

Product PN **MV32ANPPS002EC01**
MV32ANPPS004WC01

Mod. 984

Rev. 02

Description **SYRINGELESS FILTER**

SEPARA (PES membrane) Minivial autosampler



PRODUCT DESCRIPTION	Syringeless filter that integrates in one single device auto-sampler vial, filtration membrane, plunger, and cap/septa
MANUFACTURER NAME	GVS S.p.A.
INTENDED USE / APPLICATION	Syringeless filter which provide a PES Hydrophilic – Designed to remove particulates – Low protein and drug binding – High strength and durability. Compound Class: Filtration of buffers and culture media
CLASS OF THE PRODUCT	Laboratory Liquid Filtration
MATERIALS	<p>Filter media: PES hydrophilic membranes with 0.20 µm and 0.45 µm pore sizes Frame/Housing Polymer: Polypropylene Color: Transparent</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> Rohs, directive 2002/95/CE <input type="checkbox"/> BSE/TSE, directive 2003/32/CE <input type="checkbox"/> DEHP plasticizer Free and Latex free <input type="checkbox"/> Aging <input checked="" type="checkbox"/> Reach 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 free

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PRODUCT CHARACTERISTIC

Appearance/Visual:

Aesthetic part:	transparent body with colored cap
Presence of graphics/Artwork:	membrane type and pore size are pad printed on the colored cap
Flash bears admitted:	smaller than 0.3mm
Injection gate vestige:	smaller than 0.3mm
Black spots admitted (size/area):	must not be visible to the naked eyes at arm's length
Infiltration into insert admitted:	smaller than 25% of filtration area

Physical/Mechanical:

Dimensions:	12 x 32 mm
Weight:	1.9 g
Operating temperature Range:	From 10 °C to 40 °C
Storage temperature Range:	From 10 °C to 40 °C

Functional:

Liquid Flow Rate with 0.20 µm :	> 2.6 ml/min/cm ² @ 80 cm H ₂ O
Liquid Flow Rate with 0.45 µm :	> 5.1 ml/min/cm ² @ 80 cm H ₂ O
Bubble Point Pressure with 0.20 µm :	> 2.2 bar for 10 sec
Bubble Point Pressure with 0.45 µm :	> 1.7 bar for 10 sec
Maximum volume	480 µL
Dead Volume:	< 30µL
Operating Lifetime:	3 years
Shelf Lifetime:	3 years

Cleanliness:

Clean-room Production required: Class ISO 8

INSTRUCTIONS

IFU: English French Italian Spanish Portuguese German Chinese Japanese Korean Russian
 Other(Specify):

WARNINGS

STERILIZATION

Not required

PACKAGING AND LABELLING

Packaging : External with the box with product logo [dim 170x80x120 mm]
 2 Internal plastic bags with zip lock [dim 125x180 mm]

Labelling: Standard
 Each box carton shall be labelled with the product part number and lot number.
 100pcs per box . Different lots in one box are not allowed. IFU available (only when required by customer).

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CERTIFICATE OF COMPLIANCE

With each shipment, GVS S.p.A. 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

DRAWING

The attached drawing is part of this material specification and must not be duplicated or made accessible to a third party without prior written GVS SpA consent.

VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Magnification: unaided eye, approximately 45 cm (18") from eye
Illumination: 1000 ± 200 lx or equivalent
Light type: Fluorescent
Timings: 5 sec per unit

Acceptance Requirement		AQL	Sampling Plan
1	1. Incomplete / deformation of plastic support, shrinkages of material	1	ISO 2859 part.1 1 st Level
	2. Incomplete / missing / misplaced / unsealed membrane		
	3. Membrane broken, pierced, crushed, peeled away		
	4. Infiltration > 25% of material membrane surface		
	5. Membrane incorporated residual		
	6. No missing components or wrong color cap		
	7. Serious mold, rust dirty		
2	8. Flashes > 0.3 mm	4	
	9. Infiltration < 0.25% of the membrane surface		
	10. * Embedded particulate matter > 0.1 mm ²		
	11. Color not uniform		
	12. Marks or scratches		
	13. Loose particulate > 0.1 mm ² or fibers		

- Embedded particulate matter : according to Dirt Estimation Chart (Tappi Standard)

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PERFORMANCE REQUIREMENTS	Acceptance Requirement		AQL	Sampling Plan
	1	Bubble point test with 0.20µm pore size	≥ 2.2 bar (32 psig) for 10 sec	ISO 2859-1 Level S-3
	2	Bubble point test with 0.45µm pore size	≥ 1.7 bar (25 psig) for 10 sec	

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)
10.05.2017	00	First emission	Project leader Simone Reggiani <i>S. Reggiani</i> Project leader Filippo Trascinelli <i>FT</i>	Quality Assurance Roberta Frulla <i>RF</i>

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.