

Product PN

MV32ANPRC002GC01 MV32ANPRC004LC01

Mod. 984

Rev. 02

Description

SYRINGELESS FILTER

SEPARA (RC 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 RC Hydrophilic - Very low protein binding – Resistant to a wide range of solvents. Compound Class: Aqueous and organic solutions
CLASS OF THE PRODUCT	Laboratory Liquid Filtration
MATERIALS	Filter media: NY hydrophilic membranes with 0.20 µm and 0.45 µm pore sizes Frame/Housing Polymer: Polypropylene Transparent Regulatory Documentation Required: □Biocompatibility according ISO 10993-1 □IMDS □Rohs, directive 2002/95/CE □BSE/TSE, directive 2003/32/CE □DEHP plasticizer Free and Latex free □Aging □Reach 1907/2006/CE (hazardous substances regulation) □Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) □Conflict minerals free



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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: Injection gate vestige: smaller than 0.3mm smaller than 0.3mm

Black spots admitted (size/area): Infiltration into insert admitted:

must not be visible to the naked eyes at arm's length

smaller than 25% of filtration area

Physical/Mechanical:

Dimensions:

12 x 32 mm

Weight:

1.9 g

From 10 °C to 40 °C

Operating temperature Range: Storage temperature Range:

10 °C to 40 °C From

Functional:

Liquid Flow Rate with 0.20 µm: Liquid Flow Rate with 0.45 µm: Bubble Point Pressure with 0.20 µm: > 15 ml/min/cm2 @ 1bar > 30 ml/min/cm² @ 1bar

Bubble Point Pressure with 0.45 µm:

> 3.0 bar for 10 sec > 2.0 bar for 10 sec

Maximum volume **Dead Volume:** Operating Lifetime: Shelf Lifetime:

480 µL < 30µL 3 years 3 years

Cleanliness:

Clean-room Production required:

Class ISO 8

INSTRUCTIONS

WARNINGS

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

STERILIZATION

Not required

PACKAGING AND LABELLING

Packaging: External withe 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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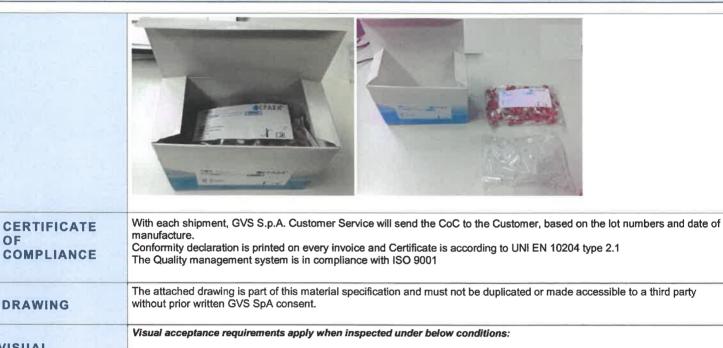
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VISUAL REQUIREMENTS

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.	Incomplete / deformation of plastic support, shrinkages of material			
	2.	Incomplete / missing / misplaced / unsealed membrane			
	3.	3. Membrane broken, pierced, crushed, peeled away			
1	4.	Infiltration > 25% of material membrane surface	1		
	5.	5. Membrane incorporated residual			
	6.	6. No missing components or wrong color cap			
	7.	Serious mold, rust dirty		ISO 2859 part.1 1 st Level	
	8.	Flashes > 0.3 mm			
2	9.	Infiltration < 0.25% of the membrane surface			
	10.). * Embedded particulate matter > 0.1 mm²			
	11.	Color not uniform	4		
	12.	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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	Acceptance Req	AQL	Sampling Plan		
1	Bubble point test with 0.20µm pore size	≥ 3.0 bar (43 psig) for 10 sec	0.4		
2	Bubble point test with 0.45µm pore size	≥ 2.0 bar (29 psig) for 10 sec	0.4	ISO 2859-1 Level S-3	

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 Projet Leader Filippo Trascinelli	Quality Asserance Roberta Frula

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.