PRODUCT SPECIFICATION

Product PN	**RS051- RS052- RS053- RS054- RS055- RS056- RS057- RS058 - RS062 – RS078 – RS079**	**Mod. 984 c**
Description	**Baby Speedflow neonate IV filter 0,2 – 0,2 positive - 1,2 – 5,0 µm**	**Rev. 04**

Baby Speedflow neonate IV filter

PRODUCT DESCRIPTION	Baby Speedlflow is a non-sterile, non-toxic, self venting, 120 hours filtration (0,2 positive) / 96 hour filtration (0,2 micron) / 24 hour filtration (1.2 micron), single use device with hydrophilic PES membrane (0.2 , 0.2 positive, 1.2 or 5.0 µm) and hydrophobic PTFE membrane (0,03 µm) in a MBS housing. The product is provided in bulk packs for further manufacturing, processing, or repackaging.
INTENDED USE / APPLICATION	The filter is designed for use in filtration of intravenous or other aqueous solutions for removal of particles larger than 0.2 µm / 1,2 µm / 5.0 µm.
MATERIALS	**Filter media:** Hydrophilic PES membrane 0.2 µm / positive 0.2 µm / 1.2 µm / 5,0 µm **Vent:** Hydrophobic PTFE 0.03 µm **Housing**: Clear Modified Acrylic **Inlet/Outlet connectors:** Microbore tubing + double luer lock RS051 – ID 2.0mm RS052 – ID 2.2mm RS053 – ID 2.3mm RS054 – ID 2.4mm RS055 – ID 2.5mm RS056 – ID 2.8mm RS057 – ID 3.0mm RS062 – ID 2.85mm RS078 – ID 3.175mm RS078 – ID 2,7mm RS058 – Female Luer Lock inlet / Male Rotating Luer Lock outlet in compliance with ISO80369-7
PRODUCT CHARACTERISTIC	**Dimensions WxLxD:** 15.3x21.9x4.0 mm (filter body) **Weight** 1.35 gr. (1.7 gr. for double LL version) **Hydrophilic filtration area** 1.45 cm² **Hydrophobic filtration area** 0.25 cm² **Air Flow Rate** ~ 20 scc/min @ 100mbar (hydrophobic membrane) **Max operating pressure** 5.2 bar (75.4 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.

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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. Remove the external bag before planting into a clean room. Handle with care.** **Cyclohexanone for glueing is recommended. Nevertheless, if PES hydrophilic membrane comes in contact with it, membrane breaks down.** **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.** **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.**
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. 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. 3 bags per box (6.000 units 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 lot of goods in one shipments are packed in a manner to prevent mix-ups. Different lot in one box are separately closed and separately labeled to prevent mix-ups.
CERTIFICATE OF COMPLIANCE	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 9001:2000, ISO 13485:2003, 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 consent.

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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 (functional)	0.1	ISO 2859 part. 1 1st Level
2	Incomplete or misplaced membrane	0,1	
3	Incomplete plastic support (not functional)	0.4	
4	Damages, cracks or deformation on the pieces (functional)	0,1	
5	Damages, cracks or deformation on the pieces (non functional)	0,4	
6	Foreign material / Contamination > 0.2 mm2	0,1	
7	Embedded particles < 0.2 mm2 * (max 3 per viewing area) - TAPPI DIRT ESTIMATION CHART	0,4	
8	Air bubbles > 0.7 mm2	0,4	
9	Fitting / Burr at the connection	0,4	
10	Burrs > 1,0 mm2	0,1	
11	Projecting threads from external and cones (burrs)	0.4	
12	Dents leaving traces, porosity, scratches.	0.4	
13	Plastics residual or internal membrane threads	0.4	
14	No loose foreign particulate upstream of the filter, plastics particles or internal membrane threads (upstream)	0.4	
15	Incomplete printing - pore size not readable (functional)	0,1	
16	Printing with smudges (max 3 < 0,2 mm2 or max 5 < 0,05 mm2) - TAPPI DIRT ESTIMATION CHART		

(*) Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).

Contamination Loose PM:
free of visible particles > 0,2 mm^2

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	WBT to verify PTFE	- 5,2 bar for 15	0,1	
3	Burst test to verify housing pressure integrity	- 5,2 bar for 15 "	0,1	
4	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	

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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)
19-SEP-2018	09	Added: details for part description; sterilization suitability; characteristics for visual requirements.	Barbara Finessi **Process Quality Assurance**	Tiziana Landi **Quality Assurance Director** *Electronically approved – Database*
31/07/2019	10	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.