# PRODUCT SPECIFICATION

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| **Product P/N** | **6421/04** | **Mod. 984A Rev. 06** |
| **Description** | **Insufflation Filter** | |

## *6421/04*

## *Insufflation Filter*

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| **PRODUCT DESCRIPTION** | Inlet/Outlet Connectors: 22mm Male/15mm Female – 22mm Female/15mm Male ISO connector.<br>Bidirectional Filter.<br>Approx. dimensions: 61.5mm x 48.9mm x 48.9mm.<br>Weight: 22g (approx.). |
| **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** | To be used in conjunction with insufflators for intra-abdominal insufflation. |
| **CLASS OF THE PRODUCT** | Disposable medical device - Class IIa<br><br>Rule 2 Annex IX 93/42 / EEC<br><br>Rule 2 Annex VIII MDR 2017/745 |
| **MATERIALS** | **Filter media:** ***Electrostatic Blended Synthetic Fibre with Polypropylene mesh and Glass Microfibre Media***<br><br>**Frame/Housing Polymer:** ***Clear Styrene - Butadiene Copolymer (SBC)***<br><br>**Colour:** ***Transparent Clear.***<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 |

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| | - Conflict minerals |
| **PRODUCT CHARACTERISTICS** | **Appearance/Visual**<br>As shown on drawing.<br><br>**Physical/Mechanical**<br>*Approx. dimensions:* ***61.5mm x 48.9mm x 48.9mm.***<br>*Weight:* ***22gm (approx.).***<br>Interfaces (ex: Input / Output connectors): ***22mm Male/15mm Female – 22mm Female/15mm Male ISO.***<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:<br>*Filter Efficiency @ 30L/min using TSI 8130:* ***Min. 99%*** (REP 0580/15 with Factor of Safety)<br><br>Pressure Drop:<br>*Flow Resistance @ 30L/min in accordance with EN ISO 9360-1:* ***Max. 1373Pa***<br>*Flow Resistance @ 60L/min in accordance with EN ISO 9360-1****: Max. 2918Pa***<br>*Flow Resistance @ 90L/min in accordance with EN ISO 9360-1****: Max. 4741Pa***<br>(REP 0533/15 with 10% Factor of Safety applied to Maximum)<br><br>Internal Volume: ***24ml (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)* REP: EXT846022-S01<br><br>*Viral Filtration Efficiency in accordance with ASTM F2101-07:* ***Min.99.997%***<br>*(Bacteriophage @ 30L/ minute)* REP: EXT846021-S01<br><br>**Cleanliness**<br>Device assembled within Class 8 Cleanroom.<br><br>**Testing**<br>Leakage: ***Furness Leak test @ 4.5 psi*** |

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| | Other: ***ISO connector Test Rig*** (Rep. 0594/15) |
| **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.* |
| **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>*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>*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><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><br>*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.* |

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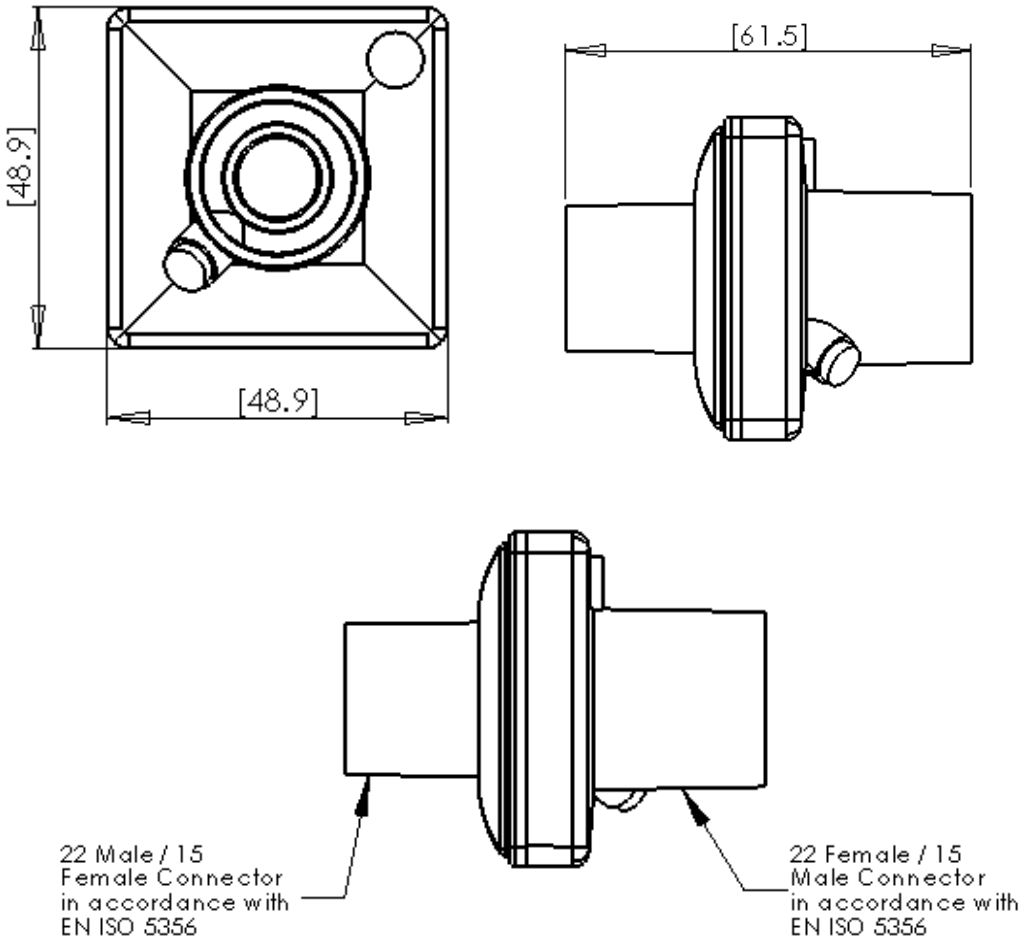
Approximate dimension for reference only

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| **ACCEPTABLE QUALITY LEVEL** | AQL: with sampling Plan: 0.65 AQL to ISO 2859-1 |
| **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 |
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| 1 | Black particle contamination | 0.65 | |

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| | 2 | Damaged/broken item | 0.65 | ISO 2859 Part 1 General Inspection Level 1 |
| | 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.**

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## REVISIONS AND APPROVALS:

| DATE | REV. | REASON FOR CHANGE | ISSUED AND CONTROLLED BY: (NAME/FUNCTION/SIGNATURE) | APPROVED BY: (NAME/FUNCTION/SIGNATURE) |
|---|---|---|---|---|
| 09/09/2021 | 2 | Sterilization section 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.*