PRODUCT SPECIFICATION

Product PN	**RS059**	**Mod. 984 c**
Description	**Baby Speedflow epidural IV filter non vented 0.2 – 0,2 positive - 1,2 – 5,0 µm**	**Rev. 04**

Baby Epicare IV filter

PRODUCT DESCRIPTION	Baby Speedlflow Epicare is a non-sterile, non-toxic single use device with hydrophilic PES membrane (0.2 , 0.2 positive, 1.2 or 5.0 µm) in a MBS housing, particularly suitable for the g filtration applications. 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	**Filter media:** Hydrophilic PES membrane 0.2 µm **Housing**: Clear Modified Acrylic **Inlet/Outlet connectors:** double luer lock - Female Luer Lock inlet / Male Rotating Luer Lock outlet in compliance with ISO80369-7
PRODUCT CHARACTERISTICS	**Dimensions WxLxD:** 15.3x21.9x4.0 mm (filter body) **Weight** 1.7 gr. **Hydrophilic filtration area** 1.45 cm² **Max operating pressure** 8.0 bar (116 psi) **Max operating temperature** 55 °C (131 °F) **Minimum Water Bubble Point:** PES 0.2/0.2pos µm: 3.7÷ 4,8 bar PES 1.2 µm: 0.7 ÷ 1,0 bar PES 5.0 µm: 0.15 ÷ 0,3 bar **Minimum Water Flow Rate:** PES 0.2pos µm : ≥ 3,5 ml/min @ 80 cm (31.5 in) water head pressure PES 0.2 µm : ≥ 4 ml/min @ 80 cm (31.5 in) water head pressure PES 1.2 µm : ≥ 30 ml/min @ 80 cm (31.5 in) water head pressure PES 5.0 µm : ≥ 55 ml/min @ 80 cm (31.5 in) water head pressure **Bacterial Retention** Brevundimonas diminuta / Candida Albicans (PES 1.2) / Not available (PES 5.0) **Priming volume <** 0.35 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
INSTRUCTIONS **WARNINGS**	Suggestion for easy priming procedure: keep Speedflow 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 Speedflow 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 - When using Speedflow 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. **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.**

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	To prevent filter breakage it is recommended to fix properly Epicare filter in order to avoid benting of the filter connectors or filter body. **Do not use for blood delivery, the filter clogs with whole blood or red blood cells.** **Filters with 0,2 micron and 0,2 micron positive membranes, not recommended for TPN or lipids administration.**
STERILIZATION	Ethylene oxide (Max 55°C) and gamma irradiation (Max 25 kGy)
APPLICABLE STANDARDS AND REGULATIONS	**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	Box of 2.000 pcs. 2 inner PE bags of 1.000 pcs. each. Bags are separately hot sealed. 3 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.

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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	Incomplete plastic support (non functional)	0.4	ISO 2859 part. 1 1st Level
2	Incomplete plastic support (functional)	0.1	
3	Damages, cracks or deformation on the pieces (functional)	0,1	
4	Damages, cracks or deformation on the pieces (non functional)	0,4	
5	Foreign material / Contamination > 0.2 mm2	0,1	
6	Embedded particles > 0.2 mm2 - Acceptable max 3 particles ≤ 0,2 mm2 per viewing area.	0,4	
7	Air bubbles > 0.7 mm2	0,4	
8	Fitting / Burr at the connection	0,4	
9	Burrs > 1,0 mm2	0,1	
10	Projecting threads from external and cones (burrs)	0.4	
11	Dents leaving traces, porosity, scratches.	0.4	
12	Plastics residual or internal membrane threads	0.4	
13	Damaged or deformed pieces	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.

PERFORMANCE REQUIREMENTS

	Acceptance Requirement		AQL	Sampling Plan
1	Bubble point to verify PES integrity	- 0.2 / 0.2pos µm: 3.7÷ 4,8 bar (ramped pressure in 15 seconds) - 1.2 µm: 0.7 ÷ 1,0 bar - 5.0 µm: 0.15 ÷ 0,3 bar	0,1	ISO 2859 part. 1 1st Level
2	Burst test to verify housing pressure integrity	- 8 bar for 15 "	0,1	
3	Water Flow rate @ 80 cm water head pressure	- 0.2pos µm: ≥ 3,5 ml/min - 0.2 µm: ≥ 4 ml/min - 1.2 µm: ≥ 30 ml/min - 5.0 µm: ≥ 55 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.

FILTER TECHNOLOGY

PRODUCT SPECIFICATION

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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)
31/07/2019	03	Introduction of compliance with ISO80369-7 for Luer Connectors	**Martina Miele – RP**	**Barbara Finessi - AQP**

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.