

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 | <p>Filter media: NY 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 | <p>Appearance/Visual:</p> <p>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</p> <p>Physical/Mechanical:</p> <p>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</p> <p>Functional:</p> <p>Liquid Flow Rate with 0.20 µm : > 15 ml/min/cm² @ 1bar Liquid Flow Rate with 0.45 µm : > 30 ml/min/cm² @ 1bar Bubble Point Pressure with 0.20 µm : > 3.0 bar for 10 sec Bubble Point Pressure with 0.45 µm : > 2.0 bar for 10 sec Maximum volume 480 µL Dead Volume: < 30µL Operating Lifetime: 3 years Shelf Lifetime: 3 years</p> <p>Cleanliness:</p> <p>Clean-room Production required: Class ISO 8</p> |
| INSTRUCTIONS WARNINGS | <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> |
| STERILIZATION | <p>Not required</p> |
| PACKAGING AND LABELLING | <p>Packaging : External with the box with product logo [dim 170x80x120 mm] 2 Internal plastic bags with zip lock [dim 125x180 mm]</p> <p>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).</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 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 | ≥ 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 <i>Simone Reggiani</i> Project Leader Filippo Trascinelli <i>Filippo Trascinelli</i> | Quality Assurance Roberta Frulla <i>Roberta Frulla</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.