

Product PN	FJ13ASCCA002DL01, FJ13ASCCA004FL01, FJ13ASCCA008EL01, FJASCCA012CL01, FJ13ASCCA050PL01	Mod. 984
Description	13 mm ABLUO Syringe Filters w/Cellulose Acetate Membrane, Sterile	Rev. 02



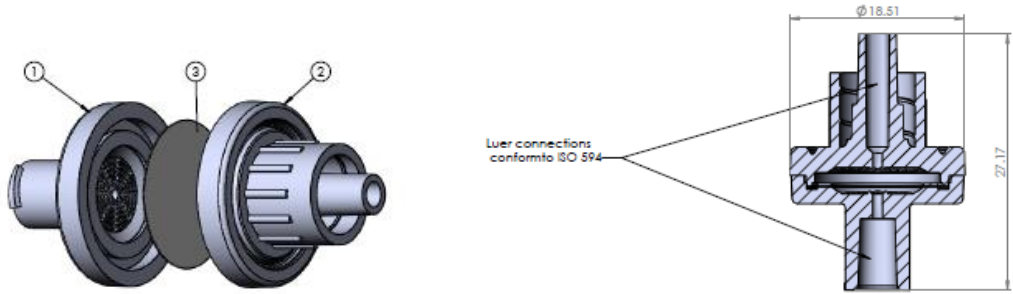
13 mm ABLUO, Cellulose Acetate (CA), Sterile



PRODUCT DESCRIPTION	Sterile 13 mm syringe filter made of Acrylic housing, assembled with various pore sizes of Cellulose Acetate (CA) Membrane						
	Membrane	Pore Size (um)	End Fitting	Housing Material	Color	Packaging	Item Number
	Cellulose Acetate (CA)	0.22	FLL/MLL	Acrylic	Blue	50/pk	FJ13ASCCA002DL01
	Cellulose Acetate (CA)	0.45	FLL/MLL	Acrylic	Yellow	50/pk	FJ13ASCCA004FL01
	Cellulose Acetate (CA)	0.80	FLL/MLL	Acrylic	Green	50/pk	FJ13ASCCA008EL01
	Cellulose Acetate (CA)	1.20	FLL/MLL	Acrylic	Red	50/pk	FJ13ASCCA012CL01
	Cellulose Acetate (CA)	5.00	FLL/MLL	Acrylic	Brown	50/pk	FJ13ASCCA050PL01
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 • Filtration of Aqueous Solutions • Analytical Sample Preparation • IC Chromatography • Sterile Filtration and Clarification • Protein Chemistry • Cell Culture • Clarification						
MATERIALS	Filter media: Cellulose Acetate Frame/Housing Polymer: Acrylic Color: Varies depending on pore size 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	Membrane Diameter: 13 mm Effective Filtration Area: 0.76 cm² Housing Diameter: 18 mm Housing Materials: Acrylic Inlet / Outlet: FLL / MLL Holdup Volume: <50 microliter Maximum Operating Temperature: Acrylic Abluo 50°C /122°F Maximum Operating Pressure: 80 psi Sterile: Yes
PRODUCT SHELF LIFE	When stored under normal storage conditions, this product should be stable for 3 years
STERILIZATION	☐ EtO ☒ Gamma ☐ Beta ☐ Steam ☐ e-beam ☐ Not Required
CERTIFICATE OF COMPLIANCE	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 The Quality management system is in compliance with ISO 9001:2015
DRAWING	 1. Female Luer Lock Inlet (ISO 594) 2. Male Luer Lock Outlet (ISO 594) 3. CA Membrane Dimensions in mm, for ref. only

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VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

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%

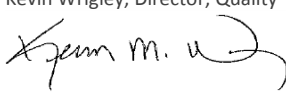
PERFORMANCE REQUIREMENTS

Acceptance Requirement						Sampling Plan
Pore size	0.22 um	0.45 um	0.80 um	1.2 um	5.0 um	AQL 0.1 Special inspection level S3
Pressure	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	ANSI/ASQ Standard Z1.4 - 2008
Min. Bubble point (psi)	45	27	12	10	5	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.