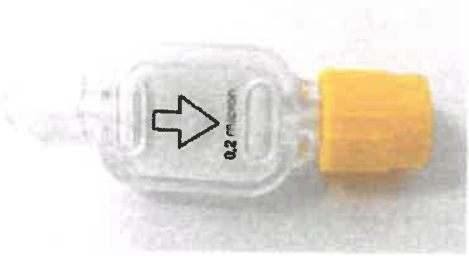
FILTER TECHNOLOGY

PRODUCT SPECIFICATION

Product PN	**RS090BMEDH002AF0**	☐ **PRELIMINARY** ☐ **R&D RELEASED** ☒ **RELEASED**	**Mod. 984c** **Rev. 05**
Description	**Baby Speedflow epidural IV filter non vented 0.2 µm neuraxial**		

Baby Epicare
IV filter



PRODUCT DESCRIPTION	Baby Speedflow Epicare is a non-sterile, non-toxic single use filtration device with hydrophilic PES membrane (0.2 µm) and a reinforced MBS housing. The connections are small bore connectors for neuraxial applications female lock inlet and rotating male lock outlet. Rotating nut is available in neutral or yellow colour. The product is provided in bulk packs for further manufacturing, processing or repackaging.
INTENDED USE / APPLICATION	The filter is designed for use in neuraxial applications.
MATERIALS	**Filter media:** Hydrophilic PES membrane 0.2 µm **Frame/Housing Polymer:** Acrylic-based multipolymer (MBS) **Rotating Nut Polymer:** Polypropylene (PP) **Color:** Neutral housing with neutral or yellow rotating nut **Inlet/Outlet connectors:** Neuraxial female lock inlet and neuraxial rotating male lock outlet
PRODUCT CHARACTERISTICS	**Dimensions WxLxD:** 15.3x21.9x4.0 mm (filter body) **Weight:** 1.7 g **Max operating temperature:** 40 °C (104 °F) **Storage temperature range:** from 0 °C (32°F) to 55°C (131°F) **Minimum Water Bubble Point:** 3.7÷4,8 bar **Minimum Water Flow Rate:** 4 ml/min @ 80 cm (31.5 in) water head pressure **Bacterial Retention:** LRV > 7 (B. Diminuta) **Dead volume:** ~ 0.35 ml **Pyrogenicity:** < 0.25 EU/ml using the LAL test method **Shelf Lifetime:** 5 years **Operating Lifetime:** single use **Other:** Performance requirements described in ISO 80369-6 Paragraph 6: - 6.2 Fluid leakage - 6.3 Subatmospheric-pressure air leakage - 6.4 Stress cracking - 6.5 Resistance to separation from axial load - 6.6 Resistance to separation from unscrewing - 6.7 Resistance to overriding
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.

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	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 Speedflow filters with any pump model, always arrange pump section above the filter and preferably keep at least 50 cm 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.** **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	**STERILE :** ☐ Yes ☑ No **SUITABLE FOR STERILIZATION : :** ☑ Yes ☐ No ☑ EtO (Max 55°C); ☑ Gamma (Max 25kGy);
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	Double PE bags containing 500 pcs. each. Bags are separately hot sealed. **Secondary Packaging:** Box of 12 bags, for a total of 6.000 pcs. 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 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 and ISO 13485.
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 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	Incomplete plastic support (non functional)	0.4	ISO 2859 part. 1 1st Level
2	Incomplete plastic support (functional)	0.1	
3	Incomplete or misplaced membrane	0.1	
4	Damages, cracks or deformation on the pieces (functional)	0.1	
5	Damages, cracks or deformation on the pieces (non functional)	0.4	
6	No broken inlet or outlet	0.1	
7	Foreign material / Contamination > 0.2 mm²	0.1	
8	No blockage in inlet or outlet	0.1	
9	Embedded particles < 0.2 mm² (max 3 per viewing area) - TAPPI DIRT ESTIMATION CHART	0.4	
10	Protruding injection > 0.3 mm	0.4	
11	Projecting threads from external and cone (burrs)	0.4	
12	Non-uniform coloration	0.4	
13	Dents leaving traces, porosity, scratches	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	Bubbles > 0.7 mm²	0.4	
17	Incomplete printing - pore size not readable (functional)	0.1	
18	Printing with smudges (max 3 < 0,2 mm² or max 5 < 0,05 mm²) - TAPPI DIRT ESTIMATION CHART	0.4	
19	No excess flash greater than 0.15 mm	0.4	

* Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).
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	3.7÷ 4.8 bar (ramped pressure in 15 s)	0.1	ISO 2859 part 1 1st Level
2	Burst test to verify housing pressure integrity	8 bar for 15" (ramped pressure in 15 s)	0.1	
3	**Water Flow rate @ 80 cm water head pressure**	**≥ 4 ml/min**	0.1	
4	**Burst test to verify housing pressure integrity**	**Ramped pressure 0 bar → burst Registering burst pressure**	**Ŷ-3σ > 8**	

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Control Note:
Customers who want to clarify requirements where judgmental differences may develop between the Customer and GVS S.p.A. may submit limit samples for GVS S.p.A. approval. If limits have not been established and approved, best judgement by GVS S.p.A. 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)
09/01/2020	00	First emission	Chiara Porcu - RP	Barbara Finessi - AQ Tiziana Landi – DAQ Luca Zanini – DAM Paolo Sarogoni – RP ROG

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.