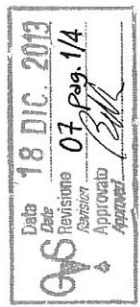
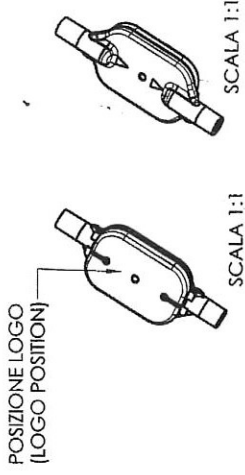


LOGHI LOGOS	
1	0,2 micron
2	1,2 micron
3	5,0 micron
4	0,2 positive

NOTE: CUSTOMER DRAWING; other sheets internal use



FOR P/N TABLE SEE SHEET 2/4

07	1	18/12/2013	Aggiornato diametro interno connettori	Piaggi	Bellini
REV.	POC.	Date - Data	Description of modification - Descrizione modifica	Disegnato - Disegnatore	Controllato - Controllore
General Tolerances - Tolleranze generali ±					
Date - Data 10/03/2008		Disegnato - Disegnatore Paggiari	Controllato - Controllo Bellini	Scala - Scala 2:1	Formato - Formato A3
Re / Subject - Oggetto BABY SPEEDFLOW TUBE-TUBE VERSIONS					
Materiale - Material 1-2 : clear modified acrylic 3-4 : see table					
Articolo - Articolo RS051-057-062 (see table)					
Mould - Stampo ATD28				ODL 1795	
<p>This drawing belongs to GVS SpA and control has copied or given to other Companies without our authorization. Qualsiasi riproduzione o utilizzo non autorizzato sarà perseguito legalmente e penalmente.</p>					
File name - Nome file baby speedflow T-I_rev07				Sheet - Foglio 1/4	



PRODUCT SPECIFICATION

Product PN	RS051- RS052- RS053- RS054- RS055- RS056- RS057- RS058 - RS062 – RS078	Mod. 984
Description	Baby Speedflow neonate IV filter 0,2 – 0,2 positive - 1,2 – 5,0 µm	Rev. 00

Baby Speedflow neonate



PART DESCRIPTION	Baby Speedflow is a non-sterile, non-toxic, self venting, 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.
MATERIALS	<p>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</p> <p>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</p> <p>RS058 – Female Luer Lock inlet / Male Rotating Luer Lock outlet</p>
PRODUCT CHARACTERISTICS	<p>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)</p> <p>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</p> <p>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</p> <p>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.</p>
PRIMING 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 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 glueing 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. It is not recommended to use any kind of disinfectant in direct contact with the filter. 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>
STERILIZATION	Ethylene oxide (Max 55°C) and gamma irradiation (M ax 25 kGy)



PRODUCT SPECIFICATION

Product PN	RS051- RS052- RS053- RS054- RS055- RS056- RS057- RS058 - RS062 – RS078	Mod. 984
Description	Baby Speedflow neonate IV filter 0,2 – 0,2 positive - 1,2 – 5,0 µm	Rev. 00

BIOLOGICAL REQUIREMENTS	<p>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).</p> <p>Test report available at GVS premises.</p>
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PACKAGING AND LABELLING	<p>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:</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. Different lot in one box are separately closed and separately labeled to prevent mix-ups.</p>
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CERTIFICATE OF COMPLIANCE	<p>Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1</p> <p>The Quality management system is in compliance with ISO 9001:2000, ISO 13485:2003, ISO/TS 16949</p>
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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>
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VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions:</p> <p>Magnification: unaided eye, approximately 45 cm (18") from eye Illumination: 1000 ± 200 lx or equivalent Light type: Fluorescent Timings: 5 sec per unit</p>
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	Acceptance Requirement	AQL	Sampling Plan
1	Incomplete plastic support (non functional)	0,4	ISO 2859 part. 1 1 st Level
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)	0,4	
5	Foreign material / Contamination > 0.2 mm ²	0,1	
6	Embedded particles > 0.2 mm ² - Acceptable max 3 particles ≤ 0,2 mm ² per viewing area.	0,4	
7	Air bubbles > 0.7 mm ²	0,4	
8	Fitting / Burr at the connection	0,4	
9	Burrs > 1,0 mm ²	0,1	
10	Projecting threads from external and cones (burrs)	0,4	
11	Dents leaving traces, porosity, scratches.	0,4	
12	Plastics residual or internal membrane threads	0,4	
113	Damaged or deformed pieces	0,4	

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

Contamination Loose PM: free of visible particles > 0,2 mm²



PRODUCT SPECIFICATION

Product PN	RS051- RS052- RS053- RS054- RS055- RS056- RS057- RS058 - RS062 – RS078	Mod. 984
Description	Baby Speedflow neonate IV filter 0,2 – 0,2 positive - 1,2 – 5,0 µm	Rev. 00

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
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	

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.

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

REVISIONI / REVISIONS:

DATA /DATE	REV.	MODIFICA DA PRECEDENTE REVISIONE/ REASON FOR CHANGE	MODIFICATO DA / CHANGED BY (name /function and signature)	APPROVATO DA/APPROVED BY (name /function and signature)
26/11/2014	07	New Product PN RS062 and RS078.	Barbara Finessi - Process Quality Assurance	Barbara Finessi - Process Quality Assurance 

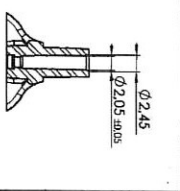
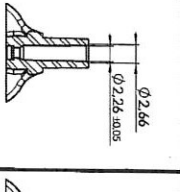
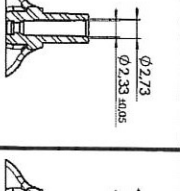
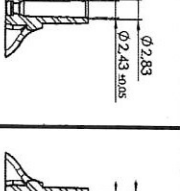
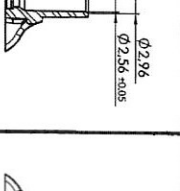
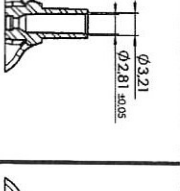
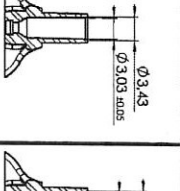
Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Date _____ Signature _____
(Company, Name, Function, Signature)


_____ (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.

ASSEMBLATO ASSEMBLE		COMPONENTI COMPONENTS					
DIMENSIONI CONNETTORI CONNECTORS DIMENSIONS	CARATTERISTICHE CHARACTERISTICS	CODICE ARTICOLO PART NUMBER	CORPO (1-2) BODY	INSERTO IDROFILICO (3) HYDROPHILIC INSERT	INSERTO IDROFOBICO (4) HYDROPHOBIC	N° LOGO LOGO N°	
	RS051... Ver. 02.0 mm	0,2 µm	RS051BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
		0,2 µm	RS051BCYRH002M00	amber	PES 0,2 µm	PTFE 0,03 µm	1
		1,2 µm	RS051BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS051BCYRH012D00	blue	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS051BCYRH012M00	amber	PES 1,2 µm	PTFE 0,03 µm	2
		5 µm	RS051BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
		0,2 µm positive	RS051BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm positive	RS051BCYCH002M00	amber	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm	RS052BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
		0,2 µm	RS052BCYRH002M00	amber	PES 0,2 µm	PTFE 0,03 µm	1
	RS052... Ver. 02.2 mm	1,2 µm	RS052BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS052BCYRH012D00	blue	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS052BCYRH012M00	amber	PES 1,2 µm	PTFE 0,03 µm	2
		5 µm	RS052BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
		0,2 µm positive	RS052BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm	RS053BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
		0,2 µm	RS053BCYRH002M00	amber	PES 0,2 µm	PTFE 0,03 µm	1
		1,2 µm	RS053BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS053BCYRH012D00	blue	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS053BCYRH012M00	amber	PES 1,2 µm	PTFE 0,03 µm	2
	RS053... Ver. 02.3 mm	5 µm	RS053BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
		0,2 µm positive	RS053BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm	RS054BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
		0,2 µm	RS054BCYRH002M00	amber	PES 0,2 µm	PTFE 0,03 µm	1
		1,2 µm	RS054BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS054BCYRH012D00	blue	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS054BCYRH012M00	amber	PES 1,2 µm	PTFE 0,03 µm	2
		5 µm	RS054BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
		0,2 µm positive	RS054BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm	RS055BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
	RS054... Ver. 02.4 mm	0,2 µm	RS055BCYRH002M00	amber	PES 0,2 µm	PTFE 0,03 µm	1
		1,2 µm	RS055BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS055BCYRH012D00	blue	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS055BCYRH012M00	amber	PES 1,2 µm	PTFE 0,03 µm	2
		5 µm	RS055BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
		0,2 µm positive	RS055BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm positive	RS056BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
		0,2 µm	RS056BCYRH002M00	amber	PES 0,2 µm	PTFE 0,03 µm	1
		1,2 µm	RS056BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS056BCYRH012D00	blue	PES 1,2 µm	PTFE 0,03 µm	2
	RS055... Ver. 02.5 mm	1,2 µm	RS056BCYRH012M00	amber	PES 1,2 µm	PTFE 0,03 µm	2
		5 µm	RS056BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
		0,2 µm positive	RS056BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm positive	RS056BCYCH002M00	amber	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm	RS056BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
		0,2 µm	RS056BCYRH002M00	amber	PES 0,2 µm	PTFE 0,03 µm	1
		1,2 µm	RS056BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS056BCYRH012D00	blue	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS056BCYRH012M00	amber	PES 1,2 µm	PTFE 0,03 µm	2
		5 µm	RS056BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
	RS056... Ver. 02.8 mm	0,2 µm positive	RS056BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4
		0,2 µm	RS0560CYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	NO LOGO
		1,2 µm	RS0560CYRH012A00	transparent	PES 0,2 µm	PTFE 0,03 µm	NO LOGO
		0,2 µm	RS057BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
		0,2 µm	RS057BCYRH002M00	amber	PES 0,2 µm	PTFE 0,03 µm	1
		1,2 µm	RS057BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS057BCYRH012D00	blue	PES 1,2 µm	PTFE 0,03 µm	2
		1,2 µm	RS057BCYRH012M00	amber	PES 1,2 µm	PTFE 0,03 µm	2
		5 µm	RS057BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
		0,2 µm positive	RS057BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4
	RS057... Ver. 03.0 mm	0,2 µm	RS062BCYRH002A00	transparent	PES 0,2 µm	PTFE 0,03 µm	1
		1,2 µm	RS062BCYRH012A00	transparent	PES 1,2 µm	PTFE 0,03 µm	2
		5 µm	RS062BCYRH050A00	transparent	PES 5,0 µm	PTFE 0,03 µm	3
		0,2 µm positive	RS062BCYCH002A00	transparent	PES 0,2 µm pos.	PTFE 0,03 µm	4

NOTE: CUSTOMER DRAWING; other sheets for internal use

General Tolerances - Tolleranze generali		± 0,2	
Date - Data	10/03/2008	Disegnato - Designer	Reggiani
		Disegnato - Designer	Bellini
		Scala - Scale	2:1
		Formato - Format	A2
Re / Subject - Oggetto		BABY SPEEDFLOW TUBE-TUBE VERSIONS	
Materiali - Material		1- 2: clear modified acrylic 3-4 : see table	
Articolo - Article		RS051+057-062 (see table)	
Mould - Stampo		ATD28	
Steel - Foglio		2/4	
ODL		1795	


 Date: 18 DEC, 2008
 Approved: [Signature]
 07 pag. 2/4

