

**Product PN** MV32ANPPT002TC01  
MV32ANPPT004CC01

Mod. 984

Rev. 02

**Description** SYRINGELESS FILTER

## SEPARA (PTFE membrane) Minivial autosampler



<b>PRODUCT DESCRIPTION</b>	Syringeless filter that integrates in one single device auto-sampler vial, filtration membrane, plunger, and cap/septa
<b>MANUFACTURER NAME</b>	GVS S.p.A.
<b>INTENDED USE / APPLICATION</b>	Syringeless filter which provide a PTFE Hydrophobic – Chemically and biologically inert – Superior chemical resistance.  Compound Class: Organic solvents, acids, alcohols, bases, aromatics.
<b>CLASS OF THE PRODUCT</b>	Laboratory Liquid Filtration
<b>MATERIALS</b>	<p><b>Filter media:</b> Hydrophobic ePTFE membranes on Polyester non-woven support with 0.20 µm and 0.45 µm pore sizes</p> <p><b>Frame/Housing Polymer:</b> Polypropylene</p> <p><b>Color:</b> Transparent</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 checked="" type="checkbox"/> Rohs, directive 2002/95/CE</li> <li><input type="checkbox"/> BSE/TSE, directive 2003/32/CE</li> <li><input type="checkbox"/> DEHP plasticizer Free and Latex free</li> <li><input type="checkbox"/> Aging</li> <li><input checked="" type="checkbox"/> Reach 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 free</li> </ul>



FILTER TECHNOLOGY

# PRODUCT SPECIFICATION

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<b>PRODUCT CHARACTERISTIC</b>	<p><b>Appearance/Visual:</b></p> <p><b>Aesthetic part:</b> transparent body with colored cap  <b>Presence of graphics/Artwork:</b> membrane type and pore size are pad printed on the colored cap  <b>Flash bears admitted:</b> smaller than 0.3mm  <b>Injection gate vestige:</b> smaller than 0.3mm  <b>Black spots admitted (size/area):</b> must not be visible to the naked eyes at arm's length  <b>Infiltration into insert admitted:</b> smaller than 25% of filtration area</p> <p><b>Physical/Mechanical:</b></p> <p><b>Dimensions:</b> 12 x 32 mm  <b>Weight:</b> 1.9 g  <b>Operating temperature Range:</b> From 10 °C to 40 °C  <b>Storage temperature Range:</b> From 10 °C to 40 °C</p> <p><b>Functional:</b></p> <p><b>Air Flow Rate with 0.20 µm :</b> 9.5 ÷ 19.5 l/min on 3.7 cm<sup>2</sup> sample @ 0.93 bar  <b>Air Flow Rate with 0.45 µm :</b> 16 ÷ 48 l/min on 3.7 cm<sup>2</sup> sample @ 0.93 bar  <b>Water Break Through with 0.20 µm :</b> &gt; 1.9 bar for 10 sec  <b>Water Break Through with 0.45 µm :</b> &gt; 0.9 bar for 10 sec  <b>Maximum volume</b> 480 µL  <b>Dead Volume:</b> &lt; 30µL  <b>Operating Lifetime:</b> 3 years  <b>Shelf Lifetime:</b> 3 years</p> <p><b>Cleanliness:</b></p> <p><b>Clean-room Production required:</b> Class ISO 8</p>
<b>INSTRUCTIONS</b> <b>WARNINGS</b>	<p>IFU: <input checked="" type="checkbox"/> English <input type="checkbox"/> French <input type="checkbox"/> Italian <input type="checkbox"/> Spanish <input type="checkbox"/> Portuguese <input type="checkbox"/> German <input type="checkbox"/> Chinese <input type="checkbox"/> Japanese <input type="checkbox"/> Korean <input type="checkbox"/> Russian  <input type="checkbox"/> Other(Specify):</p>
<b>STERILIZATION</b>	<p>Not required</p>
<b>PACKAGING AND LABELLING</b>	<p><b>Packaging :</b> External with box with product logo [dim 170x80x120 mm]  2 Internal plastic bags with zip lock [dim 125x180 mm]</p> <p><b>Labelling:</b> 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).</p>

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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 <sup>st</sup> 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 <sup>2</sup>		
	11. Color not uniform		
	12. Marks or scratches		
	13. Loose particulate > 0.1 mm <sup>2</sup> or fibers		

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

This material specification describes the properties of product above indicated.  
 This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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## 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   Project Leader Filippo Trascinelli 	Quality Assurance Roberta Frulla 

## 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.