

Product PN	1224143, 1224144, 1224145, 1229448, 1224146, 1224150, 1224151, 1237721, 1229450, 1224153	Mod. 984
Description	30 mm Cameo Syringe Filters w/Polytetrafluoroethylene Membrane	Rev. 02



30 mm Cameo, Polytetrafluoroethylene (PTFE)



PRODUCT DESCRIPTION	Non-Sterile 30mm Syringe Filter made of Polypropylene Housing assembled with various pore sizes of Polytetrafluoroethylene (PTFE) Membrane							
	Membrane Material	Pore Size (um)	Color	Packaging 50/pk	Packaging 200/pk	Packaging 500/pk	Packaging 1000/pk	Packaging 5000/pk
	Polytetrafluoroethylene (PTFE)	0.22	Transparent	1224143	1224144	1224145	1229448	1224146
	Polytetrafluoroethylene (PTFE)	0.45	Transparent	1224150	1224151	1237721	1229450	1224153
MANUFACTURER NAME	GVS North America 63 Community Drive Sanford, Me 04073 Phone: +1.866.736.1250 eMail: CustomerCareGVSLs@gvs.com - Website: www.gvs.com							
INTENDED USE / APPLICATION	Applications <ul style="list-style-type: none"> Analytical sample preparation Dissolution testing Content uniformity Environmental samples Composite assays Food analysis Biofuel analysis 							
MATERIALS	Filter media: Polytetrafluoroethylene Frame/Housing Polymer: Polypropylene Color: Transparent Other insert(s): N/A Regulatory Documentation Required: <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input type="checkbox"/> DEHP plasticizer Free and latex free <input checked="" type="checkbox"/> Rohs, Directive 2002/32/CE <input type="checkbox"/> Aging <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input checked="" type="checkbox"/> 1907/2006/CE (hazardous substances regulation) 							

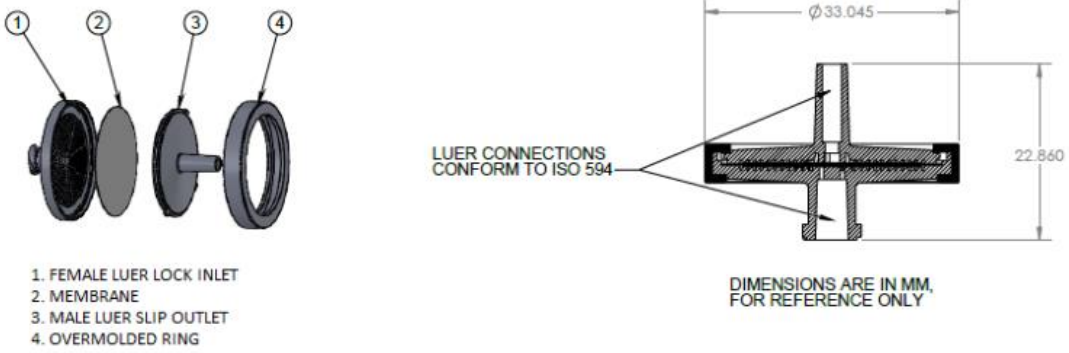
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	<input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> Conflict minerals
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PRODUCT CHARACTERISTIC	<p>Characteristics</p> <p>Membrane Material: PTFE Membrane Diameter: 30 mm Effective Filtration Area: 4.8 cm² 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: <70 microliter Maximum Operating Temperature: 82°C/180°F Maximum Operating Pressure: 80 psi Sterile: No</p>
PRODUCT SHELF LIFE	When stored under normal storage conditions, this product should be stable for 5 years
STERILIZATION	<p>This is a non-sterile product, compatible with these sterilization techniques*:</p> <p><input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (up to 40 kGy) <input type="checkbox"/> Autoclave (121°C) <input type="checkbox"/> eBeam</p> <p><i>*user has the responsibility to validate their process</i></p>
COMPLIANCE	The Quality management system is in compliance with ISO 9001:2015

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DRAWING



1. FEMALE LUER LOCK INLET
2. MEMBRANE
3. MALE LUER SLIP OUTLET
4. OVERMOLDED RING

LUER CONNECTIONS CONFORM TO ISO 594

DIMENSIONS ARE IN MM, FOR REFERENCE ONLY

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%



PRODUCT SPECIFICATION

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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 (in IPA)	17	11	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

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.