

PRODUCT SPECIFICATION

Product PN RS061BCYRH002A00 - RS061BCYRH012A00 - RS061BCYRH050A00
RS061BCYRH002M00

Mod. 984

Description SPEEDFLOW BABY IV filter - logo 0.2µm / 1.2µm / 5.0µm
with clear and amber housing

Rev. 02

SPEEDFLOW BABY 0.2µm- 1.2µm – 5.0µm IV filter



PRODUCT DESCRIPTION	IV filter Speedflow Baby is a non-sterile, non-toxic, self-venting, single use filtration device with a 0.2 / 1.2 / 5.0 µm hydrophilic PES membrane and a 0.03 µm hydrophobic PTFE vent in a clear modified acrylic clear and amber housing, The connections are tube inlet and tube outlet. 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. The filter with amber housing is for UV blocking.	
MATERIALS	Filter media: Hydrophilic PES membrane 0.2 / 1.2 / 5.0 µm Vent: Hydrophobic PTFE 0.03 µm Housing: Clear Modified Acrylic and amber masterbatch. Inlet/Outlet connectors: Microbore tubing - 2,85 mm inner diameter. The membrane pore size is printed on each filter : 0,2 micron – 1,2 micron – 5,0 micron.	
PRODUCT CHARACTERISTICS	Dimensions WxLxD: 15.3x21.9x4.0 mm (filter body) Weight: 1.35 gr. Hydrophilic filtration area: 1.45 cm² Hydrophobic filtration area: 0.25 cm² Air Flow Rate: > 9 scc/min @ 150mbar (hydrophobic membrane) Max operating pressure: 3.0 bar (43.5 psi) Max operating temperature: 55 °C (131 °F) Minimum Water Bubble Point: PES 0.2 µm: 3.0 bar PES 1.2 µm: 0.7 ÷ 1,0 bar PES 5.0 µm: 0.15 ÷ 0,3 bar Minimum Water Flow Rate: PES 0.2 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 (0,2 µm) and C. Albicans (1,2 µm) 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 gluing 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 and the venting membrane (hydrophobic PTFE membrane become hydrophilic, until until disinfectant has dried). 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.

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 Externally Communicating Device (Blood Path, Indirect).

Test report available at GVS premises.

All materials DEHP free and phthalates free.

All materials Latex free.

PACKAGING AND LABELLING

Box of 6.000 pcs. 3 inner PE bags of 2.000 pcs. each. 3 bags per box. – Tolerance on quantity per bag = ± 1.5%

Bags are separately hot sealed.

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.

STORAGE RECOMMENDATIONS

All filter components shall be stored in closed boxes, under room temperature if possible but not exceeding 55°C and as dry as possible. Condensation of water should be avoided. Direct sun light should be avoided.

CERTIFICATE OF COMPLIANCE

Below declaration is printed out in every invoice, in which all the product traceability information are listed and it is electronically signed by QA Manager:

----- Declaration of compliance with order (EN 10204:2004 type 2.1) -----

We herewith certify that all products regarding the invoice following here under have been tested in respect of their

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	physical and chemical characteristics, we have produced them using the required materials and we have complied with all specifications and requirements as called out on the drawing and the purchase order. The above products have been tested and produced according to ISO 9001 - IATF 16949 - ISO 13485 - ISO 14001.																																																																
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.																																																																
VISUAL REQUIREMENTS	Sampling plan according to ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection. Visual acceptance requirements apply when inspected under below conditions: Illumination: 1000 ± 200 lx or equivalent Light type: Fluorescent Magnification: unaided eye, approximately at a distance of 300-450 mm from eye. Timing: visual for 5 sec. per unit. <table border="1"> <thead> <tr> <th></th><th>Acceptance Requirement</th><th>AQL</th><th>Sampling Plan</th></tr> </thead> <tbody> <tr> <td>1</td><td>Incomplete plastic support (not functional)</td><td>0,4</td><td rowspan="19">ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection.</td></tr> <tr> <td>2</td><td>Incomplete plastic support (functional)</td><td>0,1</td></tr> <tr> <td>3</td><td>Damages, cracks or deformation on the pieces (functional)</td><td>0,1</td></tr> <tr> <td>4</td><td>Damages, cracks or deformation on the pieces (not functional) Note: As a result of the welding process, some white signs could be created at the filter welding edge (plastic housing). These are acceptable.</td><td>0,4</td></tr> <tr> <td>5</td><td>Foreign material in fluid path / Contamination > 0.2 mm2</td><td>0,04</td></tr> <tr> <td>6</td><td>Foreign material / Contamination > 0.2 mm2 (not in fluid path way)</td><td>0,1</td></tr> <tr> <td>7</td><td>Embedded particles ≤ 0.2 mm2 (*) - Acceptable max 3 particles ≤ 0,2 mm2 per viewing area.</td><td>0,4</td></tr> <tr> <td>8</td><td>Air bubbles > 0.7 mm2</td><td>0,4</td></tr> <tr> <td>9</td><td>Fitting / Burr at the connection</td><td>0,4</td></tr> <tr> <td>10</td><td>Burr > 1,0 mm2</td><td>0,1</td></tr> <tr> <td>11</td><td>Projecting threads from external and cone (burrs)</td><td>0,4</td></tr> <tr> <td>12</td><td>Dents leaving traces, porosity, scratches</td><td>0,4</td></tr> <tr> <td>13</td><td>Plastics residual or internal membrane threads (not in fluid pathway)</td><td>0,4</td></tr> <tr> <td>14</td><td>No grease or dirt in the filter assembly.</td><td>0,4</td></tr> <tr> <td>15</td><td>Incomplete printing</td><td>0,4</td></tr> <tr> <td>16</td><td>Printing with smudges or spots.</td><td>0,4</td></tr> <tr> <td colspan="2">Packaging status: delivery terms ex-works GVS Italia (Inco terms 2000)</td><td>No breakage or damaging</td></tr> <tr> <td colspan="2">Blood / Human hair / Insects</td><td>Nothing</td></tr> <tr> <td colspan="2">Difference of indications</td><td>Nothing</td></tr> </tbody> </table> (*) Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).				Acceptance Requirement	AQL	Sampling Plan	1	Incomplete plastic support (not functional)	0,4	ISO 2859 part. 1 – 1 st Level inspection, single sampling plan, normal inspection.	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 (not functional) Note: As a result of the welding process, some white signs could be created at the filter welding edge (plastic housing). These are acceptable.	0,4	5	Foreign material in fluid path / Contamination > 0.2 mm2	0,04	6	Foreign material / Contamination > 0.2 mm2 (not in fluid path way)	0,1	7	Embedded particles ≤ 0.2 mm2 (*) - Acceptable max 3 particles ≤ 0,2 mm2 per viewing area.	0,4	8	Air bubbles > 0.7 mm2	0,4	9	Fitting / Burr at the connection	0,4	10	Burr > 1,0 mm2	0,1	11	Projecting threads from external and cone (burrs)	0,4	12	Dents leaving traces, porosity, scratches	0,4	13	Plastics residual or internal membrane threads (not in fluid pathway)	0,4	14	No grease or dirt in the filter assembly.	0,4	15	Incomplete printing	0,4	16	Printing with smudges or spots.	0,4	Packaging status: delivery terms ex-works GVS Italia (Inco terms 2000)		No breakage or damaging	Blood / Human hair / Insects		Nothing	Difference of indications		Nothing
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PERFORMANCE REQUIREMENTS

Acceptance Requirement		AQL	Sampling Plan
1	Bubble point to verify PES membrane integrity - 0.2 µm: 3,0 bar 15 sec. - 1.2 µm: 0.7 ÷ 1,0 bar - 5.0 µm: 0.15 ÷ 0,3 bar	0,1	ISO 2859 part. 1 Level S 2
2	WBT to verify PTFE membrane integrity - 3.0 bar for 15 sec.	0,1	
3	Bursting test - 3.0 bar for 15 sec.	0,1	
4	Priming test / air eliminating - observe the filter after priming complete and liquid coming out from outlet connector for about 2 seconds	0,1	
5	Water Flow rate test - @ 80 cm water head pressure - 0.2 µm: ≥ 4 ml/min - 1.2 µm: ≥ 30 ml/min - 5.0 µm: ≥ 55 ml/min	0,1	

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 judgment by GVS SpA Quality Assurance will apply.

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)
01/09/2026	03	Corrected PSI value at pag.1	Barbara Palmieri – QA Specialist 	Barbara Finessi – QA Manager  Luca Zanini – VP LifeScience & Healthcare 

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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.