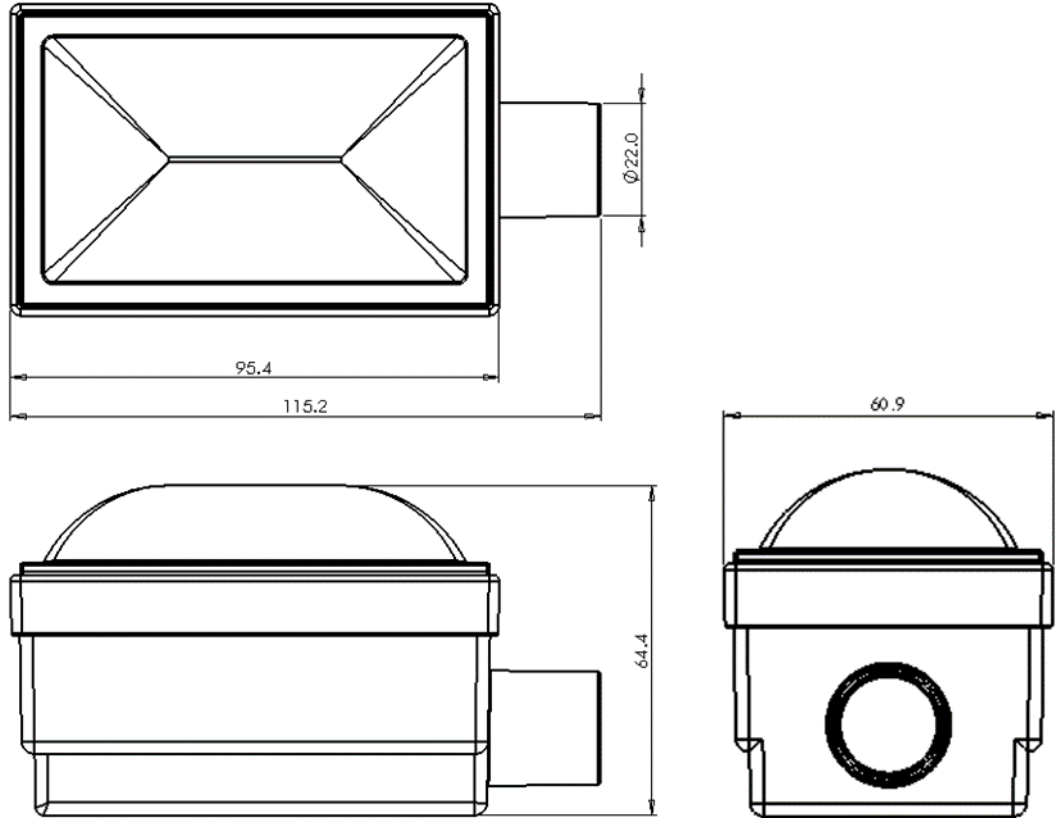
PRODUCT SPECIFICATION

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	<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>
PACKAGING AND LABELING	<p><i>Number of pcs per bag is determined by the sales order.</i> <i>The first barcode label is applied to the outside of the bags.</i> <i>The second barcode label is applied onto the outside of the box.</i> <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> <i>Bulk products will be packed 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> <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 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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Approximate dimensions for reference only

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:

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	

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	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: Product characteristic which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product.</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: NaCl Filter Efficiency @ 30L/min using TSI 8130 in accordance with EN 13274-7.</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)
28/10/2021	1	New release on Mod.984 form.	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.