# PRODUCT SPECIFICATION

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|---|---|---|
| **Product PN** | **1233547, 1233548, 1233544, 3049950, 1233545, 3019423** | **Mod. 984** |
| **Description** | **17 mm Cameo Syringe Filters w/Polyethersulfone Membrane** | **Rev. 02** |

## 17 mm Cameo, Polyethersulfone (PES)

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|---|---|
| **PRODUCT DESCRIPTION** | Non-Sterile 17mm Syringe Filter made of Polypropylene Housing assembled with various pore sizes of Polyethersulfone (PES) Membrane |

| Membrane Material | Pore Size (um) | Color | Packaging 50/pk | Packaging 200/pk | Packaging 500/pk | Packaging 1000/pk | Packaging 5000/pk |
|---|---|---|---|---|---|---|---|
| Polyethersulfone (PES) | 0.22 | Transparent | 1233547 | N/A | N/A | 1233544 | 3049950 |
| Polyethersulfone (PES) | 0.45 | Transparent | 1233548 | N/A | N/A | 1233545 | 3019423 |

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| **MANUFACTURER NAME** | **GVS North America**<br>**63 Community Drive**<br>**Sanford, Me 04073**<br>Phone: +1.866.736.1250<br>eMail: CustomerCareGVSLS@gvs.com - Website: www.gvs.com |
| **INTENDED USE / APPLICATION** | **Applications**<br>• Analytical Sample Preparation<br>• Dissolution testing<br>• Content uniformity<br>• Environmental samples<br>• Composite assays<br>• Food analysis<br>• Biofuel analysis |
| **MATERIALS** | **Filter media:** Polyethersulfone<br><br>**Frame/Housing Polymer:** Polypropylene<br><br>**Color:** Transparent<br><br>**Other insert(s):** N/A<br><br>**Regulatory Documentation Required:**<br>☐ Biocompatibility according ISO 10993-1<br>☐IMDS<br>☐DEHP plasticizer Free and latex free<br>☒Rohs, Directive 2002/32/CE |

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| | ☐Aging<br>☒BSE/TSE, directive 2003/32/CE<br>☒ 1907/2006/CE (hazardous substances regulation)<br>☐Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)<br>☒Conflict minerals |

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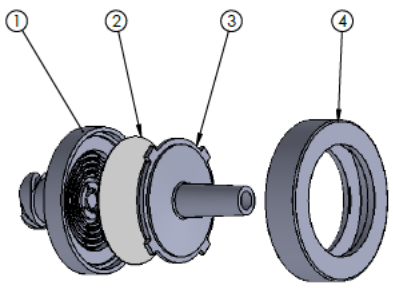
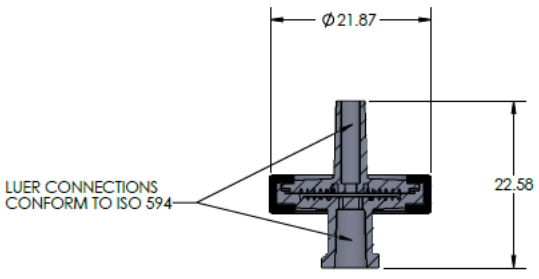
| **PRODUCT CHARACTERISTIC** | **Characteristics**<br>Membrane Materials: Polyethersulfone (PES)<br>Membrane Diameter: 17 mm<br>Effective Filtration Area: 1.4 $cm_2$<br>Housing Diameter: 22 mm<br>Housing Material: Heat-sealed pure polypropylene without the use of glues or sealants<br>Inlet / Outlet: FLL-MLS<br>Prefilter: 1.0 µ binderless glass-fiber, in some configurations<br>Holdup Volume: <40 microliter<br>Maximum Operating Temperature: 82°C/180°F<br>Maximum Operating Pressure: 80 psi<br>Sterile: No |
| **PRODUCT SHELF LIFE** | When stored under normal storage conditions, this product should be stable for 5 years |
| **STERILIZATION** | This is a non-sterile product, compatible with these sterilization techniques*:<br><br>☒EtO<br>☒Gamma (up to 40 kGy)<br>☒Autoclave (121°C)<br><br>**user has the responsibility to validate their process* |
| **COMPLIANCE** | The Quality management system is in compliance with ISO 9001:2015 |
| **DRAWING** |  <br><br>1. FEMALE LUER LOCK INLET<br>2. MEMBRANE<br>3. MALE LUER SLIP OUTLET<br>4. OVERMOLDED RING<br><br>  <br><br>DIMENSIONS ARE IN MM, FOR REFERENCE ONLY |

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## VISUAL REQUIREMENTS

*Visual acceptance requirements apply when inspected under below conditions:*

**Magnification:**
**Light type:**
**Timings:**

| Acceptance Requirement | | | Sampling Plan |
|---|---|---|---|
| 1 | Mold Flash | <0.2 mm | 100% |
| 2 | Voids/Sinks | None | 100% |
| 3 | Short shots | None | 100% |
| 4 | Missing/Jutting Media/Mesh | None | 100% |
| 5 | Scuffing | Total length of scuff exceed 2 ribs | 100% |
| 6 | Luer Damage | None | 100% |
| 7 | Weld Damage | None | 100% |
| 8 | Heat Stake Issues | None | 100% |
| 9 | Spots Molded in Plastic | None | 100% |
| 10 | Discoloring | None | 100% |
| 11 | Mesh out of Place/Media Off-Center | None | 100% |
| 12 | Pad Printing Incomplete | None | 100% |
| 13 | Embedded Particles | < 0.8 $mm^2$ (Maximum 3 particles) | 100% |

## PERFORMANCE REQUIREMENTS

| Acceptance Requirement | | | Sampling Plan |
|---|---|---|---|
| Pore size | 0.22 um | 0.45 um | AQL 0.1 Special inspection level S3 |
| Pressure | ≥ 80 PSI 10 Seconds | ≥ 80 PSI 10 Seconds | ANSI/ASQ Standard Z1.4 - 2008 |
| Bubble point | 45 | 31 | AQL 0.1 Special inspection level S3 |

**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 and signature) | APPROVED BY: (name /function and signature) |
|---|---|---|---|---|
| 11/18/19 | 0 | Initial Release | Joe DeSisto, Director, Process Engineering | Kevin Wrigley, Director, Quality |

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## *CustomerApproval:*

**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.*