

PRODUCT SPECIFICATION

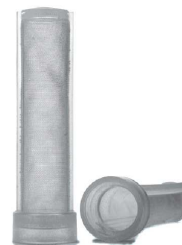
Product PN **FI644PPNY200**

Mod. 984 c

Rev. 03

Description Tubular filter with mesh Ny 200µm

Tubular filter
with Mesh Ny 200µm



PRODUCT DESCRIPTION	Tubular filter Is a non-sterile tubular filter with mesh Ny 200µm The product is provided in bulk packs for further manufacturing									
INTENDED USE / APPLICATION	Transfusion									
MATERIALS	Mesh: Polyamide 6.6 fabric (Ny 200 µm) Housing: Polypropylene, Homopolymer Purell HP371P For raw materials used to produce components, Regulatory Documentation Required: <div><input checked="" type="checkbox"/> Biocompatibility according ISO 10993-1 and USP class VI <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <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"/> Conflict minerals <input checked="" type="checkbox"/> Latex free <input checked="" type="checkbox"/> Phthalates Free</div>									
PRODUCT CHARACTERISTIC	<table><tr><th colspan="2">Dimensions:</th></tr><tr><td>Total length</td><td>62,10 mm</td></tr><tr><td>Outside diameter (assembling side)</td><td>17,25 mm</td></tr><tr><td>Inside diameter (assembling side)</td><td>14,30 mm</td></tr></table>		Dimensions:		Total length	62,10 mm	Outside diameter (assembling side)	17,25 mm	Inside diameter (assembling side)	14,30 mm
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PRODUCT SHELF LIFE	5 years									
STERILIZATION	SUITABLE FOR STERILIZATION : Ethylene oxide									
PACKAGING AND LABELLING	8.000 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. Each bag is labeled with the following traceability information: <div><div>- Quantity</div><div>- Product description</div></div>									

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PACKAGING AND LABELLING	<ul style="list-style-type: none">- Product date- Lot number (OL and batch number to trace back to raw materials used)- Operator code <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>														
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, 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>Visual acceptance requirements apply when inspected under below conditions:</p> <p>Instrument inspection with naked eye and light source</p> <p>Distance of 300-450 mm. Timings: 5 sec per unit</p> <table><tr><th colspan="2">Acceptance Requirement</th><th>AQL</th><th>Sampling plan</th></tr><tr><td>1</td><td><p>1. Plastic support not complete.</p><p>2. Loose filter tissue.</p><p>3. Short filter mesh, detached from the plastic support.</p><p>4. Broken filter mesh.</p><p>5. Open mesh out of specification (uneven mesh).</p><p>6. *Air bubbles on calotte > 3 mm²</p></td><td>0,1</td><td rowspan="3">ISO 2859 part. 1 1st General inspection Levels</td></tr><tr><td>2</td><td><p>7. Mesh jutting out of the rib.</p><p>8. Weld of filter tube out of the rib.</p><p>9. Burrs > 0,3 mm.</p><p>10. Jutting injection gate >0.3 mm.</p><p>11. *Loose particulate matter > 0,1 mm².</p><p>12. Plastic material on the filter mesh > 2nd .</p><p>13. Dents/Scratches with plastic residual</p></td><td>0,65</td></tr><tr><td>3</td><td><p>14. Not detachable filter mesh threads.</p><p>15. Dirty of oil, grease.</p><p>16. *Embedded particulate matter > 0,2 mm²</p></td><td>1,5</td></tr></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	Sampling plan	1	<p>1. Plastic support not complete.</p> <p>2. Loose filter tissue.</p> <p>3. Short filter mesh, detached from the plastic support.</p> <p>4. Broken filter mesh.</p> <p>5. Open mesh out of specification (uneven mesh).</p> <p>6. *Air bubbles on calotte > 3 mm²</p>	0,1	ISO 2859 part. 1 1 st General inspection Levels	2	<p>7. Mesh jutting out of the rib.</p> <p>8. Weld of filter tube out of the rib.</p> <p>9. Burrs > 0,3 mm.</p> <p>10. Jutting injection gate >0.3 mm.</p> <p>11. *Loose particulate matter > 0,1 mm².</p> <p>12. Plastic material on the filter mesh > 2nd .</p> <p>13. Dents/Scratches with plastic residual</p>	0,65	3	<p>14. Not detachable filter mesh threads.</p> <p>15. Dirty of oil, grease.</p> <p>16. *Embedded particulate matter > 0,2 mm²</p>	1,5
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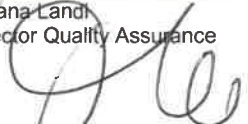
PERFORMANCE REQUIREMENTS

	Acceptance Requirement	Value of reference	AQL	Sampling Plan
1	Total lenght	62,1 +/- 0,4 mm	0,1	ISO 2859 part. 1 S3 Special inspection level
2	Outside diameter	17,25 +/- 0,1 mm		
3	Internal diameter	14,3 +/- 0,1 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)
09/11/2018	02	This revision replaces the previous rev.01. In this rev.02 it was changed the layout of the module.	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.