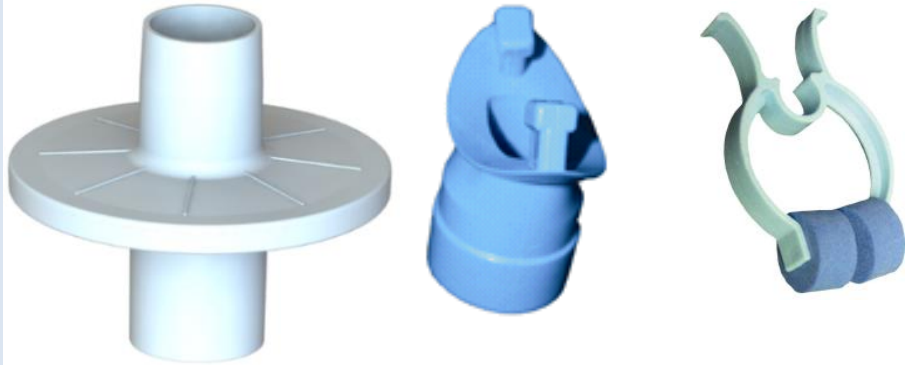


PRODUCT SPECIFICATION

Product P/N	2800/22DAK	Mod. 984A
Description	Spiroguard with Nose Clip and Bite Grip	Rev. 06

2800/22DAK

**Spiroguard
with Nose Clip
and Bite Grip**



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> <p>DAK – nose clip + bite grip:</p> <p>Inlet/Outlet Connectors of bite grip: OD36mm/ID32mm. Approx. dimensions of bite grip: OD36mm x 60mm height. Approx. dimensions of nose clip: 66mm length x 41.8mm width.</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</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></p> <p>Frame/Housing Polymer: 2800/22: <i>White Polypropylene Homopolymer (PP)</i> <i>Bite grip: Blue Thermoplastic Elastomer (TPE)</i> <i>Nose clip: Acetal Copolymer (POM) and Ethylene vinyl acetate Copolymer (EVA)</i></p> <p>Colour: 2800/22: <i>White</i>. DAK = bite grip + nose clip: <i>blue</i>.</p>

PRODUCT SPECIFICATION

Product P/N	2800/22DAK	Mod. 984A
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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 of **2800/22**: **97mm diameter x 85mm height.**

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

DAK – nose clip + bite grip:

Approx. dimensions of **bite grip**: **OD36mm x 60mm height.**

Approx. dimensions of **nose clip**: **66mm length x 41.8mm width.**

Interfaces (ex: Input / Output connectors):

2800/22:

- **OD34mm ID29.25mm - Machine Side;**

- **OD31.2mm ID26.09mm - Patient Side.**

Inlet/Outlet Connectors of **bite grip**: **OD36mm/ID32mm.**

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**

For kit performance characteristics for 2800/22DAK – Please refer to 2800/22 Technical data sheet.

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.132Pa

(REP:1255/17 with 10% of safety margin added to Max.)

Internal Volume: **74ml (approx.)**

PRODUCT SPECIFICATION

Product P/N	2800/22DAK	Mod. 984A Rev. 06
Description	Spiroguard with Nose Clip and Bite Grip	

	<p>Operating Lifetime: Refer to Instructions for Use. Shelf Lifetime: 5 years from the date of manufacture.</p> <p><i>Bacterial Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (Staphylococcus aureus @ 30L /minute) REP: EXT607770.</i></p> <p><i>Viral Filtration Efficiency in accordance with ASTM F2101-07: Min. 99.999% (Bacteriophage @ 30L/ minute) REP: EXT620332.</i></p> <p>Cleanliness Device assembled within Class 8 Cleanroom.</p> <p>Testing Torque test @ 10Nm. (REP: 1348/17)</p>
INSTRUCTIONS / WARNINGS	Multi-language IFU available.
PRODUCT SHELF LIFE	<p>5 years from the date of manufacture.</p> <p>Expiration date and date of manufacture are detailed on the product labelling.</p>
STERILIZATION	N/A
APPLICABLE STANDARDS AND REGULATIONS	<p>Product Certification required:</p> <ul style="list-style-type: none"> - CE mark - FDA <p>Applicable Standards and Technical Regulations: <i>Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.</i> <i>Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration - BS EN 13274-7.</i> <i>Medical devices- Application of risk management to medical devices - BS EN ISO 14971.</i> <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>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:</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>Different lots in one box are separately closed and separately labelled. Bulk products will be packed in double PE bags.</p>
CERTIFICATE OF COMPLIANCE	With each shipment, GVS UK Customer Service will send the CoC to the Customer, based on the lot numbers and date of manufacture.

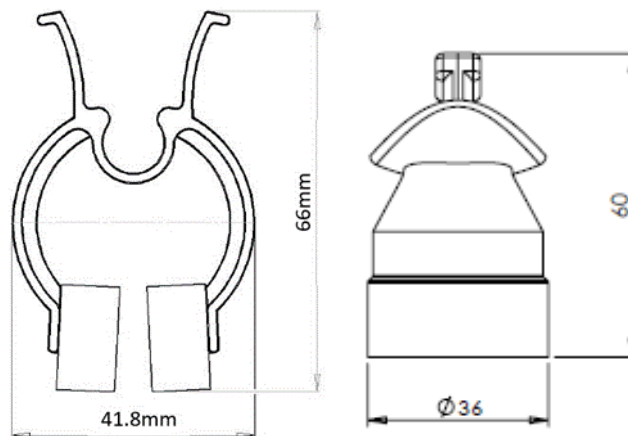
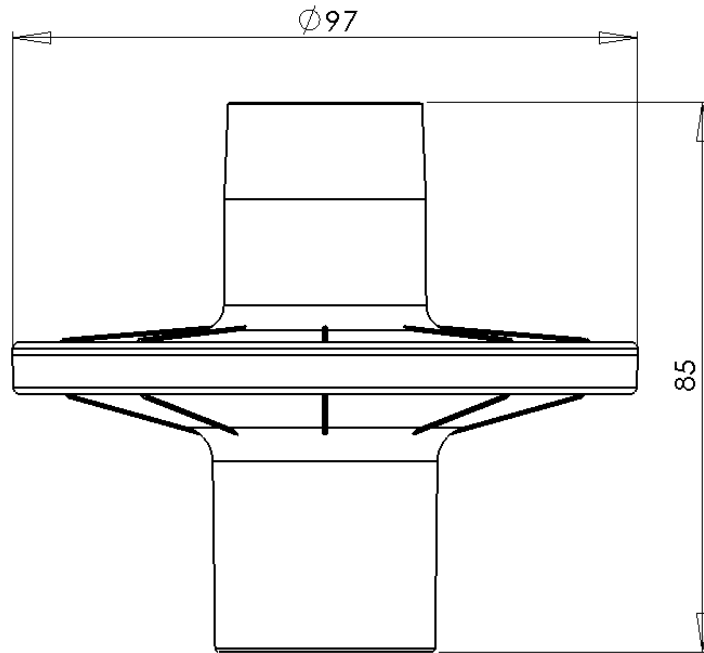
PRODUCT SPECIFICATION

Product P/N	2800/22DAK	Mod. 984A
Description	Spiroguard with Nose Clip and Bite Grip	Rev. 06

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 Lt



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.

PRODUCT SPECIFICATION

Product P/N	2800/22DAK	Mod. 984A Rev. 06
Description	Spiroguard with Nose Clip and Bite Grip	

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	
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.

PRODUCT SPECIFICATION

Product P/N	2800/22DAK	Mod. 984A
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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 

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.