MediGard UK

PRODUCT SPECIFICATION

Product P/N	**3000/740**	**Mod. 984A Rev. 06**
Description	**Expiratory Filter**	

3000/740

Expiratory Filter

PRODUCT DESCRIPTION	Inlet Outlet Connectors: 15mm Female / 22mm Male ISO connector and 22mm Female ISO connector. Approx. Dimensions: 78.8mm diameter x 111.5mm height. Weight: 60g (approx.). Bidirectional Filter.
MANUFACTURER NAME	GVS Filter Technology Supplied in the UK by MediGard UK Ltd Email address: info@medigard.co.uk Tel No: 07392 615804
INTENDED USE / APPLICATION	Filter for use with ventilators. The filter reduces particles and bacteria in the patient's exhaled gas, protecting the ventilator's exhalation and spirometry systems.
CLASS OF THE PRODUCT	Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC Rule 2 Annex VIII MDR 2017/745
MATERIALS	**Filter media:** ***Hydrophobic Glass Microfibre Media*** **Frame/Housing Polymer:** ***Transparent Clear Polypropylene (PP)*** **Colour:** ***Transparent Clear*** **Adhesive:** ***Hot Melt Adhesive and PVA Adhesive*** **Regulatory Documentation Required:** - Biocompatibility according ISO 10993-1 - ROHS - BSE/TSE - DEHP plasticizer Free and latex free - Aging - REACH - Conflict minerals

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PRODUCT CHARACTERISTICS

Appearance/Visual
As shown on drawing.

Physical/Mechanical
Approx. Dimensions: ***78.8mm diameter x 111.5mm height.***
Weight: ***90g (approx.).***
Interfaces (ex: Input / Output connectors): ***15mm Female / 22mm Male ISO connector and 22mm Female ISO connector.***
Operating temperature Range: ***N/A***
Storage temperature Range: ***5 °C to 40 °C***
Bidirectional Filter.

Biological
Pyrogenicity: ***<0.3 EU/ml***
Biocompatibility to ISO10993
Category – ***Surface device***
Contact – ***Mucosal Membrane***
Use Duration (Contact): **Up to 48 hours (<24 hours)**
Single Patient Use Only.

Functional
Air Flow Rate: ***30l/min, 60l/min, 90l/min.***

Filtration Efficiency:
NaCl Filter Efficiency @ 30L/min using TSI 8130: ***Min. 99.970%*** (REP: 2230/21 with Factor of Safety)

Pressure Drop:
Flow Resistance @ 30l/min in accordance with EN ISO 9360-1: ***Max. 92.4Pa***
Flow Resistance @ 60l/min in accordance with EN ISO 9360-1: ***Max. 204.6Pa***
Flow Resistance @ 90l/min in accordance with EN ISO 9360-1: ***Max. 336.6Pa*** (REP: 2231/21 with 10% Factor of Safety added to Max.)

Internal Volume: ***216ml (approx.)***

Operating Lifetime: ***Refer to Instructions for Use.***

Shelf Lifetime: ***5 years from the date of manufacture.***
Bacterial Filtration Efficiency in accordance with ASTM F2101-07: ***Min. 99.999%*** (Staphylococcus aureus @ 30L /minute) REP: EXT.598057.

Viral Filtration Efficiency in accordance with ASTM F2101-07: ***Min. 99.999%*** (Bacteriophage @ 30L/ minute) REP: EXT.598056.

Cleanliness
Device assembled within Class 8 Cleanroom.

Testing
Leak test @ 0.30 bar.

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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.
APPLICABLE STANDARDS AND REGULATIONS	**Product Certification required:** - CE mark - FDA **Applicable Standards and Technical Regulations:** *Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.* *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 device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1.* *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance - ISO 23328-1.*
PACKAGING AND LABELING	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 Different lots in one box are separately closed and separately labelled. Bulk products will be packed in double PE bags.
CERTIFICATE OF COMPLIANCE	With each shipment, GVS 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. The Quality management system is in compliance with ISO 9001, ISO 13485.
DRAWING	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 Ltd.

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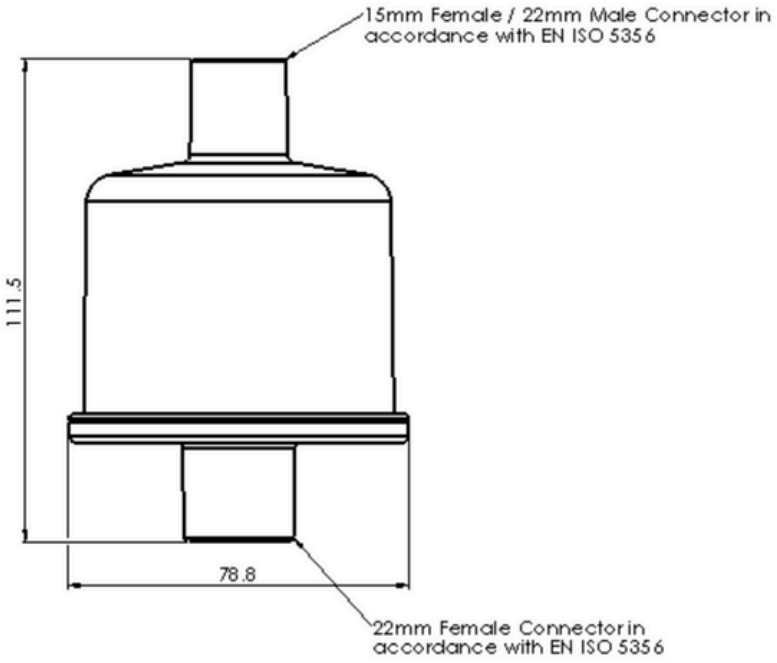

Approximate dimensions for reference only

ACCEPTABLE QUALITY LEVEL

AQL: 0.65 with sampling Plan: ISO2859.

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
2	Damaged/broken item	0.65	General Inspection
3	Blocked connector/luer	0.65	Level 1
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

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: *NaCl Filter Efficiency @ 30L/min using TSI 8130.*

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.