

Product PN	FJ25BSCPS002AL01, FJ25BSCPS004AL01, FJ25BSCPS008AL01	Mod. 984
Description	25 mm ABLUO Syringe Filters w/Polyethersulfone (PES), Sterile	Rev. 02

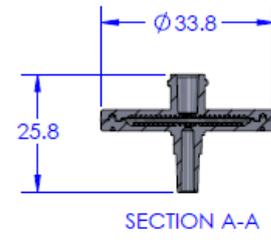


25 mm ABLUO, Polyethersulfone (PES), Sterile



PRODUCT DESCRIPTION	Sterile 25 mm syringe filter made of Acrylic housing, assembled with various pore sizes of Polyethersulfone (PES) Membrane						
	Membrane Material	Pore Size (um)	End Fitting	Color	Housing Material	Packaging	Product Code
	Polyethersulfone	0.22	FLL/MLS	Transparent	Acrylic	50/pk	FJ25BSCPS002AL01
	Polyethersulfone	0.45	FLL/MLS	Transparent	Acrylic	50/pk	FJ25BSCPS004AL01
	Polyethersulfone	0.80	FLL/MLS	Transparent	Acrylic	50/pk	FJ25BSCPS008AL01
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 Biological fluids Buffer solutions Sterile filtering of tissue culture media Protein aqueous solutions 						
MATERIALS	Filter media: Polyethersulfone (PES) Frame/Housing Polymer: Acrylic Color: Transparent Other insert(s): N/A Regulatory Documentation Required: <ul style="list-style-type: none"> <input checked="" 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 1907/2006/CE (hazardous substances regulation) <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>Membrane Materials: PES Membrane Diameter: 25 mm Effective Filtration Area: 4.6 cm² Housing Diameter: 33 mm Housing Materials: Acrylic Inlet / Outlet: FLL / MLS Holdup Volume: <100 microliter Maximum Operating Temperature: Acrylic Abluo 50°C /122°F Maximum Operating Pressure: 80 psi Sterile: Yes</p>
PRODUCT SHELF LIFE	When stored under normal storage conditions, this product should be stable for 3 years
STERILIZATION	<p>This is a non-sterile product, compatible with these sterilization techniques*:</p> <ul style="list-style-type: none"> <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><i>*user has the responsibility to validate their process</i></p>
CERTIFICATE OF COMPLIANCE	<p>Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1</p> <p>The Quality management system is in compliance with ISO 9001:2015</p>
DRAWING	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>1. Male Luer Slip Outlet (ISO 594) 2. PES Membrane 3. Female Luer Lock Inlet (ISO 594)</p> </div> <div style="text-align: center;">  <p>SECTION A-A</p> </div> </div> <p style="text-align: center;">All Dimensions are in mm, for ref. only</p>

PRODUCT SPECIFICATION

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VISUAL REQUIREMENTS	<i>Visual acceptance requirements apply when inspected under below conditions:</i>					
	Magnification: None					
	Light type: Standard					
			Acceptance Requirement		Sampling Plan	
	1	Contamination	None		100%	
	2	Damaged Luer Fitting	None		100%	
	3	Missing Membrane	None		100%	
	4	Incomplete Membrane	None		100%	
	5	Membrane Displacement	None		100%	
	6	Membrane Protruding Out of Part	None		100%	
	7	Scuffed Surface	Total length of scuff exceed 2 ribs		100%	
	8	Cracked Housings	None		100%	
	9	Weld Flash	None		100%	
10	Burn Outside of the Stake Ring	None		100%		
11	Embedded Particles	< 0.8 mm ² (Maximum 3 particles)		100%		
12	Mold Flash	< 0.2 mm		100%		

PERFORMANCE REQUIREMENTS	Acceptance Requirement			Sampling Plan	
	Pore size	0.22 um	0.45 um	0.80 um	AQL 0.1 Special inspection level S3
	Pressure	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	ANSI/ASQ Standard Z1.4 - 2008
	Bubble point (psi)	45	31	11	AQL 0.1 Special inspection level S3

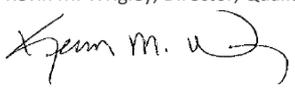
This material specification describes the properties of product above indicated.
 This document contains general requirements, material description, drawing references, defect specification, biological material requirements.



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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)
1/29/18	0	Initial Release	Joe DeSisto, Director, Process Engineering 	Kevin M. 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.