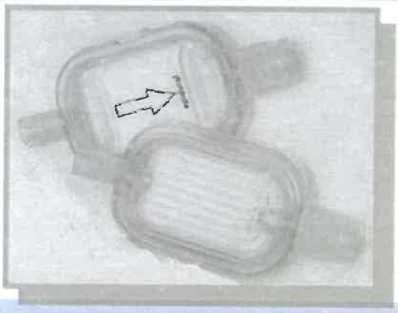
PRODUCT SPECIFICATION

Product PN	**RS065D**	☐ **PRELIMINARY** ☐ **R&D RELEASED** ☑ **RELEASED**	**Mod. 984c** **Rev. 05**
Description	**EPI-MAX Filter 0,2-1,2µm with neutral nut**		

Epi-Max
Epidural filter



PRODUCT DESCRIPTION	Epi-Max is a single use filtration device with an hydrophilic PES membrane 0.2µm and a reinforced MBS housing, particularly suitable for the following filtration applications: ampoule drug injection, epidural anesthesia, intraocular injectables, TPN solutions additives, low volume pain control, small volume sterilization, pharmacy admixture. The connections are female luer lock inlet and rotating male luer lock outlet. The product is provided in bulk packs for further manufacturing, processing, or repackaging.
MATERIALS	**MATERIALI** *MATERIALS* **VERSIONE** *VERSION* / **CODICE ART.** *PART NUMBER* / CORPO *BODY* / COPERCHIO *COVER* / INSERTO IDROFILICO *HYDROPHILIC INSERT* / GHIERA GIREVOLE *REVOLVING L.L. NUT* EPICARE / **RS065DCYRH002A02** / Acrylic-based multipolymer compound, Clear G-20 / PES 0,2 µm membrane / Clear PP EPICARE / **RS065DCYRH012A02** / Acrylic-based multipolymer compound, Clear G-20 / PES 1,2 µm membrane / Clear PP EPICARE / **RS065DMEDH002A02** / Acrylic-based multipolymer compound, Clear MED2 / PES 0,2 µm membrane / Clear PP **Inlet/Outlet connectors:** Female Luer Lock inlet / Male Rotating Luer Lock outlet_ FLL/RMLL connectors dimensionally compliance with ISO 80369-7
PRODUCT CHARACTERISTICS	**Dimensions:** WxLxD 30x64,75x7.2 mm _dimensionally compliance with ISO 80369-7 **Weight** : 7 gr. **Hydrophilic filtration area**: 5 ,00 cm2 **Max burst pressure:** 8 bar (tested for 15") **Max operating temperature**: 55°C (131°F) **Minimum Water Bubble Point:** PES 0.2 µm: 3.7÷ 4,8 bar PES 1.2 µm: 0.7 ÷ 1,0 bar **Minimum Water Flow Rate:** PES 0.2 µm : ≥ 15 ml/min @ 80 cm (31.5 in) water head pressure PES 1.2 µm : ≥ 90 ml/min @ 80 cm (31.5 in) water head pressure **Bacterial Retention:** Brevundimonas diminuta. **Priming volume**: 1,2 ml **Pyrogenicity** < 0.06 EU/ml using the LAL test method **Low binding test:** performed with Piperacillin Sodium, Insulin, Paclitaxel, Lidocaine HCL, Nitro-glycerin, Sodium Citrate.
INSTRUCTIONS WARNINGS	For easy priming procedure, start with a dry EPI-MAX in a vertical position with the flow arrow pointed up, i.e. invert to prime. The liquid will push the air through the filter before flow begins. After priming is completed (all air is evacuated form the housing), EPI-MAX can stay in any position. Filter for medical use, to be assembled in clean room. Handle with care. Remove the external bag before planting into a clean room. Verify compatibility of drugs to use with the raw materials declared in specifications. It is not recommended to use any kind of disinfectant in direct contact with the filter. For more details, please contact GVS. It is not recommended to use the filter with syringe smaller than 10 ml. To prevent filter breakage it is recommended to fix properly Epi-Max in order to avoid benting of the filter connectors or filter body.

FILTER TECHNOLOGY

PRODUCT SPECIFICATION

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STERILIZATION	Ethylene oxide (Max 55°C) and gamma irradiation (Max 25 kGy)
BIOLOGICAL REQUIREMENTS	**FOR RAW MATERIALS USED TO PRODUCE COMPONENTS:** Test performed in compliance with USP class VI and/or ISO 10993-1. All materials are DEHP free, Latex free and BSE/TSE free Chemical composition complies with the recommendation or regulation for food contact applications. USA - Code of Federal Regulations, issued by Food and Drug Administration (FDA) paragraph 21 CFR 177.1500 (nylon resins). Test report available at GVS premises.
PACKAGING AND LABELLING	Box of 2.000 pcs. 2 inner PE bags of 1.000 pcs. each. Bags are separately hot sealed. 2 bags per box. The first bar-code label is outside the 2 bags. The second bar-code label is stuck outside the box. Each bag is labeled with the following traceability information: ✓ Quantity ✓ Product description ✓ Product date ✓ Lot number (OL and 5 digit batch number to trace back to raw materials used) ✓ Operator code Different lots of goods in one shipments are packed in a manner to prevent mix-ups. Different lots in one box are separately closed and separately labeled to prevent mix-ups.
CERTIFICATE OF COMPLIANCE	The 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, ISO 13485 and ISO/TS 16949.
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 permission.
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	Embedded particles > 0.2 mm2 * (visual for 5" at a distance pf 300-450 mm)	0.4	ISO 2859 part. 1 General Inspection I
2	Projecting threads from external and cone (burrs)	0.4	
3	Incomplete plastic support (not functional)	0.4	
4	Incomplete plastic support (functional)	0.1	
5	Incomplete or misplaced membrane	0.1	
6	Dents leaving traces, porosity, scratches	0.4	
7	Plastics residual or internal membrane threads	0.4	
8	Damages, cracks or deformation on the pieces (functional)	0.1	
9	Damages, cracks or deformation on the pieces (not functional)	0.4	
10	Bubbles > 0.7 mm^2	0.4	
11	External pollution and wandering dirtiness > 0.05 mm	0.4	
12	Incomplete or smudged pad printing.	0.4	

* Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).
Loose Particulate Matter: free of visible particles > 0,2 mm2
The characteristics above listed are statistically inspected during the manufacturing process.

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PERFORMANCE REQUIREMENTS

	Acceptance Requirement		AQL	Sampling Plan
1	Bubble point to verify PES integrity	- 0.2 µm: 3.7÷ 4,8 bar (ramped pressure in 15 seconds) - 1.2 µm: 0.7 ÷ 1,0 bar	0,1	ISO 2859 part. 1 General Inspection I
3	Burst test to verify housing pressure integrity	≥ 8 bar (ramped 1 sec.)	0,1	
4	Water Flow rate @ 80 cm water head pressure	- 0.2 µm: ≥ 15 ml/min - 1.2 µm: ≥ 90 ml/min	0,1	

Control Note:
Customers who want to clarify requirements where judgmental differences may develop between the Customer and GVS SpA may submit limit samples for GVS SpA approval. If limits have not been established and approved, best judgement by GVS SpA Quality Assurance will apply.

The characteristics above listed are statistically inspected during the manufacturing process.

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)
24/09/2021	07	Introduction of compliance with ISO80369-7 for Luer connectors	Elsa Caruso – PM	Barbara Finessi – AQP Enrico Salvarani – RPROG Luca Zanini – DAM Tiziana Landi – DAQ

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.