PRODUCT SPECIFICATION

Product P/N	**2800/21**	**Mod. 984A Rev. 06**
Description	**Spiroguard Integral Mouthpiece**	

2800/21

Spiroguard Integral Mouthpiece

PRODUCT DESCRIPTION	Inlet/Outlet Connectors: - OD34mm ID29.25mm - Machine Side; - Integral Mouthpiece - Patient Side. Approx. dimensions: 97mm diameter x 93mm height. Weight: 37gm (approx.). Bidirectional 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	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.
CLASS OF THE PRODUCT	Disposable medical device - Class IIa Rule 2 Annex IX 93/42 / EEC Rule 5 Annex VIII MDR 2017/745
MATERIALS	**Filter media:** ***Electrostatic Blended Synthetic Fiber*** **Frame/Housing Polymer**: ***White Polypropylene Homopolymer (PP)*** **Colour:** ***White.*** **Regulatory Documentation Required:** - 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. **Physical/Mechanical** Approx. dimensions: ***97mm diameter x 93mm height.*** Weight: ***37gm (approx.).*** Interfaces (ex: Input / Output connectors): ***OD 34mm ID 29.25mm - Machine Side; Integral Mouthpiece - 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.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.127.6Pa*** (REP:1251/17 with 10% of safety margin added to Max.) Internal Volume: ***77ml (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: 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

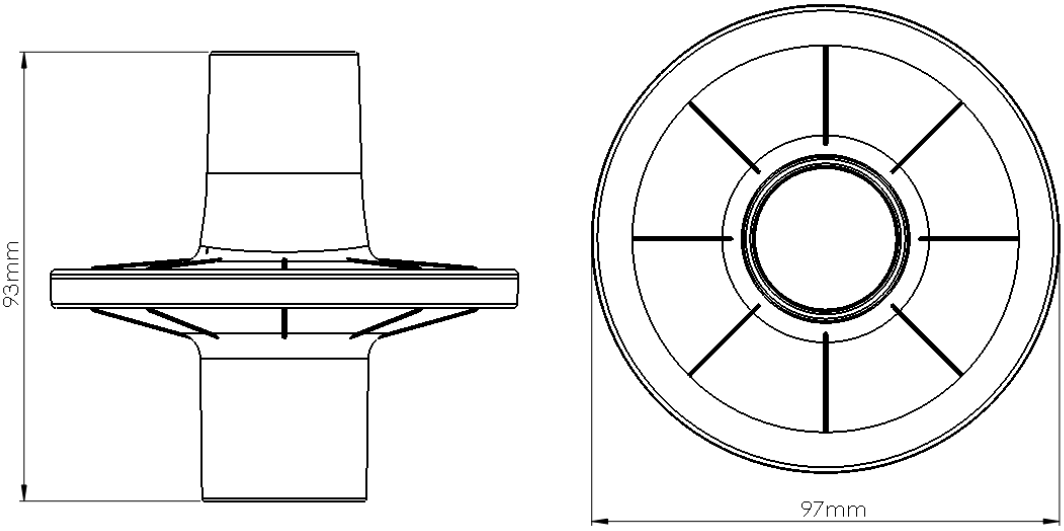
Product P/N	**2800/21**	**Mod. 984A Rev. 06**
Description	**Spiroguard Integral Mouthpiece**	

	Testing ***Torque test @ 10Nm.*** (REP: 1347/17)
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.*
STERILIZATION	*N/A*
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.*
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 UK 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 UK Ltd.*

PRODUCT SPECIFICATION

Product P/N	**2800/21**	**Mod. 984A Rev. 06**
Description	**Spiroguard Integral Mouthpiece**	

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	
7	Pronounced injection gate	0.65	
8	Deformation/distortion	0.65	

PRODUCT SPECIFICATION

Product P/N	**2800/21**	**Mod. 984A Rev. 06**
Description	**Spiroguard Integral Mouthpiece**	

	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)
10/08/2021	3	IFU languages section and internal volume amended.	Kinga Gawdzik – Engineering Support Technician 	Andrew Pearce – Quality Manager 

PRODUCT SPECIFICATION

Product P/N	**2800/21**	**Mod. 984A Rev. 06**
Description	**Spiroguard Integral Mouthpiece**	

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.