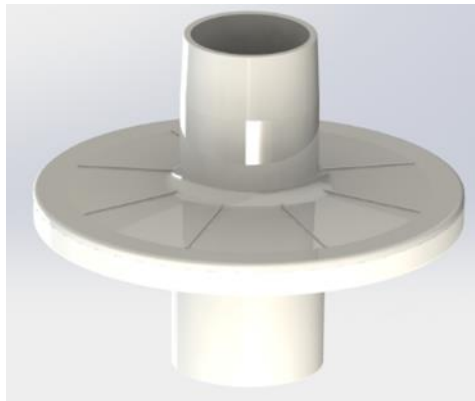


PRODUCT SPECIFICATION

Product P/N	2800/26	Mod. 984A Rev. 06
Description	Spiroguard	

2800/26

Spiroguard



PRODUCT DESCRIPTION	<p>Inlet/Outlet Connectors:</p> <ul style="list-style-type: none"> - OD34.75mm / ID27.8mm - Machine Side; - OD31.2mm / ID26.09mm - Patient Side. <p>Approx. dimensions: 96.8mm diameter x 78.1mm 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	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.
CLASS OF THE PRODUCT	<p>Disposable medical device - Class IIa</p> <p>Rule 2 Annex IX 93/42 / EEC</p> <p>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

PRODUCT SPECIFICATION

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Description	Spiroguard	

- Conflict minerals

PRODUCT CHARACTERISTICS

Appearance/Visual

As shown on drawing.

Physical/Mechanical

Approx. dimensions: **96.8mm diameter x 78.1mm height.**

Weight: **37gm (approx.)**

Interfaces (ex: Input / Output connectors): - **OD34.75mm / ID27.8mm - Machine Side;**
- **OD31.2mm / ID26.09mm - Patient Side.**

Operating temperature Range: **N/A**

Storage temperature Range: **5 °C to 40 °C**

Bidirectional Filter, Male Connector – Patient Side.

Biological

Pyrogenicity: **<0.3 EU/ml**

Biocompatibility to ISO10993

Category – **Surface device**

Contact – **Oral cavity**

Contact Duration - **<24hrs**

Functional

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

Filtration Efficiency: *Filter Efficiency @ 30L/min using TSI 8130: **Min. 99%***
(REP: 1433/17 with factor of safety applied to Min.)

Pressure Drop:

*Flow Resistance @ 30l/min in accordance with EN ISO 9360-1: **Max.28.6Pa***

*Flow Resistance @ 60l/min in accordance with EN ISO 9360-1: **Max.56.1Pa***

*Flow Resistance @ 90l/min in accordance with EN ISO 9360-1: **Max.93.5Pa***

(REP:1423/17 with 10% of safety factor added to Max.)

Internal Volume:

☐ N/A ☒ Specify: **72ml (approx.)**

Operating Lifetime:

☐ N/A ☒ Specify: **Refer to Instructions for Use.**

Shelf Lifetime:

☐ N/A ☒ Specify: **5 years from the date of manufacture.**

*Bacterial Filtration Efficiency in accordance with ASTM F2101-07: **Min. 99.999%***
(*Staphylococcus aureus @ 30L /minute*) REP: EXT607770.

*Viral Filtration Efficiency in accordance with ASTM F2101-07: **Min. 99.999%***
(*Bacteriophage @ 30L/ minute*) REP: EXT620332.

Cleanliness

Device assembled within Class 8 Cleanroom.

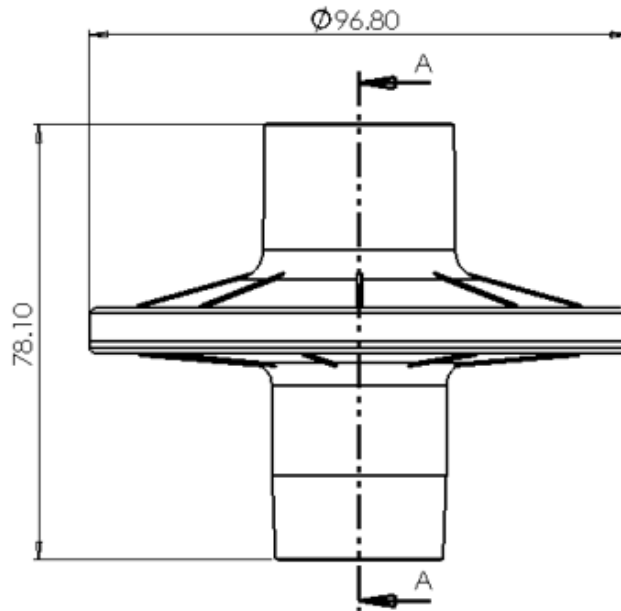
PRODUCT SPECIFICATION

Product P/N	2800/26	Mod. 984A Rev. 06
Description	Spiroguard	

	Testing <i>Torque test @ 10Nm. (REP: 1424/17)</i>
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	<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 Lt</i>

PRODUCT SPECIFICATION

Product P/N	2800/26	Mod. 984A
Description	Spiroguard	Rev. 06



Approximate dimensions for reference only

ACCEPTABLE QUALITY LEVEL	AQL: 0.65 with sampling Plan: ISO2859.																												
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions:</p> <p>Magnification: <i>Unaided eye at a distance of approximately 35-40cm.</i></p> <p>Light type: <i>Lighting level must be reasonable for visual detection.</i></p> <p>Timings: <i>Maximum inspection period per item is 25 seconds.</i></p> <p><i>For detailed defect list, refer to product control plan.</i></p> <table border="1"> <thead> <tr> <th></th><th>Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr> </thead> <tbody> <tr> <td>1</td><td>Black particle contamination</td><td>0.65</td><td rowspan="7">ISO 2859 Part 1 General Inspection Level 1</td></tr> <tr> <td>2</td><td>Damaged/broken item</td><td>0.65</td></tr> <tr> <td>3</td><td>Blocked connector/luer</td><td>0.65</td></tr> <tr> <td>4</td><td>Weld marks</td><td>0.65</td></tr> <tr> <td>5</td><td>Short fill moulding</td><td>0.65</td></tr> <tr> <td>6</td><td>Rough surface or edges</td><td>0.65</td></tr> <tr> <td>7</td><td>Pronounced injection gate</td><td>0.65</td></tr> </tbody> </table>				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
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PRODUCT SPECIFICATION

Product P/N	2800/26	Mod. 984A Rev. 06
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	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	2800/26	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.