

**Product PN** FJ25BSCPV002AL01, FJ25BSCPV004AL01

Mod.  
984

**Description** 25 mm ABLUO Syringe Filters w/Polyvinylidene Fluoride (PVDF)

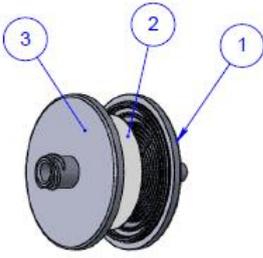
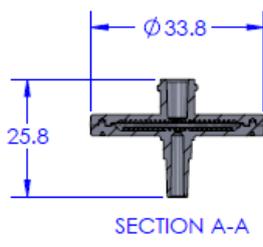
Rev. 02



**25 mm ABLUO, Polyvinylidene Fluoride (PVDF), Sterile**

<b>PRODUCT DESCRIPTION</b>	Sterile 25 mm syringe filter made of Acrylic housing, assembled with various pore sizes of Polyvinylidene Fluoride (PVDF) Membrane						
	Membrane Material	Pore Size (um)	End Fitting	Color	Housing Material	Packaging	Product Code
	Polyvinylidene Fluoride (PVDF)	0.22	FLL/MLS	Transparent	Acrylic	50/pk	FJ25BSCPV002AL01
	Polyvinylidene Fluoride (PVDF)	0.45	FLL/MLS	Transparent	Acrylic	50/pk	FJ25BSCPV004AL01
<b>MANUFACTURER NAME</b>	<p><b>GVS North America</b>  <b>63 Community Drive</b>  <b>Sanford, Me 04073</b>          Phone: +1.866.736.1250          eMail: <a href="mailto:CustomerCareGVSLs@gvs.com">CustomerCareGVSLs@gvs.com</a> - Website: <a href="http://www.gvs.com">www.gvs.com</a></p>						
<b>INTENDED USE / APPLICATION</b>	<p><b>Applications</b></p> <ul style="list-style-type: none"> <li>• Analytical sample preparation</li> <li>• Biological fluids</li> <li>• Buffer solutions</li> <li>• Sterile filtering of tissue culture media</li> <li>• Protein aqueous solutions</li> </ul>						
<b>MATERIALS</b>	<p><b>Filter media:</b> Polyvinylidene Fluoride (PVDF)</p> <p><b>Frame/Housing Polymer:</b> Acrylic</p> <p><b>Color:</b> Transparent</p> <p><b>Other insert(s):</b> N/A</p> <p><b>Regulatory Documentation Required:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Biocompatibility according ISO 10993-1</li> <li><input type="checkbox"/> IMDS</li> <li><input type="checkbox"/> DEHP plasticizer Free and latex free</li> <li><input checked="" type="checkbox"/> Rohs, Directive 2002/32/CE</li> <li><input type="checkbox"/> Aging</li> <li><input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE</li> <li><input checked="" type="checkbox"/> 1907/2006/CE (hazardous substances regulation)</li> <li><input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)</li> <li><input checked="" type="checkbox"/> Conflict minerals</li> </ul>						

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<b>PRODUCT CHARACTERISTIC</b>	<p>Membrane Materials: PVDF          Membrane Diameter: 25 mm          Effective Filtration Area: 4.6 cm<sup>2</sup>          Housing Diameter: 33 mm          Housing Materials: Acrylic          Inlet / Outlet: FLL / MLS          Holdup Volume: &lt;100 microliter          Maximum Operating Temperature: Acrylic Abluo 50°C /122°F          Maximum Operating Pressure: 80 psi          Sterile: Yes</p>
<b>PRODUCT SHELF LIFE</b>	When stored under normal storage conditions, this product should be stable for 3 years
<b>STERILIZATION</b>	<input type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma <input type="checkbox"/> Beta <input type="checkbox"/> Steam <input type="checkbox"/> e-beam
<b>CERTIFICATE OF COMPLIANCE</b>	<p>With each shipment, GVS NA Customer Service will send the CoC to the Customer, based on the lot numbers and date of manufacture.          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>
<b>DRAWING</b>	<div style="display: flex; justify-content: space-around; align-items: center;">   </div> <p>1. Male Luer Slip Outlet (ISO 594)          2. PES Membrane          3. Female Luer Lock Inlet (ISO 594)</p> <p>All Dimensions are in mm, for ref. only</p>

# PRODUCT SPECIFICATION

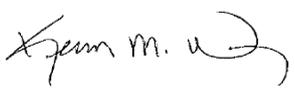
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<b>VISUAL REQUIREMENTS</b>	<i>Visual acceptance requirements apply when inspected under below conditions:</i>			
	<b>Magnification: None</b>			
	<b>Light type: Standard</b>			
	Acceptance Requirement		Sampling Plan	
	1	Contamination	None	100%
	2	Damaged 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 <sup>2</sup> (Maximum 3 particles)	100%	
12	Mold Flash	> 0.2 mm	100%	

<b>PERFORMANCE REQUIREMENTS</b>	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	23      14.6	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)
6/20/19	0	Initial Release	Joe DeSisto, Director, Process Engineering 	Kevin M. Wrigley, Director, Quality Engineering 



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## *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.*