PRODUCT SPECIFICATION

Product PN	**1227204, 1227205, 1229451, 1226150, 1227207, 1227208, 1227209**	**Mod. 984**
Description	**30 mm Cameo Syringe Filters w/Glass Fiber Membrane**	**Rev. 02**

30 mm Cameo, Glass Fiber (GF)

PRODUCT DESCRIPTION

Non-Sterile 30mm Syringe Filter made of Polypropylene Housing assembled with various pore sizes of Glass Fiber/Polypropylene (GF/PP) Membrane

Membrane Material	Pore Size (um)	Color	Packaging 50/pk	Packaging 200/pk	Packaging 500/pk	Packaging 1000/pk	Packaging 5000/pk
Glass Fiber (GF)	1.00	Transparent	1227204	N/A	1227205	1229451	1226150
Glass Fiber (GF)	0.70	Transparent	1227207	N/A	N/A	1227208	1227209

MANUFACTURER NAME

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INTENDED USE / APPLICATION

Applications
- Analytical sample preparation
- Dissolution testing
- Content uniformity
- Environmental samples
- Composite assays
- Food analysis
- Biofuel analysis

MATERIALS

Filter media: Glass Fiber

Frame/Housing Polymer: Polypropylene

Color: Transparent

Other insert(s): N/A

Regulatory Documentation Required:
☐ Biocompatibility according ISO 10993-1
☐IMDS
☐DEHP plasticizer Free and latex free
☒Rohs, Directive 2002/32/CE
☐Aging
☒BSE/TSE, directive 2003/32/CE
☒ 1907/2006/CE (hazardous substances regulation)
☐Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)
☒Conflict minerals

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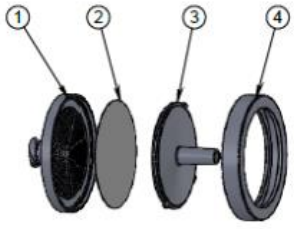
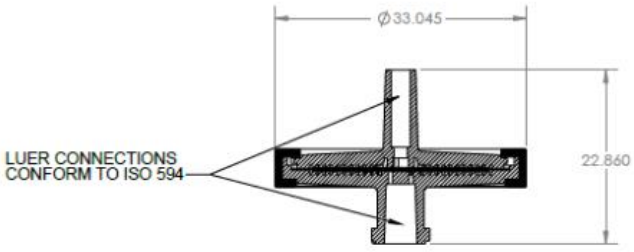
PRODUCT CHARACTERISTIC	**Characteristics** Membrane Material: Glass Fiber Membrane Diameter: 30 mm Effective Filtration Area: 4.8 cm_2 Housing Diameter: 33 mm Housing Material: Pure polypropylene is heat-sealed without the use of glues or sealants Inlet / Outlet: FLL-MLS Prefilter: 1.0 µ binderless glass-fiber, in some configurations Holdup Volume: <120 microliter Maximum Operating Temperature: 82°C/180°F Maximum Operating Pressure: 80 psi 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*: ☒EtO ☒Gamma (up to 40 kGy) ☐ Autoclave (121°C) ☐ eBeam **user has the responsibility to validate their process*
COMPLIANCE	The Quality management system is in compliance with ISO 9001:2015
DRAWING	 1. FEMALE LUER LOCK INLET 2. MEMBRANE 3. MALE LUER SLIP OUTLET 4. OVERMOLDED RING  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	1.0 um	0.70 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	N/A	N/A	N/A

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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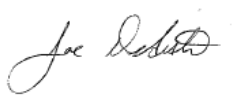
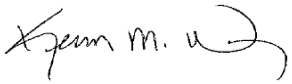
REVISIONS AND APPROVALS:

DATE	REV.	*REASON FOR CHANGE*	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
11/18/19	0	Initial Release	Joe DeSisto, Director, Process Engineering 	Kevin Wrigley, Director, Quality 

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.