

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



<p>PRODUCT DESCRIPTION</p>	<p>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. 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.</p>
<p>MATERIALS</p>	<p>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.</p> <p>The membrane pore size is printed on each filter : 0,2 micron – 1,2 micron – 5,0 micron.</p>
<p>PRODUCT CHARACTERISTIC</p>	<p>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 (75.4 psi) Max operating temperature 55 °C (131 °F)</p> <p>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</p> <p>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</p> <p>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.</p>

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<p>INSTRUCTIONS</p> <p>WARNINGS</p>	<p>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.</p> <p>Filter for medical use, to be assembled in clean room. Remove the external bag before planting into a clean room. Handle with care.</p> <p>Cyclohexanone for gluing is recommended. Nevertheless, if PES hydrophilic membrane comes in contact with it, membrane breaks down.</p> <p>Verify compatibility of drugs to use with the raw materials declared in specifications.</p> <p>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.</p> <p>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.</p> <p>Do not use for blood delivery, the filter clogs with whole blood or red blood cells.</p> <p>Filters with 0,2 micron and 0,2 micron positive membranes, not recommended for TPN or lipids administration</p>
<p>STERILIZATION</p>	<p>Ethylene oxide (Max 55°C) and gamma irradiation (Max 25 kGy)</p>
<p>BIOLOGICAL REQUIREMENTS</p>	<p>FOR RAW MATERIALS USED TO PRODUCE COMPONENTS:</p> <p>Test performed in compliance with USP class VI and/or ISO 10993-1 Externally Communicating Device (Blood Path, Indirect).</p> <p>Test report available at GVS premises.</p> <p>All materials DEHP free and phthalates free.</p> <p>All materials Latex free.</p>
<p>PACKAGING AND LABELLING</p>	<p>2.000 units per bag. 3 bags per box (6.000 units per box). Bags are separately hot sealed.</p> <p>The first bar-code label is outside the 2 bags.</p> <p>The second bar-code label is stuck outside the box.</p> <p>Each bag is labeled with the following traceability information:</p> <ul style="list-style-type: none"> - Quantity - Product description - Product date - Lot number (OL and 5 digit batch number to trace back to raw materials used) - Operator code <p>Different lot of goods in one shipments are packed in a manner to prevent mix-ups.</p> <p>Different lot in one box are separately closed and separately labeled to prevent mix-ups.</p> <p>STORAGE RECOMMENDATIONS</p> <p>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.</p>
<p>CERTIFICATE OF COMPLIANCE</p>	<p>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 Director:</p> <p>----- Declaration of compliance with order (EN 10204:2004 type 2.1) -----</p> <p>We herewith certify that all products regarding the invoice following here under have been tested in respect of their physical and chemical characteristics, we have produced them using the required</p>

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	<p>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 UNI EN ISO 9001 - UNI ISO/TS 16949 – UNI EN ISO 13485 - UNI EN ISO 14001.</p>																																																																	
DRAWING	<p>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.</p>																																																																	
VISUAL REQUIREMENTS	<p>Sampling plan according to ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection. Embedded Particulate Matter: according to Dirt Estimation Chart.</p> <p>Visual acceptance requirements apply when inspected under below conditions:</p> <p>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.</p> <table border="1"> <thead> <tr> <th colspan="2">Acceptance Requirement</th> <th>AQL</th> <th>Sampling Plan</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Incomplete plastic support (non functional)</td> <td>0,4</td> <td rowspan="16">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 (non functional) <i>Note: As a result of the welding process, some white signs could be created at the filter welding edge (plastic housing). These are acceptable.</i></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 colspan="2">No breakage or damaging</td> </tr> <tr> <td colspan="2">Blood/Human hair / Insects</td> <td colspan="2">Nothing</td> </tr> <tr> <td colspan="2">Difference of indications</td> <td colspan="2">Nothing</td> </tr> </tbody> </table>	Acceptance Requirement		AQL	Sampling Plan	1	Incomplete plastic support (non 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 (non functional) <i>Note: As a result of the welding process, some white signs could be created at the filter welding edge (plastic housing). These are acceptable.</i>	0,4	5	Foreign material in fluid path / Contamination > 0.2 mm ²	0,04	6	Foreign material / Contamination > 0.2 mm ² (not in fluid path way)	0,1	7	Embedded particles > 0.2 mm ² - Acceptable max 3 particles ≤ 0,2 mm ² per viewing area.	0,4	8	Air bubbles > 0.7 mm ²	0,4	9	Fitting / Burr at the connection	0,4	10	Burr > 1,0 mm ²	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 - 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)
08/05/2014	00	This revision 00 is for the new PN RS061B (logo printed on the filter) and replaces the previous revision for RS0610 (without printing logo on the filter).	Barbara Finessi QA Product & Process	Barbara Finessi QA Product & Process
12/04/2017	01	Added Part Number RS061BCYRH002M00 with amber housing (PJ 477),	Filippo Trascinelli (Project Leader - Engineering) 	Barbara Finessi QA Product & Process

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.