

# PRODUCT SPECIFICATION

Product PN

**FI108PPNY200**  
**FI108PPNY263**

Mod. 984 c

Rev. 03

Description

Tubular filter with mesh Ny 200µm or Ny 263µm

**Tubular filter with Mesh  
Ny 200µm and Ny 263µm**



PRODUCT DESCRIPTION	Tubular filter Is a non-sterile tubular filter with mesh Ny 200µm or Ny 263µm The product is provided in bulk packs for further manufacturing									
INTENDED USE / APPLICATION	Transfusion									
MATERIALS	<p><b>Mesh:</b> Polyamide 6.6 fabric (Ny 200 µm or Ny 263 µm) <b>Housing:</b> Polypropylene, Homopolymer Purell HP371P</p> <p><b>For raw materials used to produce components, Regulatory Documentation Required:</b></p> <ul style="list-style-type: none"><li>☒ Biocompatibility according ISO 10993-1 and USP class VI</li><li>☒ Reach 1907/2006/CE (hazardous substances regulation)</li><li>☒ RoHS, directive 2002/95/CE</li><li>☒ BSE/TSE, directive 2003/32/CE</li><li>☒ DEHP plasticizer Free and latex free</li><li>☒ Conflict minerals</li><li>☒ Latex free</li><li>☒ Phthalates Free</li></ul>									
PRODUCT CHARACTERISTIC	<table><tr><th colspan="2">Dimensions:</th></tr><tr><td>Total length</td><td>69,90 mm</td></tr><tr><td>Outside diameter (assembling side)</td><td>16,20 mm</td></tr><tr><td>Inside diameter (assembling side)</td><td>12,70 mm</td></tr></table>		Dimensions:		Total length	69,90 mm	Outside diameter (assembling side)	16,20 mm	Inside diameter (assembling side)	12,70 mm
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Outside diameter (assembling side)	16,20 mm									
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PRODUCT SHELF LIFE	5 years									
STERILIZATION	SUITABLE FOR STERILIZATION : Ethylene oxide									
PACKAGING AND LABELLING	9.000 pcs packed in two PE bags. Bags are separately closed. The first bar-code label is between the 2 bags. The second bar-code label is stuck outside the box.									

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PACKAGING AND LABELLING	<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. Different lots in one box are separately closed and separately labeled to prevent mix-ups.</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, ISO 13485.</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 S.p.A. consent.</p>															
ACCEPTABLE QUALITY LEVEL	<p>AQL (see the below table)</p>															
VISUAL REQUIREMENTS	<p><b>Visual acceptance requirements apply when inspected under below conditions:</b> Instrument inspection with naked eye and light source Distance of 300-450 mm. Timings: 5 sec per unit</p> <table><thead><tr><th colspan="2">Acceptance Requirement</th><th colspan="2">AQL</th></tr></thead><tbody><tr><td>1</td><td>1. Plastic support not complete. 2. Loose filter tissue. 3. Short filter mesh, detached from the plastic support. 4. Broken filter mesh. 5. Open mesh out of specification (uneven mesh). 6. *Air bubbles on calotte &gt; 3 mm²</td><td>0,1</td><td rowspan="2">ISO 2859 part. 1 1<sup>st</sup> Level</td></tr><tr><td>2</td><td>7. Mesh jutting out of the rib. 8. Weld of filter tube out of the rib. 9. Burrs &gt; 0,3 mm. 10. Jutting injection gate &gt;0.3 mm. 11. *Loose particulate matter &gt; 0,1 mm². 12. Plastic material on the filter mesh &gt; 3mm. 13. Dents/Scratches with plastic residual</td><td>0,65</td></tr><tr><td>3</td><td>14. Not detachable filter mesh threads. 15. Dirty of oil, grease. 16. *Embedded particulate matter &gt; 0,2 mm²</td><td>1,5</td><td></td></tr></tbody></table> <p>*Embedded Particulate Matter, loose contamination and air bubbles : according to Dirt Estimation Chart (Tappi Standard).</p> <p>The characteristics above listed are statistically inspected during the manufacturing process.</p>	Acceptance Requirement		AQL		1	1. Plastic support not complete. 2. Loose filter tissue. 3. Short filter mesh, detached from the plastic support. 4. Broken filter mesh. 5. Open mesh out of specification (uneven mesh). 6. *Air bubbles on calotte > 3 mm²	0,1	ISO 2859 part. 1 1 <sup>st</sup> Level	2	7. Mesh jutting out of the rib. 8. Weld of filter tube out of the rib. 9. Burrs > 0,3 mm. 10. Jutting injection gate >0.3 mm. 11. *Loose particulate matter > 0,1 mm². 12. Plastic material on the filter mesh > 3mm. 13. Dents/Scratches with plastic residual	0,65	3	14. Not detachable filter mesh threads. 15. Dirty of oil, grease. 16. *Embedded particulate matter > 0,2 mm²	1,5	
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## PERFORMANCE REQUIREMENTS

	Acceptance Requirement	Value of reference	AQL	Sampling Plan
1	Total lenght	60,9 +/- 0,3 mm	0,1	ISO 2859 part. 1 S3 Special inspection level
2	Outside diameter	16 + 0 / - 0,2 mm		
3	Internal diameter	12,7 +/- 0,3 mm		
4	Height ring	7,9 +/- 0,1 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.

## REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
11/10/2018	00	First Emission	Isabella Frignani Process Quality Assurance 	Tiziana Landi Director 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.