

PRODUCT SPECIFICATION

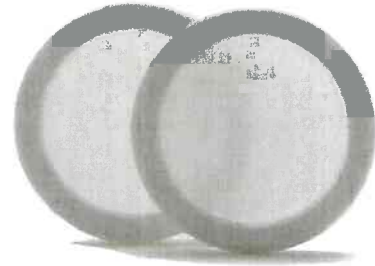
Product PN **FD230AAKUN015B02 mesh NY15µm**
FD230AAKUN025B02 mesh NY25µm
FD230AAKUN050B02 mesh NY50µm

Mod. 984

Rev. 02

Description **Disc filter**

**Disc filter
 for infusion set**



PRODUCT DESCRIPTION	Disc Filter Is a non-sterile filter with mesh NY15µm - mesh NY25µm -mesh NY50µm The product is provided in bulk packs for further manufacturing.										
INTENDED USE / APPLICATION	Infusion										
MATERIALS	<table border="1" data-bbox="339 1093 1559 1339"> <thead> <tr> <th data-bbox="339 1093 544 1155">Item:</th> <th data-bbox="544 1093 1137 1155">Material:</th> <th data-bbox="1137 1093 1559 1155">Color:</th> </tr> </thead> <tbody> <tr> <td data-bbox="339 1155 544 1245">Housing</td> <td data-bbox="544 1155 1137 1245">PA 6 Akulon + white colorant</td> <td data-bbox="1137 1155 1559 1245">White</td> </tr> <tr> <td data-bbox="339 1245 544 1339">Filter material</td> <td data-bbox="544 1245 1137 1339">Mesh PA 6.6 (Polyamide 6.6)</td> <td data-bbox="1137 1245 1559 1339">Natural</td> </tr> </tbody> </table> <p data-bbox="339 1368 1559 1429">FOR RAW MATERIALS USED TO PRODUCE COMPONENTS based on the available documentation from raw materials suppliers:</p> <p data-bbox="339 1462 1559 1491">Regulatory Documentation:</p> <ul data-bbox="443 1525 1166 1733" style="list-style-type: none"> ✓ Biocompatibility according ISO 10993-1 ✓ 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 		Item:	Material:	Color:	Housing	PA 6 Akulon + white colorant	White	Filter material	Mesh PA 6.6 (Polyamide 6.6)	Natural
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PRODUCT CHARACTERISTIC	<p data-bbox="339 1816 1559 1906">FD230AAKUN015B02 mesh NY15µm FD230AAKUN025B02 mesh NY25µm FD230AAKUN050B02 mesh NY50µm</p> <p data-bbox="339 1939 1559 2000">External diameter 15,70 mm Total height 3,00 mm</p>										

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STERILIZATION	Ethylene oxide - Gamma 25kGy														
PACKAGING AND LABELLING	<p>50.000 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> <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 S.p.A. consent.</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 border="1"> <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. Missing or incomplete filter mesh. 3. Mesh dirty. 4. Broken filter mesh. 5. Open mesh out of specification. 6. Plastic material on the filter mesh > 0,2 mm. 7. Burrs > 0,15 mm. 8. Jutting injection gate > 0.15 mm. 9. Loose particulate matter > 0,1 mm². </td> <td>0,1</td> <td rowspan="3">ISO 2859 part. 1 1st Level</td> </tr> <tr> <td>2</td> <td> 10. Mold, rust dirty. 11. Double or partially double mesh. 12. Projecting mesh, threads (not detachable). </td> <td>0,65</td> </tr> <tr> <td>3</td> <td> 13. Embedded particulate matter > 0,1 mm². 14. Not uniform coloring. </td> <td>1,5</td> </tr> </tbody> </table> <p>* Embedded Particulate Matter and loose contamination : according to Dirt Estimation Chart (Tappi Standard).</p>	Acceptance Requirement		AQL		1	1. Plastic support not complete. 2. Missing or incomplete filter mesh. 3. Mesh dirty. 4. Broken filter mesh. 5. Open mesh out of specification. 6. Plastic material on the filter mesh > 0,2 mm. 7. Burrs > 0,15 mm. 8. Jutting injection gate > 0.15 mm. 9. Loose particulate matter > 0,1 mm ² .	0,1	ISO 2859 part. 1 1 st Level	2	10. Mold, rust dirty. 11. Double or partially double mesh. 12. Projecting mesh, threads (not detachable).	0,65	3	13. Embedded particulate matter > 0,1 mm ² . 14. Not uniform coloring.	1,5
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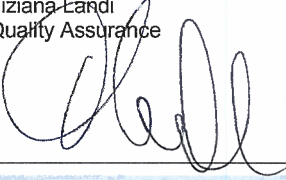
Rev. 02

Description **Disc filter**

PERFORMANCE REQUIREMENTS	Dimensional		AQL	Sampling Plan
	1	External diameter 15.7 mm +/- 0.05 mm (gauge go/no go)	0,1	Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level, single sampling plan, normal inspection
	2	Total height 3.0 mm +/- 0.15 mm (gauge go/no go)		

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)
14/10/2015	02	This revision replaces the previous rev.01. In this rev. 01 it was changed the layout of the module.	Isabella Frignani Quality Assurance Process/Product 	Tiziana Landi 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.