PRODUCT SPECIFICATION

Product P/N	**2802/28**	**Mod. 984A Rev. 06**
Description	**Spiroguard adaptor**	

2802/28

Spiroguard adaptor

PRODUCT DESCRIPTION	Inlet/Outlet connectors: OD40mm/ID34.3mm and OD32.2mm/29.2mm (approx.) Approx. Dimensions: 44mm length. Weight: 15g (approx.)
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	Spiroguard Machine Adaptor acts as an adaptor between the spiroguard filter and the pulmonary function machine.
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: *N/A*** **Frame/Housing Polymer**: ***Acetal*** **Colour: *White*** **Regulatory Documentation Required:** -ROHS -BSE/TSE -DEHP plasticizer Free and latex free -Aging -REACH -Conflict minerals
PRODUCT CHARACTERISTICS	**Appearance/Visual** As shown on drawing

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	Physical/Mechanical Approx. Dimensions: ***44mm length.*** Weight: ***15g (approx.)*** Interfaces (ex: Input / Output connectors): ***OD40mm/ID34.3mm and OD32.2mm/29.2mm (approx.)*** Operating temperature Range: ***N/A*** Storage temperature Range: ***5 °C to 40 °C*** **Biological** Pyrogenicity: ***<0.3 EU/ml*** *Category – **Surface device*** *Contact – **Skin*** *Contact Duration - **<24hrs*** **Functional** Air Flow Rate: ***N/A*** Filtration Efficiency: ***N/A*** Pressure Drop: ***N/A*** Internal Volume: ***N/A*** Operating Lifetime: ***Refer to Instructions for Use.*** Shelf Lifetime: ***5 years from the date of manufacture.*** **Cleanliness** Part cleanliness: ***Hand wash adaptor with hot water and a mild soap. Rinse it in clean water, shake off excess water and allow to air dry. Wipe with alcohol impregnated wipes before reconnecting it to the machine. Adaptor must be cleaned after each patient.*** **Testing** ***N/A***
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:** *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.*

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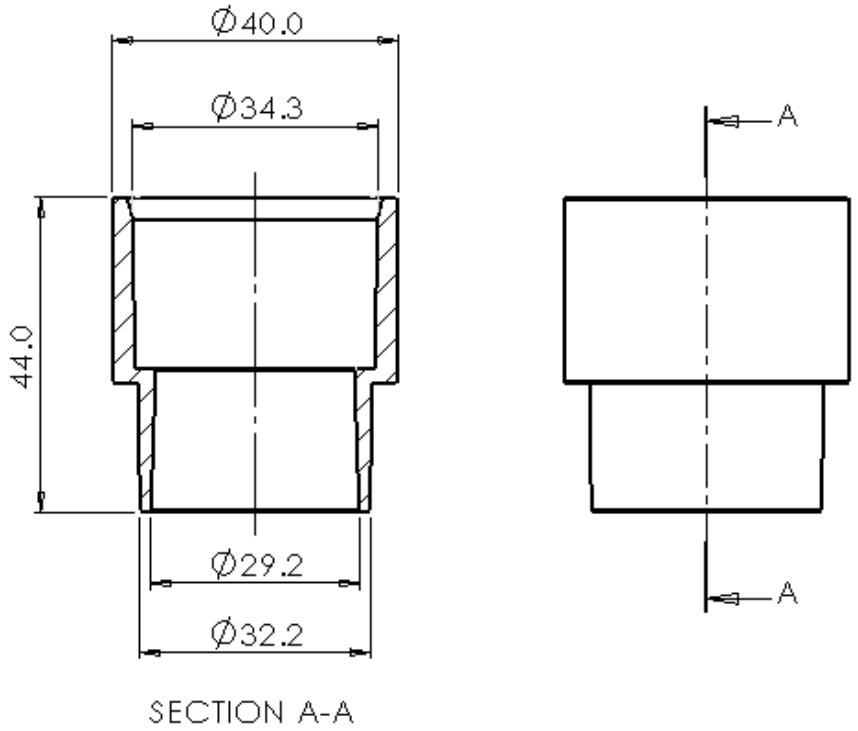
PACKAGING AND LABELING	*Number of pcs per bag is determined by the sales order.* *The first barcode label is applied to the outside of the bags.* *The second barcode label is applied onto the outside of the box.* *Each bag is labelled with the following traceability information:* ✓ *Quantity* ✓ *Product 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 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.* Approximate dimensions for reference only 
ACCEPTABLE QUALITY LEVEL	AQL: 0.65 with sampling Plan: ISO2859.

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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	Rough surface or edges	0.65	
4	Deformation/distortion	0.65	
5	Crack	0.65	
6	Oil/grease	0.65	
7	Wrong colour	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.* *None identified.*

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)
17/08/2021	1	Initial release.	Kinga Gawdzik – Engineering Support Technician	Andrew Pearce – Quality Manager

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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.