# PRODUCT SPECIFICATION

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|---|---|---|
| **Product P/N** | **4222/703** | **Mod. 984A Rev. 06** |
| **Description** | **MAXI Maxi Filter** | |

## *4222/703*

## *MAXI Maxi Filter*

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| **PRODUCT DESCRIPTION** | Inlet/Outlet Connectors: 22mm Male/15mm Female – 22mm Female ISO Connectors.<br>Approx. dimensions: 68.5mm diameter x 67.2mm height.<br>Weight: 25g (approx.).<br>Bidirectional Filter. |
| **MANUFACTURER NAME** | **GVS Filter Technology UK**<br>NFC House<br>Vickers Industrial Estate<br>Mellishaw Lane, Morecambe<br>Lancashire LA3 3EN - United Kingdom<br><br>**Information**<br>Tel. +44 (0) 1524 847600<br>e-mail: gvsuk@gvs.com |
| **INTENDED USE / APPLICATION** | Filters protect the patient's airways effectively from exogenous microbial loads, thus reducing the risk of extrinsic colonisation and infection. Used to help reduce cross contamination between patient and machine. |
| **CLASS OF THE PRODUCT** | Disposable medical device - Class IIa<br><br>Rule 2 Annex IX 93/42 / EEC<br><br>Rule 5 Annex VIII MDR 2017/745 |
| **MATERIALS** | **Filter media:** ***Electrostatic Blended Synthetic Fiber***<br>**Frame/Housing Polymer**: ***Transparent Green Tinted Polypropylene (PP)***<br>**Colour:** ***Transparent Green***<br><br>**Regulatory Documentation Required:**<br>- Biocompatibility according ISO 10993-1<br>- ROHS<br>- BSE/TSE<br>- DEHP plasticizer Free and latex free<br>- Aging<br>- REACH<br>- Conflict minerals |
| **PRODUCT CHARACTERISTICS** | **Appearance/Visual**<br>As shown on drawing.<br><br>**Physical/Mechanical**<br>*Approx. dimensions:* ***68.5mm diameter x 67.2mm height.*** |

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| | *Weight:* ***25g (approx.)***<br>Interfaces (ex: Input / Output connectors): ***22mm Male/15mm Female – 22mm Female ISO Connectors.***<br>Operating temperature Range: ***N/A***<br>Storage temperature Range: ***5 °C to 40 °C***<br>***Bidirectional Filter.***<br><br>**Biological**<br>Pyrogenicity: ***<0.3 EU/ml***<br>***Biocompatibility to ISO10993***<br>*Category –* ***Surface device***<br>*Contact –* ***Skin***<br>*Contact Duration -* ***<24hrs***<br><br>**Functional**<br>Air Flow Rate: ***30l/min, 60l/min, 90l/min.***<br><br>Filtration Efficiency: *NaCl Filter Efficiency @ 30L/min using TSI 8130:* ***Min. 98.5%***<br>(REP: 0840/16 with factor of safety applied to Min.)<br><br>Pressure Drop:<br>*Flow Resistance @ 30l/min in accordance with EN ISO 9360-1:* ***Max.88Pa***<br>*Flow Resistance @ 60l/min in accordance with EN ISO 9360-1:* ***Max.187Pa***<br>*Flow Resistance @ 90l/min in accordance with EN ISO 9360-1:* ***Max.297Pa***<br>(REP:0853/16 with 10% of safety margin added to Max.)<br><br>Internal Volume: ***27ml (approx.)***<br><br>Operating Lifetime: ***Refer to Instructions for Use.***<br><br>Shelf Lifetime: ***5 years from the date of manufacture.***<br><br>*Bacterial Filtration Efficiency in accordance with ASTM F2101-07:* ***Min. 99.999%***<br>*(Staphylococcus aureus @ 30L /minute)* Ref.4222/701 REP: EXT486704B<br><br>*Viral Filtration Efficiency in accordance with ASTM F2101-07:* ***Min. 99.999%***<br>*(Bacteriophage @ 30L/ minute)* Ref.4222/701 REP: EXT486705B.1<br><br>*Gas leakage in accordance with EN9360:* ***Max.0.0 ml/min*** (REP:1269/17)<br><br>**Cleanliness**<br>Device assembled within Class 8 Cleanroom.<br><br>**Testing**<br>***Leak test at 3PSI.*** |
| **INSTRUCTIONS / WARNINGS** | *Multi-language IFU available.* |
| **PRODUCT SHELF LIFE** | *5 years from the date of manufacture.*<br><br>*Expiration date and date of manufacture are detailed on the product labelling.* |

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| **STERILIZATION** | *Sterile version of product available (Ethylene oxide - Max 55°C)* |
| **APPLICABLE STANDARDS AND REGULATIONS** | **Product Certification required:**<br>- CE mark<br>- FDA<br><br>**Applicable Standards and Technical Regulations:**<br>*Biological evaluation of Medical Devices - Part 1: Evaluation and Testing - ISO 10993-1.*<br><br>*Respiratory protective devices - Method for test - Part 7: Determination of particle filter penetration - BS EN 13274-7.*<br><br>*Medical devices- Application of risk management to medical devices - BS EN ISO 14971.*<br><br>*Medical devices – symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements - ISO 15223-1.*<br><br>*Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance - ISO 23328-1.*<br><br>*Anaesthetic and respiratory equipment – conical connectors – part 1: Cones and sockets – ISO 5356-1.*<br><br>*Sterilization of health care products – Ethylene oxide sterilization – ISO 11135-1.*<br><br>*Sterilization of medical devices – Microbiological Methods – Part 1: Estimation of population of microorganisms on products – ISO 11737-1.* |
| **PACKAGING AND LABELING** | *Number of pcs per bag is determined by the sales order.*<br>*The first barcode label is applied to the outside of the bags.*<br>*The second barcode label is applied onto the outside of the box.*<br>*Each bag is labelled with the following traceability information:*<br>✓ *Quantity*<br>✓ *Product description*<br>✓ *Product Date*<br>✓ *Lot Number (OL and 5-digit batch number to trace back to raw materials used)*<br>✓ *Operator Code*<br>*Different lots in one box are separately closed and separately labelled.*<br>*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.*<br>*Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1.*<br>*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.* |

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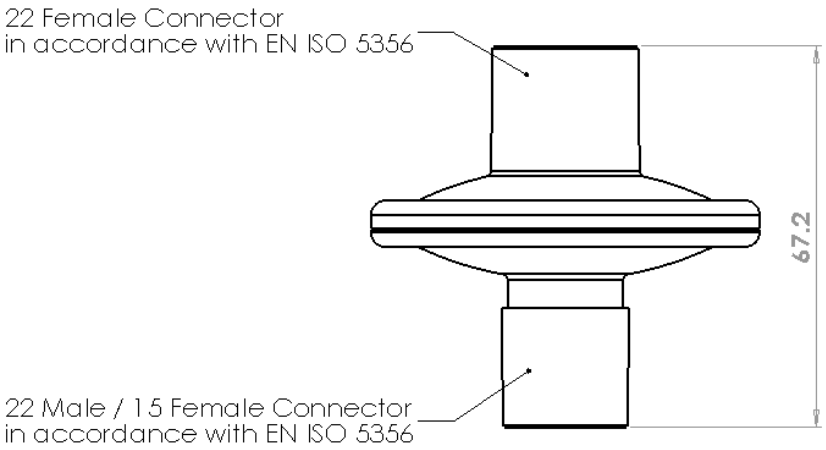


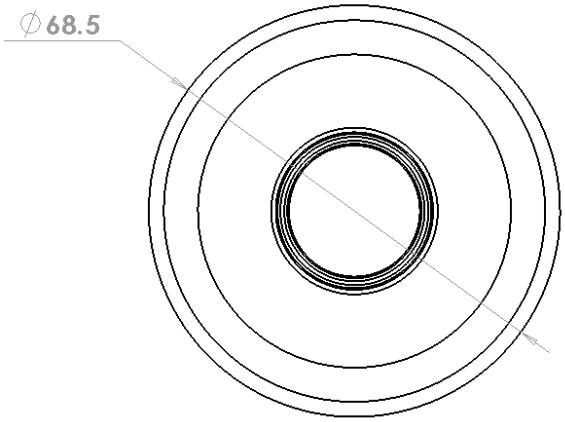


Approximate dimensions for reference only

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| **ACCEPTABLE QUALITY LEVEL** | AQL: 0.65 with sampling Plan: ISO2859. |
| **VISUAL REQUIREMENTS** | **Visual acceptance requirements apply when inspected under below conditions:**<br><br>Magnification: *Unaided eye at a distance of approximately 35-40cm.*<br>Light type: *Lighting level must be reasonable for visual detection.*<br>Timings: *Maximum inspection period per item is 25 seconds.*<br>*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 | |

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|---|---|---|---|---|---|
| | 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:** *NaCl 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.*

**Special Characteristic # 04:** *Conical connectors compliant in accordance with EN5356.*

**Special Characteristic # 05:** *Gas Leakage compliant in accordance with EN9360.*

**This material specification describes the properties of product above indicated. This document contains general requirements, material description, drawing references, defect specification, biological material requirements.**

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## REVISIONS AND APPROVALS:

| DATE | REV. | REASON FOR CHANGE | ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE) | APPROVED BY: (NAME/FUNCTION/SIGNATURE) |
|---|---|---|---|---|
| 03/08/2021 | 4 | Functional characteristics 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.*