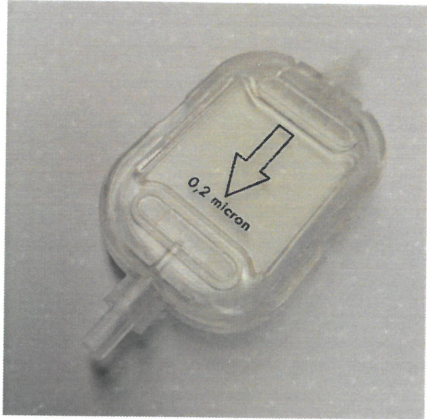


PRODUCT SPECIFICATION

Product PN	RS206BCYRH002A00	<input type="checkbox"/> PRELIMINARY	Mod. 984c Rev. 05
Description	Non-Vented Speedflow Adult Filter 0.2 µm	<input checked="" type="checkbox"/> RELEASED	

RS206BCYRH002A00
NON-VENTED SPEEDFLOW ADULT FILTER
0.2 µm



PRODUCT DESCRIPTION	<p>Detailed description of the product: Speedflow RS206BCYRH002A00 is a non-sterile, non-toxic and non-vented single use device with a 0.2 µm hydrophilic PES membrane in MBS housings (96 hours filtration). The product is provided in bulk packs for further manufacturing, processing or repackaging.</p> <p>Similar existing product: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: RS041BCYRH002A02</p>
INTENDED USE / APPLICATION	The filter is designed to be used in intravenous and/or other aqueous solutions filtration for removal of particles larger than 0.2 µm
MATERIALS	<p>Filter media: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Hydrophilic PES membrane 0.2 µm Frame/Housing Polymer: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Clear Modified Acrylic Color: <input type="checkbox"/> N/A <input checked="" type="checkbox"/> Specify: Clear Other insert(s): <input checked="" type="checkbox"/> N/A <input type="checkbox"/> Specify:</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Biocompatibility according ISO 10993-1 <input checked="" type="checkbox"/> Rohs, directive 2002/95/CE <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input checked="" type="checkbox"/> DEHP plasticizer Free and latex free <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input checked="" type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> Conflict minerals
PRODUCT CHARACTERISTICS	<p>Dimensions: 30x(60+62.8)x 9.6 mm (depending by inlet/outlet connector versions) Weight: 7.5 + 7.9 g (depending by inlet/outlet connector versions) Hydrophilic filtration area 10.0 cm² Max burst pressure 3.2 bar (46.4 psi) Operating temperature 5-40 °C Storage temperature 0-55 °C</p> <p>Minimum Water Bubble Point: 3.7÷ 4,8 bar Minimum Water Flow Rate: ≥ 32 ml/min @ 80 cm (31.5 in) water head pressure</p> <p>Bacterial Retention: Brevundimonas diminuta 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.</p>

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INSTRUCTIONS WARNINGS	<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 completed, Speedflow filter can stay in any position.</p> <p>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.</p> <p>Verify compatibility of drugs to use with the raw materials declared in specifications.</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 50 cm between pump section and filter inlet connector. Do not use for blood delivery, the filter clogs with whole blood or red blood cells.</p> <p>Not recommended for TPN or lipids administration.</p>
STERILIZATION	<p>STERILE : <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>SUITABLE FOR STERILIZATION : <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><input checked="" type="checkbox"/> EtO; Max 55 °C <input checked="" type="checkbox"/> Gamma; Max 25 kGy</p>
PACKAGING AND LABELLING	<p>Box of 2.000 pcs. 2 inner PE bags of 1.000 pieces 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 labelled 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 raw materials used) ✓ Operator code <p>Different lots of goods in one shipment are packed in a manner to prevent mixing. Different lots in one box are separately closed and separately labelled to prevent mixing.</p>
CERTIFICATE OF COMPLIANCE	<p>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 9001:2015, ISO 13485:2016</p>
DRAWING	<p>The attached drawing is part of this material specification and must not be duplicated or made accessible to a third part without prior written GVS SpA permission</p>



PRODUCT SPECIFICATION

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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

Acceptance Requirement		AQL	Sampling Plan
1	Incomplete plastic support (functional)	0,1	ISO 2859 part 1 1 st 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	Non broken inlet or outlet	0,1	
7	Embedded particles < 0.2 mm ² * (max 3 per viewing area) – TAPPI DIRT ESTIMATION CHART	0,4	
8	Projecting threads from external and cone (burrs)	0,4	
9	Dents leaving traces, porosity, scratches	0,4	
10	No visible loose particulate matter downstream of filter membrane	0,1	
11	Bubbles > 0,7 mm ²	0,4	
12	No loose foreign particulate upstream of the filter, plastics particles or internal membrane threads (upstream)	0,4	
13	Incomplete printing – pore size not readable (functional)	0,1	
14	Printing with smudges (max 3 < 0,2 mm ² or max 5 < 0,05 mm ²) TAPPI DIRT ESTIMATION CHART	0,4	
15	No excess flash greater than 0,1 mm	0,4	

Timings: 5 seconds per unit

*Embedded Particulate Matter: 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	3,7 ÷ 4,8 bar (ramped pressure in 15 seconds)	ISO 2859 part 1 1 st Level
	2	Burst test to verify housing pressure integrity	3,2 bar for 15 seconds	
	3	Water flow rate @ 80 cm water head pressure	≥ 32 ml/min	
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.

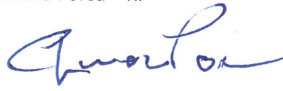

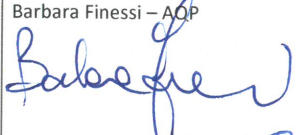
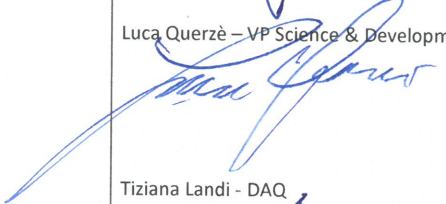



FILTER TECHNOLOGY

PRODUCT SPECIFICATION

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Description	Non-Vented Speedflow Adult Filter 0.2 µm	<input checked="" type="checkbox"/> RELEASED	

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
03/03/2020	00	First Emission	Chiara Porcu – RP  Paolo Saragoni – RPROG 	Barbara Finessi – AQP  Luca Querzè – VP Science & Development  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.