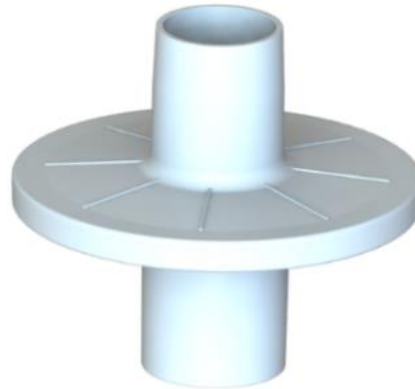


PRODUCT SPECIFICATION

Product P/N	2800/22	Mod. 984A Rev. 06
Description	Spiroguard	

2800/22

Spiroguard



PRODUCT DESCRIPTION	<p>Inlet/Outlet Connectors:</p> <ul style="list-style-type: none"> - OD34mm ID29.25mm - Machine Side; - OD31.2mm ID26.09mm - Patient Side. <p>Approx. dimensions: 97mm diameter x 85mm height. Weight: 37gm (approx.). Bidirectional Filter.</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	<p>Spirometer pre filters are used in pulmonary function tests for trapping bacteria and viruses and other particulates, reducing the risk of cross-contamination between the patient and the machine. Filters can be supplied with accessories, such as nose clip, mouthpiece and bite grip.</p>
CLASS OF THE PRODUCT	<p>Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC Rule 5 Annex VIII MDR 2017/745</p>
MATERIALS	<p>Filter media: <i>Electrostatic Blended Synthetic Fiber</i> Frame/Housing Polymer: <i>White Polypropylene Homopolymer (PP)</i> Colour: <i>White</i>.</p> <p>Regulatory Documentation Required:</p> <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 SPECIFICATION

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PRODUCT CHARACTERISTICS	<p>Appearance/Visual As shown on drawing.</p> <p>Physical/Mechanical Approx. dimensions: 97mm diameter x 85mm height. Weight: 37gm (approx.).</p> <p>Interfaces (ex: Input / Output connectors): - OD34mm ID29.25mm - Machine Side; - OD31.2mm ID26.09mm - Patient Side.</p> <p>Operating temperature Range: N/A Storage temperature Range: 5 °C to 40 °C Bidirectional Filter, Male connector – Patient Side.</p> <p>Biological Pyrogenicity: <0.3 EU/ml Biocompatibility to ISO10993 Category – Surface device Contact – Oral cavity Contact Duration - <24hrs</p> <p>Functional Air Flow Rate: 30l/min, 60l/min, 90l/min.</p> <p>Filtration Efficiency: Filter Efficiency @ 30L/min using TSI 8130: Min. 99% (REP: 1433/17 with factor of safety applied to Min.)</p> <p>Pressure Drop: Flow Resistance @ 30l/min in accordance with EN ISO 9360-1: Max.35.2Pa Flow Resistance @ 60l/min in accordance with EN ISO 9360-1: Max.75.9Pa Flow Resistance @ 90l/min in accordance with EN ISO 9360-1: Max.132Pa (REP:1255/17 with 10% of safety margin added to Max.)</p> <p>Internal Volume: 74ml (approx.)</p> <p>Operating Lifetime: Refer to Instructions for Use.</p> <p>Shelf Lifetime: 5 years from the date of manufacture.</p> <p>Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (<i>Staphylococcus aureus</i> @ 30L /minute) REP: EXT607770.</p> <p>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (<i>Bacteriophage</i> @ 30L/ minute) REP: EXT620332.</p> <p>Cleanliness Device assembled within Class 8 Cleanroom.</p> <p>Testing Torque test @ 10Nm. (REP: 1348/17)</p>
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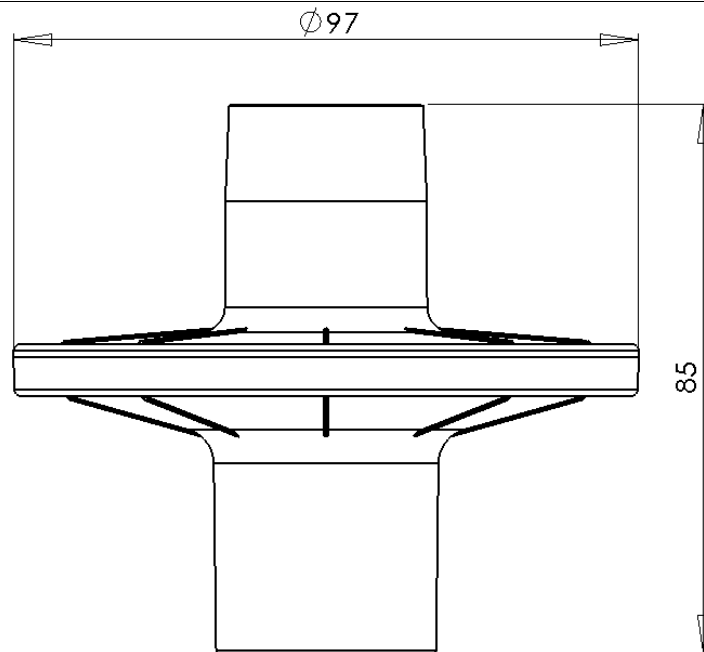
PRODUCT SPECIFICATION

Product P/N	2800/22	Mod. 984A Rev. 06
Description	Spiroguard	

INSTRUCTIONS / WARNINGS	<i>Multi-language IFU available.</i>
PRODUCT SHELF LIFE	<p><i>5 years from the date of manufacture.</i></p> <p><i>Expiration date and date of manufacture are detailed on the product labelling.</i></p>
STERILIZATION	<i>N/A</i>
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required:</p> <ul style="list-style-type: none"> - CE mark - FDA <p>Applicable Standards and Technical Regulations:</p> <p><i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i></p> <p><i>Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration - BS EN 13274-7.</i></p> <p><i>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</i></p> <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>
PACKAGING AND LABELING	<p><i>Number of pcs per bag is determined by the sales order.</i></p> <p><i>The first barcode label is applied to the outside of the bags.</i></p> <p><i>The second barcode label is applied onto the outside of the box.</i></p> <p><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></p> <p><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></p> <p><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 9001, ISO 13485.</i></p>
DRAWING	<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>

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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 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	

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	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)
11/08/2021	3	Internal volume updated.	Kinga Gawdzik – Engineering Support Technician 	Andrew Pearce – Quality Manager 

PRODUCT SPECIFICATION

Product P/N	2800/22	Mod. 984A Rev. 06
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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.