

PRODUCT SPECIFICATION

Product PN **FI135ABSNY200**

Mod. 984 c

Rev. 03

Description ABS Tubular filter, Nylon mesh 200 µm

ABS Tubular filter, Nylon
mesh 200 µm



PRODUCT DESCRIPTION	Tubular filter Is a non-sterile tubular filter with mesh Nylon 200µm The product is provided in bulk packs for further manufacturing									
INTENDED USE / APPLICATION	Transfusion									
MATERIALS	<p>Mesh: Polyamide fabric (200 µm) Housing: ABS</p> <p>For raw materials used to produce components, Regulatory Documentation Required:</p> <ul style="list-style-type: none">☒ Biocompatibility according ISO 10993-1 and USP class VI☒ Reach 1907/2006/CE (hazardous substances regulation)☒ RoHS, directive 2002/95/CE☒ BSE/TSE, directive 2003/32/CE☒ DEHP plasticizer Free and latex free☒ Conflict minerals☒ Latex free☒ Phthalates Free									
PRODUCT CHARACTERISTIC	<table><tr><th colspan="2">Dimensions:</th></tr><tr><td>Total length</td><td>57,3 mm</td></tr><tr><td>Outside diameter (assembling side)</td><td>16,33 mm</td></tr><tr><td>Inside diameter (assembling side)</td><td>11,95 mm</td></tr></table>		Dimensions:		Total length	57,3 mm	Outside diameter (assembling side)	16,33 mm	Inside diameter (assembling side)	11,95 mm
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PRODUCT SHELF LIFE	5 years									
STERILIZATION	SUITABLE FOR STERILIZATION : Ethylene oxide									
PACKAGING AND LABELLING	<p>10.000 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.</p> <p>Each bag is labeled with the following traceability information:</p>									

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PACKAGING AND LABELLING	<ul style="list-style-type: none">- Quantity- Product description- 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. 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 consent.</p>														
ACCEPTABLE QUALITY LEVEL	<p>AQL (see the below table)</p>														
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions: 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 > 3 mm²</td><td>0,1</td><td rowspan="3">ISO 2859 part. 1 1st 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 > 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</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 > 0,2 mm²</td><td>1,5</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 mm ²	0,1	ISO 2859 part. 1 1st 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 mm ² . 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 mm ²	1,5
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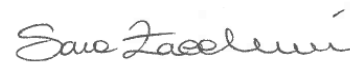
PERFORMANCE REQUIREMENTS

	Acceptance Requirement	Value of reference	AQL	Sampling Plan
1	Total length	57,3 +/- 0,3 mm	0,1	ISO 2859 part. 1 S3 Special inspection level
2	Outside diameter	16,33 +/- 0,1 mm		
3	Internal diameter	11,95 +/- 0,2 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)
23/07/2019	00	Initial submission for GVS Microfiltrazione transfer	Sara Zaccheroni (AQ)	Sara Zaccheroni (AQ) 

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.