PRODUCT SPECIFICATION

Product PN	**FJ25BNPNY002AD01, FJ25BNPNY004AD01, FJ25BNPNY002AH01, FJ25BNPNY004AH01**	**Mod. 984**
Description	**25 mm ABLUO Syringe Filters w/Nylon Membrane**	**Rev. 02**

25 mm ABLUO, Nylon (NY)

PRODUCT DESCRIPTION

Non-sterile 25 mm syringe filter made of Polypropylene housing, assembled with various pore sizes of Nylon Membrane

Membrane Material	Pore Size (um)	End Fitting	Color	Housing Material	Packaging	Product Code
Nylon (NY)	0.20	FLL/MLS	Transparent	Polypropylene	500/pk	FJ25BNPNY002AD01
Nylon (NY)	0.45	FLL/MLS	Transparent	Polypropylene	500/pk	FJ25BNPNY004AD01
Nylon (NY)	0.20	FLL/MLS	Transparent	Polypropylene	100/pk	FJ25BNPNY002AH01
Nylon (NY)	0.45	FLL/MLS	Transparent	Polypropylene	100/pk	FJ25BNPNY004AH01

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

MATERIALS

Filter media: Nylon

Frame/Housing Polymer: Polypropylene

Color: Transparent

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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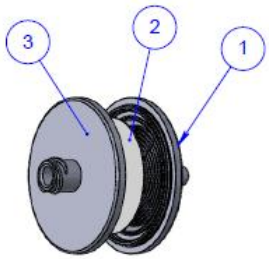
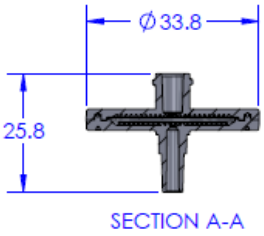
PRODUCT CHARACTERISTIC	Membrane Materials: Nylon Membrane Diameter: 25 mm Effective Filtration Area: 4.6 cm² Housing Diameter: 33 mm Housing Materials: Polypropylene Inlet / Outlet: FLL / MLS Holdup Volume: <100 microliter Maximum Operating Temperature: PP Abluo - 90°C/194°F Maximum Operating Pressure: 80 psi Sterile: No
PRODUCT SHELF LIFE	When stored under normal storage conditions, this product should be stable for 5 years
STERILIZATION	☐EtO ☐Gamma ☐Beta ☐Steam ☐e-beam ☒Not Required
COMPLIANCE	The Quality management system is in compliance with ISO 9001:2000, ISO/TS 16949:2009
DRAWING	 1. Male Luer Slip Outlet (ISO 594) 2. Nylon Membrane 3. Female Luer Lock Inlet (ISO 594)  All Dimensions are 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	0.20 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
Min. Bubble point (psi)	44	22	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)
3/31/17	0	Initial Release	Joe DeSisto, Director, Process Engineering	Kevin Wrigley, Director, Quality

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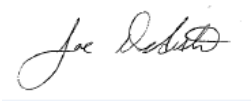
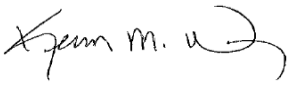
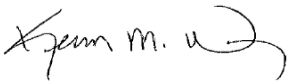
8/25/17	1	Corrected 0.2 um min BP from 40 to 44	Joe DeSisto, Director, Process Engineering 	Kevin Wrigley, Director, Quality 
9/25/2019	2	Updated information for 100/PK	Joe DeSisto, Director, Process Engineering 	Kevin Wrigley, Director, Quality 

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.