PRODUCT SPECIFICATION

Product PN	RS038 – RS041 – RS047– RS049 – RS067- RS070 – RS073 – RS074 – RS077 – RS087 – RS080 – RS088	☐ PRELIMINARY ☐ R&D RELEASED ☑ RELEASED	Mod. 984c Rev. 05
Description	Speedflow Adult filter 0,2 – 0,2pos – 1,2 – 5,0 µm		

Speedflow Adult IV Filter

PRODUCT DESCRIPTION	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 an acrylic-based multipolymer compound 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:** Acrylic-based multipolymer compound, amber or blue masterbatch for the cover. **Inlet/Outlet connectors:** RS038 : FLL female Luer Lock (inlet) - Standard IV tubing connector (outlet) RS041- RS048: Standard IV tubing connectors (inlet/outlet) RS047 : FLL female Luer Lock (inlet) – ML male Luer (outlet) RS049 : FLL female Luer Lock (inlet) - RMLL rotating male Luer Lock (outlet) [Polypropilene nut] RS067 : FLL female Luer Lock (inlet) – ML male Luer (outlet) and cone internal diameter with double-step configuration RS070 : IV tubing connectors (inlet/outlet) with external diameter 3 mm. RS073 : IV tubing connectors (inlet/outlet) with external diameter 3,6 mm. RS074 : IV tubing connectors (inlet/outlet) with external diameter 3,4 mm. RS077: IV tubing connectors: inlet for tube with external diameter 2,16 mm; outlet for tube with internal diameter 3 mm RS087: IV tubing connectors (inlet/outlet) with external diameter 3,35 mm RS080: IV tubing connectors (inlet/outlet) with external diameter 3,15 mm RS088: IV tubing connectors (inlet/outlet) with external diameter 2,8 mm
PRODUCT CHARACTERISTICS	**Dimensions WxLxD** 30x(60÷62.8)x9.6 mm (depending by inlet/outlet connector versions) **Weight** 7.5 ÷ 7.9 gr. (depending by inlet/outlet connector versions) **Hydrophilic filtration area** 10.0 cm^2 **Hydrophobic filtration area** 1.0 cm^2 **Air Flow Rate** > 100 scc/min @ 100mbar (hydrophobic membrane) **Max burst pressure** 3.2 bar (46.4 psi) **Operating temperature** 5-40 °C **Storage temperature** 0-55 °C **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 : ≥ 20 ml/min @ 80 cm (31.5 in) water head pressure ✓ PES 0.2 µm : ≥ 32 ml/min @ 80 cm (31.5 in) water head pressure ✓ PES 1.2 µm : ≥ 180 ml/min @ 80 cm (31.5 in) water head pressure ✓ PES 5.0 µm : ≥ 340 ml/min @ 80 cm (31.5 in) water head pressure **Bacterial Retention:** Brevundimonas diminuta (PES 0.2) / Candida Albicans (PES 1.2) / Not available (PES 5.0) **Priming volume** < 2.4 ml **Pyrogenicity** < 0.25 EU/ml using the LAL test method **Low binding test:** performed with Piperacillin Sodium, Insulin, Paclitaxel, Lidocaine HCL, Nitro-glycerine, 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. 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 alcohol or any kind of disinfectant in direct contact with venting membranes of the filter (the PTFE membrane become hydrophilic, until disinfectant has dried). 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)
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 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 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 (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 (not functional)	0.4	
6	No broken inlet or outlet	0.1	
7	No blockage in inlet, outlet or vent hole ports	0.1	
8	Embedded particles < 0.2 mm^2 (max 3 per viewing area) - TAPPI DIRT ESTIMATION CHART (*)	0.4	
9	Projecting threads from external and cone (burrs)	0.4	
10	Dents leaving traces, porosity, scratches	0.4	
11	No visible loose particulate matter downstream of filter membrane	0.1	
12	Bubbles > 0.7 mm^2	0.4	
13	No loose foreign particulate upstream of the filter, plastics particles or internal membrane threads (upstream)	0.4	
14	Incomplete printing - pore size not readable (functional)	0,1	
15	Printing with smudges (max 3 < 0,2 mm2 or max 5 < 0,05 mm2) - TAPPI DIRT ESTIMATION CHART	0,4	
16	No excess flash greater than 0,1 mm.	0.4	
17	Weld marks: > 4 white dots per viewing area – size ≥ 0,3 mm^2 (*)	4,0	
18	Weld marks: cosmetic only and ≤ 4 white dots – size < 0,3 mm^2 (*) **All acceptable**	-	

* 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	Water Break Through (WBT) to verify PTFE	- 3.0 bar for 15 seconds	0,1	
3	Burst test to verify housing pressure integrity	- 3,2 bar for 15 seconds	0,1	
4	Water Flow rate @ 80 cm water head pressure	- 0.2pos µm: ≥ 20 ml/min - 0.2 µm: ≥ 32 ml/min - 1.2 µm: ≥ 180 ml/min - 5.0 µm: ≥ 250 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.

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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)
22/07/2021	19	Added visual characteristics #17 and #18 – Weld marks	Barbara Finessi QA Product & Process	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.