PRODUCT SPECIFICATION

Product P/N	**2000/706**	**Mod. 984**
Description	**Gas/Air Vent Filter/Oxygen Concentrator**	**Rev. 02**

2000/706 Gas/Air Vent Filter/Oxygen Concentrator

PRODUCT DESCRIPTION	Gas/Air Vent Filter/Oxygen Concentrator	
MANUFACTURER NAME	**GVS Filter Technology UK Ltd.** NFC House Mellishaw lane Morecambe Lancashire LA3 3EN United Kingdom **Information** Tel. +44 (0) 1524 847600 Fax: +44 (0) 1524 847800 e-mail: gvsuk@gvs.com	**GVS China** Fengqiao Civil-Run Sci-Tech Park No.602 Changjiang Road S.N.D Suzhou 215129 China **Information** Tel. 0086-512-666619880 Fax: 0086-512-66619882 e-mail: gvschina@gvs.com
INTENDED USE / APPLICATION	For use with various machine venting applications.	
CLASS OF THE PRODUCT	Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC	
MATERIALS	**Filter media:** Glass Microfibre Media **Frame/Housing Polymer:** Polypropylene **Color:** Transparent with White Overmould ring	

PRODUCT CHARACTERISTIC	**Physical/Mechanical:**	
	Dimensions:	54.0mm Diameter
	Dimensions:	61.0mm Height
	Weight:	11.6gm (approx.)
	Effective Filtration Area:	14.6cm^2 (approx.)
	Interfaces (ex: Input/output connectors):	5.9mm to 8mm Hose Barb
	Operating temperature Range:	From +5°C to +40°C
	Storage temperature Range:	From 0°C to +55°C

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	Biological: **Pyrogenicity in accordance with GVS Procedure IC-656:** <0.25 Eu/ml **Sterilisation:** Ethylene Oxide (Max 55°C) **Functional:** **Resistance to Air Flow Rate @ 30l/min:** Maximum - 35.9mbar **Filtration Efficiency (DEHS @ 0.3µm @ 30l/min flow rate:** Minimum - 99.999%
INSTRUCTIONS **WARNINGS**	**Precautions:** For Your Safety and that of Your Patients. Follow the Instruction for Use of the basic machine. • To avoid contamination and soiling, the product should remain packaged until ready to be used. • Replace the filter if increase in resistance occurs. Following use, the products must be disposed of in accordance with the local hospital, hygiene and waste • Disposal regulations. **WARNING: The statements below provide important information about a potentially hazardous situation which, if not avoided, could result in injury to the patient.** • Any use of the medical device requires full understanding and strict observation of all portions of these Instructions for Use. The medical device may only be used for the purpose specified under "Intended Use". Observe all WARNING statements throughout this manual and all statements on medical device labels. The manufacturer disclaims any liability for patient injury caused by noncompliance with these statements. • Before installation, check that all system components are free of obstructions and of foreign bodies. Otherwise, use is limited, or faulty operation is possible. • Do not use the product if the packaging is damaged. • Do not use if product appears damaged
PRODUCT SHELF LIFE	5 years from the date of manufacture. Expiration date and date of manufacture are detailed on the product
STERILIZATION	Ethylene oxide (Max 55°C)
APPLICABLE STANDARDS AND REGULATIONS	Biological evaluation of Medical Devices. Part 1 Evaluation and Testing ISO 10993-1 Sterilization of health care products - Ethylene Oxide sterilisation ISO 11135-1 Sterilisation of medical devices – Microbiological Methods – Part 1: Estimation of population of Microorganisms on products ISO 11737-1 Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration BS EN 13274-7 Medical devices- Application of risk management To medical devices BS EN ISO 14971 Medical devices – symbols to be used with medical

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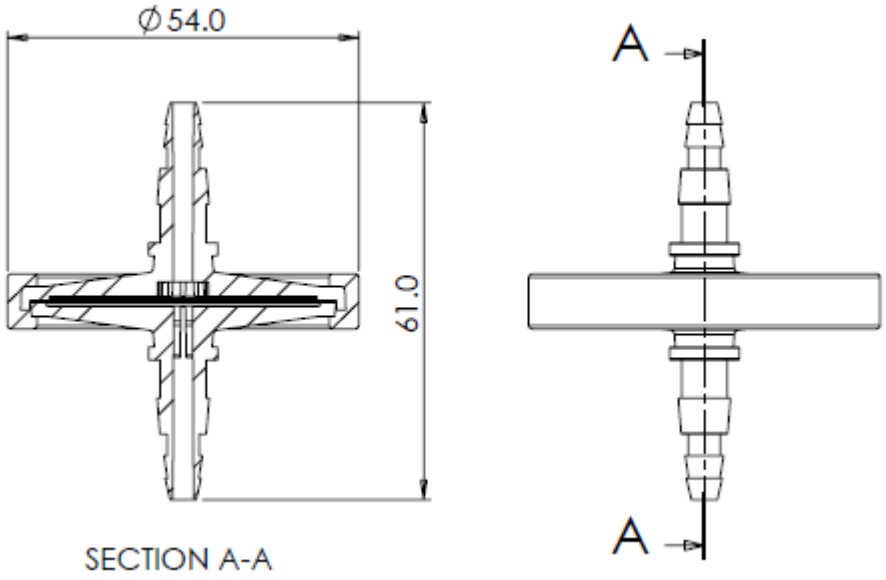
	Device labels, labelling and information to be supplied Part1: General requirements ISO 15223-1
PACKAGING AND LABELLING	Number of pcs per bag is determined by the Sales order. The first bar-code label is outside the bags. The second bar-code label is stuck outside the box. Each bag is labelled with the 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 Different lots in one box are separately closed and separately labelled. Bulk products will be packaged in double PE bags.
CERTIFICATE OF COMPLIANCE	The Quality Management system is in compliance with ISO 9001 and ISO 13485
DRAWING	
ACCEPTABLE QUALITY LEVEL	AQL: 0.65 with sampling general inspection level 1 – ISO2859

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VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Magnification: Unaided eye at a distance of approximately 35-40cm.
Illumination: Lighting level must be reasonable for visual detection i.e. 1000Lux
Timings: Maximum inspection period per item 25s

	Acceptance Requirement	AQL	Sampling Plan
1	Black particle contamination - loose (≥0.2mm2)	0.65	ISO 2859 Part 1 Inspection Level 1
2	Surface damage	0.65	
3	Blocked connector / luer	0.65	
4	Weld marks	0.65	
5	Short fill moulding (functional)	0.65	
6	Short fill moulding (non-functional)	0.65	
7	Rough surface or edges	0.65	
8	Pronounced injection gate	0.65	
9	Bubble in moulding (max 3 air bubbles)	0.65	
10	Deformation / Distortion	0.65	
11	Crack	0.65	
12	Wrong colour	0.65	
13	Flash	0.65	
14	Weld fault	0.65	
15	Oil / grease	0.65	
16	Flow marks / marbling	0.65	
17	Wrong artwork / printing	0.65	
18	Incomplete or missing membrane	0.65	

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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REVISIONS AND APPROVALS:

DATE	REV.	*REASON FOR CHANGE*	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
12/12/2017	0	First issue	Peter Diggles	Rebecca Law pp Graham Barnes

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.