

PRODUCT SPECIFICATION

Product PN	FD87ABSNY15	<input type="checkbox"/> PRELIMINARY <input type="checkbox"/> R&D RELEASED <input checked="" type="checkbox"/> RELEASED	Mod. 984c Rev. 05
Description	Disc filter ABS Ny 15µm white		

**Disc filter NY 15 µm
for infusion set**



PRODUCT DESCRIPTION	<p>Detailed description of the product: Disc filter with mesh NY 15 µm The product is provided in non-sterile bulk packs for further manufacturing</p>
INTENDED USE / APPLICATION	<p>Component for infusion set Disc filter meets the requirements of the ISO 8536-4 "Infusion sets for single use, gravity feed", specifically for the paragraph 6.7</p>
MATERIALS	<p>Filter media: NY 15 µm mesh opening Frame/Housing Polymer: ABS Sicoflex S454 1144 Color: white</p> <p>Regulatory Documentation available for raw materials, based on the documentation received from raw materials suppliers:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Biocompatibility according ISO 10993-1 <input checked="" type="checkbox"/> RoHS <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input checked="" type="checkbox"/> DEHP plasticizer Free and latex free <input checked="" type="checkbox"/> California Proposition 65 <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input checked="" type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> Conflict minerals <input checked="" type="checkbox"/> Nanomaterials <input checked="" type="checkbox"/> PFOA, Nitrosamine, BP

PRODUCT CHARACTERISTICS	Dimensions:	
	External diameter	13,05 ± 0,1 mm
	Internal diameter	10,3 ± 0,1 mm
	Total height	3,65 ± 0,15 mm

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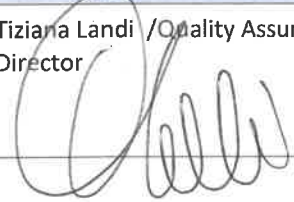
ACCEPTABLE QUALITY LEVEL, VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions:</p> <p>Instrument inspection: naked eye and light source Distance between light and part: 300-450 mm Inspection time: 5 sec per unit</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Acceptance Requirement</th> <th style="text-align: center;">AQL</th> <th style="text-align: center;">Sampling Plan</th> </tr> </thead> <tbody> <tr><td>Incomplete plastic support</td><td style="text-align: center;">0,4</td><td rowspan="14" style="text-align: center; vertical-align: middle;">ISO 2859-1 1st Level Inspection</td></tr> <tr><td>Missing or incomplete filter mesh.</td><td style="text-align: center;">0,4</td></tr> <tr><td>Broken filter mesh</td><td style="text-align: center;">0,4</td></tr> <tr><td>Double or partially double mesh</td><td style="text-align: center;">0,4</td></tr> <tr><td>Mesh protruding out of plastic support</td><td style="text-align: center;">0,4</td></tr> <tr><td>Burrs, protruding injection gate > 0,4 mm.</td><td style="text-align: center;">0,4</td></tr> <tr><td>Mesh not embedded and detachable from plastic support</td><td style="text-align: center;">0,4</td></tr> <tr><td>Scratches with residual</td><td style="text-align: center;">2,5</td></tr> <tr><td>Plastic material on the filter mesh > 0,5 mm</td><td style="text-align: center;">2,5</td></tr> <tr><td>Rust, dirty, grease</td><td style="text-align: center;">2,5</td></tr> <tr><td>Scratches without residual</td><td style="text-align: center;">4</td></tr> <tr><td>Loose particle contamination > 0,2 mm² (*)</td><td style="text-align: center;">4</td></tr> <tr><td>Threads</td><td style="text-align: center;">4</td></tr> <tr><td>Embedded particle contamination > 0,2 mm² (*)</td><td style="text-align: center;">4</td></tr> </tbody> </table> <p>(*) Embedded and loose particle contamination : according to Dirt Estimation Chart (Tappi Standard)</p>	Acceptance Requirement	AQL	Sampling Plan	Incomplete plastic support	0,4	ISO 2859-1 1 st Level Inspection	Missing or incomplete filter mesh.	0,4	Broken filter mesh	0,4	Double or partially double mesh	0,4	Mesh protruding out of plastic support	0,4	Burrs, protruding injection gate > 0,4 mm.	0,4	Mesh not embedded and detachable from plastic support	0,4	Scratches with residual	2,5	Plastic material on the filter mesh > 0,5 mm	2,5	Rust, dirty, grease	2,5	Scratches without residual	4	Loose particle contamination > 0,2 mm ² (*)	4	Threads	4	Embedded particle contamination > 0,2 mm ² (*)	4
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STERILIZATION	<p>The product is purchased in bulk non sterile It is suitable for EtO sterilization (max 55°C)</p> <p>NOTE: it is customer responsibility to verify sterilisation suitability at his conditions on finished medical device</p>																																
PACKAGING AND LABELLING	<p>Packaging : Primary double PE bag closed with lace Secondary cartonbox 60X40X25</p> <p>Labelling: Standard GVS label applied on internal bag and on cartonbox Labels report the following traceability information:</p> <ul style="list-style-type: none"> - Product code - Production date - Lot number (OL and batch number) - Quantity - Operator code <p>Different lots of the same shipment are packed to prevent mix-ups. Different lots in one box are separately closed and separately labeled to prevent mix-ups.</p>																																
CERTIFICATE OF COMPLIANCE	<p>The 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 and ISO 13485 standards.</p>																																

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DRAWING	Drawing rev 03 issued on 18 Sept. 2018. Main dimensions are reported on "Product Characteristics"
<p>This material specification describes the properties of product above indicated. This document contains general requirements, material description, drawing references, defect specification, biological material requirements.</p>	

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
26/11/2021	00	First issue	Patrizia Ercolessi / Process & Product Quality Assurance 	Tiziana Landi / Quality Assurance Director 

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.