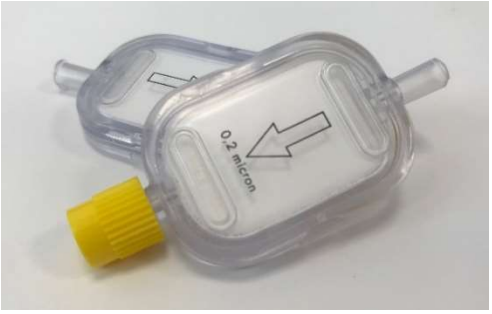
Product PN	RS085DMEDH002AF0	☐ PRELIMINARY ☐ R&D RELEASED ☑ RELEASED	Mod. 984c Rev. 05
Description	EPI-MAX Filter, 0,2 µm, Neuraxial Connector ISO 80369-6 compliant		

EPI-MAX Nrfit Epidural Filter



PRODUCT DESCRIPTION	**Detailed description of the product:** Speedlflow Epicare is a non-sterile, non-toxic single use filtration device with an hydrophilic PES membrane (0.2 µm) and a reinforced MBS housing. The connections are female neuraxial lock inlet and rotating male neuraxial lock outlet, in compliance with ISO 80369-6. Rotating nut is available in yellow colour. The product is provided in bulk packs for further assembling, processing or repackaging.
INTENDED USE / APPLICATION	Neuraxial applications, such as: wound infiltration anaesthesia delivery, other regional anaesthesia procedures or to monitor or remove cerebro-spinal fluid for therapeutic or diagnostic purposes.
MATERIALS	**Filter media:** Hydrophilic PES membrane 0.2 µm **Frame/Housing Polymer**: Acrylic-based multipolymer (MBS) MED2, suitable for alcoholic disinfectant swiping **Color:** Neutral Housing with yellow rotating nut **Inlet and outlet connectors:** Female Neuraxial Lock and Male Neuraxial Lock, in compliance with ISO 80369-6, with rotating nut
PRODUCT CHARACTERISTICS	**Dimensions:** 30x40,4x7,2 mm (filter body) **Weight:** 7 g **Hydrophillic filtration area:** 5 cm^2 **Total Filter Surface Area:** 91,2 cm^2 (internal and external surfaces) **Max operating pressure:** 8 bar (116 psi) (tested for 15 s) **Operating temperature Range:** From 5 °C (41 °F) to 40 °C (104 °F) **Storage temperature Range:** From 0 °C (32 °F) to 55 °C (131 °F) **Bacterial retention:** Brevundimonas diminuita LRV ≥ 7 **Priming volume:** 1,2 ml **Pyrogenicity:** < 0,25 EU/ml using the LAL test method. **Low binding test:** performed with Piperacillin Sodium, Insulin, Paclitaxel, Lidocaine HCL, Nitro-glycerin, Sodium Citrate. **Other:** The product is tested and compliant with following Paragraphs of the standard ISO 80369-6: 6.2 Fluid leakage 6.3 Subatmospheric-pressure air leakage 6.4 Stress cracking 6.5 Resistance to separation to from axial load 6.6 Resistance to separation to from unscrewing 6.7 Resistance to overriding
INSTRUCTIONS **WARNINGS**	Suggestion for easy priming procedure: keep Epi-Max Nr fit dry and in vertical position with the flow arrow (on the two sides of the filter) upwards. The filter will eliminate air and let the liquid flow go through. After priming is complete Epi-Max Nr fit filter can stay any position. Filter for medical use, to be assembled in clean room. Handle with care. Cyclohexanone for glueing is recommended. Nevertheless, if PES hydrophilic membrane comes in contact with it, membrane breaks down. Remove the external bag before planting into a clean room. Verify compatibility of drugs to use with the raw materials declared in specifications. Usage with electric/mechanical pumps: while using Epi-Max Nr fit filters with any pump model, always arrange pump section above the filter and preferably keep at least 50cm between pump section and filter inlet connector.

	Product designed to enter in contact with disinfectant, in case of doubt or for any 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 Epicare filter in order to avoid bending of the filter connectors or filter body.** **Do not use for blood delivery, the filter clogs with whole blood or red blood cells.** **The filter is not recommended for TPN or lipids administration.**
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. Test report available at GVS premises.
PACKAGING AND LABELLING	**Packaging : Primary** Double PE bags containing 1.000 pcs. each. Bags are separately hot sealed **Secondary** Box of 2 bags, for a total of 2.000 pcs **Labelling**: The first bar-code label is outside the 2 bags. The second bar-code label is stuck outside the box. Each bag is labelled with the following traceability information: ✓ Quantity ✓ Product description ✓ Product date ✓ Lot number (OL and 6 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 labelled 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.
DRAWING	The attached drawing is part of this material specification and must not be duplicated or made accessible to a third part without prior written GVS S.p.A. permission.

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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 * Acceptable max 3 particles ≤ 0,2 mm² per viewing area	0,4	ISO 2859 part 1 1st Level
2	Projecting threads from external and cone (burrs)	0,4	
3	Incomplete plastic support (non 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	Damages, cracks or deformations on the pieces (functional)	0,1	
8	Damages, cracks or deformation on the pieces (non functional)	0,4	
9	Bubbles > 0,7 mm²	0,4	
10	No broken inlet or outlet	0,1	
11	Foreign material / Contamination > 0,2 mm²	0,1	
12	No blockage in inlet or outlet	0, 1	
13	Protruding injection > 0,2 mm	0,4	
14	No visible loose particulate matter downstream of filter membrane	0,1	
15	No loose foreign particulate upstream of the filter, plastics particles or internal membrane threads (upstream)	0,4	
16	Incomplete printing – pore size not readable (functional)	0,1	
17	Printing with smudges (max 3 < 0,2 mm² or max 5 < 0,05 mm²) – TAPPI DIRT ESTIMATION CHART	0,4	
18	No excess flash greater than 0,15 mm	0,4	

***** Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).
Loose Particulate Matter: free of visible particles > 0.2mm²

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

PERFORMANCE REQUIREMENTS

	Acceptance Requirement		AQL	Sampling Plan
1	Bubble point to verify PES integrity	3.7÷ 4.8 bar (ramped pressure in 15 seconds)	0.1	ISO 2859 part 1 1st Level
2	Water Flow rate @ 80 cm water head pressure	≥ 15 ml/min	0.1	
3	Burst test to verify housing pressure integrity	Ramped pressure, for reference: 3 bar/s → burst Registering burst pressure	$\bar{Y}$-3σ > 8 bar	ISO 2859 part 1 2nd Level

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.

FILTER TECHNOLOGY

Product PN	**RS085DMEDH002AF0**	☐ **PRELIMINARY** ☐ **R&D RELEASED** ☑ **RELEASED**	**Mod. 984c** **Rev. 05**
Description	**EPI-MAX Filter, 0,2 µm, Neuraxial Connector ISO 80369-6 compliant**		

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)
23/07/2019	00	First emission	**AQP – Barbara Finessi** **PM – Claudia Prando** **RPROG – Paolo Saragoni**	**DAM – Luca Zanini**
10/07/2020	01	Second emission: updated with ISO 80369-6 test results	**PM – Claudia Prando**	**DAQ - Tiziana Landi** **AQP – Barbara Finessi** **DAM – Luca Zanini** **RPROG – Paolo Saragoni**
04/09/2020	02	Third emission: updated with the total filter surface area and the letterhead has been corrected	**Project Manager** Claudia Prando	**DAQ - Tiziana Landi** ..... **AQP – Barbara Finessi** ..... **DAM – Luca Zanini** ..... **RPROG – Paolo Saragoni** .....

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.