PRODUCT SPECIFICATION

Product P/N	**A539**	**Mod. 984A Rev. 06**
Description	**Bite grip Mouthpiece**	

A539

Bite grip Mouthpiece

PRODUCT DESCRIPTION	Inlet/Outlet Connectors: - OD36mm/ID32mm (approx.); - Integral Mouthpiece - Patient Side. Approx. dimensions: OD36mm x 60mm height. 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	A mouthpiece to be used in conjunction with the spiroguard filter used in pulmonary lung function testing.
CLASS OF THE PRODUCT	Disposable medical device - Class IIa Rule 5 Annex IX 93/42 / EEC Rule 5 Annex VIII MDR 2017/745
MATERIALS	**Filter media: *N/A*** **Frame/Housing Polymer**: ***Blue Thermoplastic Elastomer (TPE)*** **Colour: *Blue*** **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: **OD36mm x 60mm height.*** *Weight: **15g (approx.).*** Interfaces (ex: Input / Output connectors): ***N/A***

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	Operating temperature Range: ***N/A*** Storage temperature Range: ***5 °C to 40 °C*** **Biological** Pyrogenicity: ***<0.3 Eu/ml*** ***Biocompatibility to ISO10993*** *Category* – ***Surface device*** *Contact* – ***Oral Cavity*** *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** Device assembled within Class 8 Cleanroom or Clean Manufacturing Environment. **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:** *Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.* *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.*

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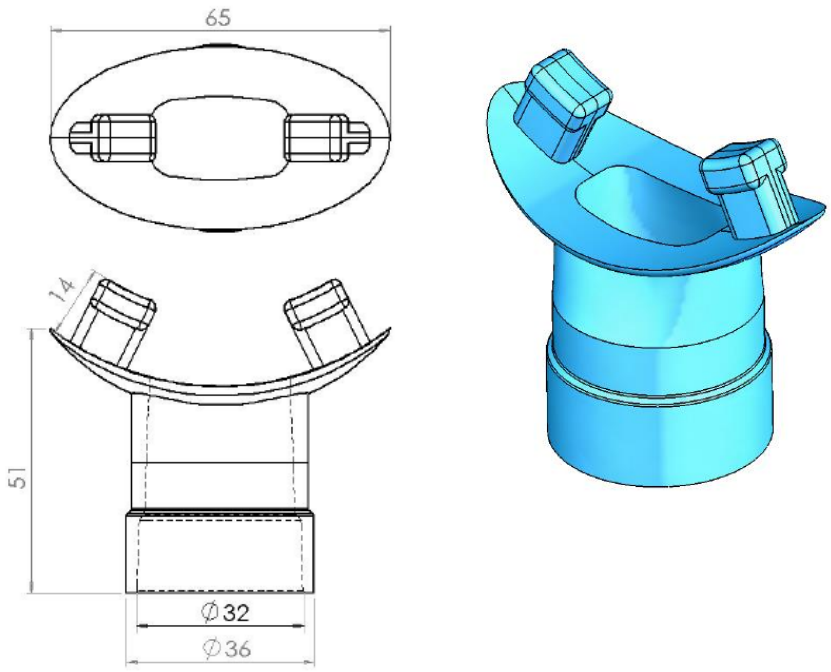
	The second barcode label is applied onto the outside of the box. *Each bag is labelled with the following traceability information:* ✓ *Quantity* ✓ *Product description* ✓ *Product Date* ✓ *Lot Number (OL and 5-digit batch number to trace back to raw materials used)* ✓ *Operator Code* *Different lots 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.* 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	Blocked connector/luer	0.65	
4	Short fill moulding	0.65	
5	Rough surface or edges	0.65	
6	Deformation/distortion	0.65	
7	Crack	0.65	
8	Oil/grease	0.65	
9	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)
12/08/2021	2	Contact section updated.	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.