

# PRODUCT SPECIFICATION

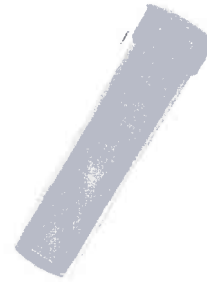
Product PN **FI148APS4N200B03 195µm NY mesh**

Mod. 984

Rev. 02

Description **Tubular filter**

**Blood Filter  
for transfusion set**



<b>PRODUCT DESCRIPTION</b>	Tubular Filter It's a non-sterile filter with a 195µm NY mesh The product is provided in bulk packs for further manufacturing.		
<b>MANUFACTURER NAME</b>	GVS SUD S.r.l. Via Tavernole,8 - 83030 Manocalzati (Avellino) - Italy		
<b>INTENDED USE / APPLICATION</b>	Transfusion		
<b>MATERIALS</b>	<b>Item:</b>	<b>Material:</b>	<b>Color:</b>
	Housing	Resin PS Styrolution	Natural
	Filter material	Mesh PA 6.6 (Polyamide 6.6)	Natural
	<b>REGULATORY DOCUMENTATION FOR RAW MATERIALS USED TO PRODUCE COMPONENTS</b> (based on the available documentation from raw materials suppliers )  <b>MESH</b> ✓ Biocompatibility according ISO 10993-1 and/or USP class VI ✓ RoHS, directive 2002/95/CE ✓ BSE/TSE, directive 2003/32/CE ✓ DEHP plasticizer Free ✓ Latex free ✓ Reach 1907/2006/CE (hazardous substances regulation) ✓ Conflict minerals  <b>RESIN</b> ✓ EU Food Contact Regulation ✓ Latex free ✓ Reach 1907/2006/CE (hazardous substances regulation) ✓ Conflict Minerals		

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# PRODUCT SPECIFICATION

Product PN **F1148APS4N200B03 195µm NY mesh**

Mod. 984

Rev. 02

Description **Tubular filter**

<b>PRODUCT CHARACTERISTIC</b>	<p>Mesh: NY 195µm</p> <p>Outer diameter: 15.0 mm</p> <p>Total length: 41.1 mm</p>
<b>PACKAGING AND LABELLING</b>	<p>8.000 pcs packed in two PE bags. Bags are separately closed.</p> <p>The first bar-code label is between 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"> <li>- Quantity</li> <li>- Product description</li> <li>- Product date</li> <li>- Lot number (OL and batch number to trace back to raw materials used)</li> <li>- Operator code</li> </ul> <p>Different lot of goods in one shipment are packed in a manner to prevent mix-ups.</p> <p>Different lots in one box are separately closed and separately labeled to prevent mix-ups.</p>
<b>CERTIFICATE OF COMPLIANCE</b>	<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, ISO 13485.</p>
<b>DRAWING</b>	<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 consent.</p>

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## VISUAL REQUIREMENTS

**Visual acceptance requirements apply when inspected under below conditions:**

Instrument inspection with naked eye and light source

Distance of 300-450 mm.

Time: 5 sec per unit

Acceptance Requirement		AQL	Sampling Plan
1	1. Short molding 2. Mesh threads protruding from plastic ring (filter top area) 3. Short mesh, detached from the plastic support. 4. Broken mesh 5. Open mesh out of specification (uneven mesh). 6. Missing mesh	0.4	ISO 2859 part. 1 1 <sup>st</sup> Level
2	7. Mesh protruding out of the rib 8. Mesh welding out of the rib 9. Flashes > 0.3 mm. 10. Gate scar > 0.3 mm. 11. Loose particulate matter > 0.1 mm <sup>2</sup> 12. Plastic infiltration on filter mesh > 2nd mesh opening 13. Dents/Scratches with plastic residual 14. Shrinkage on plastic ring (filter top area) 15. Burning marks 16. Dirty of oil, grease 17. Embedded particulate matter > 0.2 mm <sup>2</sup>	1.5	

\* Embedded and loose particles/contamination: according to Dirt Estimation Chart (Tappi Standard).

## PERFORMANCE REQUIREMENTS

Dimensional / Functional		AQL	Sampling Plan
1	Total Length: 41.1 ± 0.15 mm	0.1	ISO 2859 part. 1 S3 Special inspection level, single sampling plan, normal inspection Sampling Plan
2	Plastic Ring Height: 4.0 ± 0.10 mm		
3	Plastic Ring Outer Diameter: 15.0 ± 0.15 mm		

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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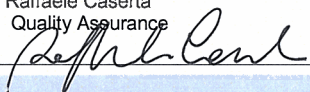
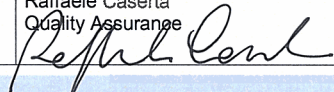
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## REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
18/10/2016	00	First Issue	Raffaele Caserta Quality Assurance 	Raffaele Caserta Quality Assurance 

## 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.