

Product PN	FJ25ANCCA002DD01, FJ25ANCCA004FD01, FJ25ANCCA008ED01, FJ25ANCCA012CD01, FJ25ANCCA050PD01, FJ25ANCCA002DH01, FJ25ANCCA004FH01, FJ25ANCCA008EH01, FJ25ANCCA012CH01, FJ25ANCCA050PH01	Mod. 984 Rev. 02
Description	25 mm ABLUO Syringe Filters w/Cellulose Acetate Membrane	



25 mm ABLUO, Cellulose Acetate (CA)



PRODUCT DESCRIPTION

Non-sterile 25 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	500/pk	FJ25ANCCA002DD01
Cellulose Acetate (CA)	0.45	FLL/MLL	Acrylic	Yellow	500/pk	FJ25ANCCA004FD01
Cellulose Acetate (CA)	0.80	FLL/MLL	Acrylic	Green	500/pk	FJ25ANCCA008ED01
Cellulose Acetate (CA)	1.20	FLL/MLL	Acrylic	Red	500/pk	FJ25ANCCA012CD01
Cellulose Acetate (CA)	5.00	FLL/MLL	Acrylic	Brown	500/pk	FJ25ANCCA050PD01
Cellulose Acetate (CA)	0.22	FLL/MLL	Acrylic	Blue	100/pk	FJ25ANCCA002DH01
Cellulose Acetate (CA)	0.45	FLL/MLL	Acrylic	Yellow	100/pk	FJ25ANCCA004FH01
Cellulose Acetate (CA)	0.80	FLL/MLL	Acrylic	Green	100/pk	FJ25ANCCA008EH01
Cellulose Acetate (CA)	1.20	FLL/MLL	Acrylic	Red	100/pk	FJ25ANCCA012CH01
Cellulose Acetate (CA)	5.00	FLL/MLL	Acrylic	Brown	100/pk	FJ25ANCCA050PH01

MANUFACTURER NAME

GVS North America
63 Community Drive
Sanford, Me 04073
Phone: +1.866.736.1250
eMail: CustomerCareGVSL@gvs.com - Website: www.gvs.com

INTENDED USE / APPLICATION

Applications

- Analytical sample preparation
- Biological fluids
- Buffer solutions
- Sterile filtering of tissue culture media
- Protein aqueous solutions

MATERIALS

Filter media: Cellulose Acetate
Frame/Housing Polymer: Acrylic
Color: Varies depending on pore size
Other insert(s): N/A

PRODUCT SPECIFICATION

Product PN	FJ25ANCCA002DD01, FJ25ANCCA004FD01, FJ25ANCCA008ED01, FJ25ANCCA012CD01, FJ25ANCCA050PD01, FJ25ANCCA002DH01, FJ25ANCCA004FH01, FJ25ANCCA008EH01, FJ25ANCCA012CH01, FJ25ANCCA050PH01	Mod. 984 Rev. 02
Description	25 mm ABLUO Syringe Filters w/Cellulose Acetate Membrane	

	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 ☒ USP Class VI	
PRODUCT CHARACTERISTIC	Membrane Materials: Cellulose Acetate Membrane Diameter: 25 mm Effective Filtration Area: 4.6 cm ² Housing Diameter: 33 mm Housing Materials: Acrylic Inlet / Outlet: FLL / MLL Holdup Volume: <100 microliter Maximum Operating Temperature: Acrylic Abluo 50°C /122°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 <i>*user has the responsibility to validate their process</i>	
COMPLIANCE	The Quality management system is in compliance with ISO 9001:2015	

PRODUCT SPECIFICATION

Product PN

FJ25ANCCA002DD01, FJ25ANCCA004FD01, FJ25ANCCA008ED01,
FJ25ANCCA012CD01, FJ25ANCCA050PD01, FJ25ANCCA002DH01,
FJ25ANCCA004FH01, FJ25ANCCA008EH01, FJ25ANCCA012CH01,
FJ25ANCCA050PH01

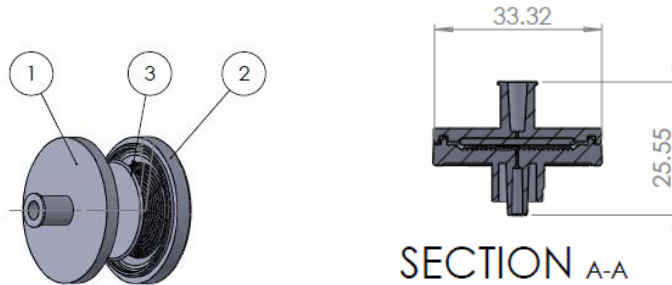
Mod. 984

Rev. 02

Description

25 mm ABLUO Syringe Filters w/Cellulose Acetate Membrane

DRAWING



1. Female Luer Lock Inlet (ISO 594)
2. Male Luer Lock Outlet (ISO 594)
3. CA membrane

All Dimensions are in mm, for ref. only

1. Female Luer Lock Inlet (ISO 594)
2. Male Luer Lock Outlet (ISO 594)
3. CA membrane

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

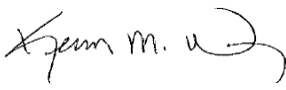
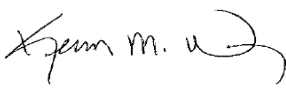
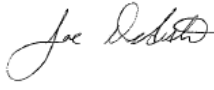
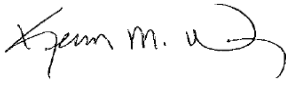
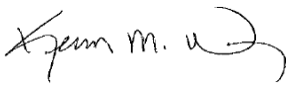
Acceptance Requirement						Sampling Plan
Pore size	0.22 um	0.45 um	0.80 um	1.20 um	5.0 um	AQL 0.1 Special inspection level S3
Pressure	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	≥ 80 PSI 10 Seconds	ANSI/ASQ Standard Z1.4 - 2008
Min. Bubble point (psi)	45	27	12	10	5	AQL 0.1 Special inspection level S3

PRODUCT SPECIFICATION

Product PN	FJ25ANCCA002DD01, FJ25ANCCA004FD01, FJ25ANCCA008ED01, FJ25ANCCA012CD01, FJ25ANCCA050PD01, FJ25ANCCA002DH01, FJ25ANCCA004FH01, FJ25ANCCA008EH01, FJ25ANCCA012CH01, FJ25ANCCA050PH01	Mod. 984 Rev. 02
Description	25 mm ABLUO Syringe Filters w/Cellulose Acetate Membrane	

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)
3/31/17 5/25/17	0 1	Initial Release Corrected typo in Performance Requirements, changed "8.0 um" to "5.0 um"	Joe DeSisto, Director, Process Engineering 	Kevin Wrigley, Director, Quality 
6/21/18	2	Added "Class VI" to Regulatory Documentation List and added "up to 40 kGy" to the sterilization section	Joe DeSisto, Director, Process Engineering 	Kevin Wrigley, Director, Quality 
09/25/2019	3	Updated information for 100/PK	Joe DeSisto, Director, Process Engineering 	Kevin Wrigley, Director, Quality 
09/28/2021	4	Corrected misplacement of information in drawing section	Joe DeSisto, Director, Process Engineering 	Kevin Wrigley, Director, Quality 

PRODUCT SPECIFICATION

Product PN	FJ25ANCCA002DD01, FJ25ANCCA004FD01, FJ25ANCCA008ED01, FJ25ANCCA012CD01, FJ25ANCCA050PD01, FJ25ANCCA002DH01, FJ25ANCCA004FH01, FJ25ANCCA008EH01, FJ25ANCCA012CH01, FJ25ANCCA050PH01	Mod. 984 Rev. 02
Description	25 mm ABLUO Syringe Filters w/Cellulose Acetate Membrane	

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.