

Product PN **FD142AAKUN015A02**

Mod. 984

Description Disc filter in PA and NY 15 µm - clear

Rev. 02

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



<b>PRODUCT DESCRIPTION</b>	Disc Filter Is a non-sterile filter with mesh NY 15 µm The product is provided in bulk packs for further manufacturing.											
<b>INTENDED USE / APPLICATION</b>	Infusion Disc filter meets the requirements of the ISO 8536-4 "Infusion sets for single use, gravity feed", specifically for the paragraph 6.7											
<b>MANUFACTURER NAME</b>	GVS SUD S.r.l. Via Tavernole n. 8, 83030 Manocalzati (AV) Italy											
<b>MATERIALS</b>	<table border="1" data-bbox="331 1086 1533 1319"> <thead> <tr> <th data-bbox="331 1086 523 1133">Item:</th> <th data-bbox="523 1086 1126 1133">Material:</th> <th data-bbox="1126 1086 1533 1133">Color:</th> </tr> </thead> <tbody> <tr> <td data-bbox="331 1133 523 1227">Housing</td> <td data-bbox="523 1133 1126 1227">PA 6 Akulon</td> <td data-bbox="1126 1133 1533 1227">Natural</td> </tr> <tr> <td data-bbox="331 1227 523 1319">Filter material</td> <td data-bbox="523 1227 1126 1319">* Mesh PA 6.6 (Polyamide 6.6)- 15 µm Open area 10% nominal value</td> <td data-bbox="1126 1227 1533 1319">Natural</td> </tr> </tbody> </table> <p data-bbox="331 1330 1385 1429">* <b>Note:</b> the mesh used (double supplier) only depend on production batches and are not discriminated by the part number, depending on our planning and without any further communication to Customers.</p> <p data-bbox="331 1451 1136 1514"><b>FOR RAW MATERIALS USED TO PRODUCE COMPONENTS</b> based on the available documentation from raw materials suppliers:</p> <p data-bbox="331 1525 657 1554">Regulatory Documentation:</p> <ul data-bbox="427 1570 1152 1753" style="list-style-type: none"> <li>✓ Rohs, directive 2002/95/CE</li> <li>✓ BSE/TSE, directive 2003/32/CE</li> <li>✓ DEHP plasticizer Free</li> <li>✓ Latex free</li> <li>✓ Reach 1907/2006/CE (hazardous substances regulation)</li> <li>✓ Conflict minerals</li> </ul> <p data-bbox="331 1771 1072 1823"><u>raw material mesh:</u> Test performed in compliance with USP class VI and/or ISO 10993-1.</p> <p data-bbox="331 1850 555 1904"><u>raw material granule:</u> Food contact</p>			Item:	Material:	Color:	Housing	PA 6 Akulon	Natural	Filter material	* Mesh PA 6.6 (Polyamide 6.6)- 15 µm Open area 10% nominal value	Natural
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<b>PRODUCT CHARACTERISTIC</b>	External diameter 15,10 mm Internal diameter 11,50 mm Total height 3,50 mm											

# PRODUCT SPECIFICATION

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<b>STERILIZATION</b>	Ethylene oxide - Gamma 25kGy																
<b>PACKAGING AND LABELLING</b>	<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"> <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>																
<b>CERTIFICATE OF COMPLIANCE</b>	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.																
<b>DRAWING</b>	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.																
<b>VISUAL REQUIREMENTS</b>	<p><b>Visual acceptance requirements apply when inspected under below conditions:</b></p> <p>Instrument inspection with naked eye and light source Distance of 300-450 mm. Timings: 5 sec per unit</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #d3d3d3;"> <th style="width: 5%;"></th> <th style="width: 70%;">Acceptance Requirement</th> <th style="width: 10%;">AQL</th> <th style="width: 15%;"></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">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 &gt; 0,2 mm.            7. Burrs &gt; 0,15 mm.            8. Jutting injection gate &gt; 0.15 mm.            9. Loose particulate matter &gt; 0,1 mm<sup>2</sup>.         </td> <td style="text-align: center;">0,1</td> <td rowspan="3" style="text-align: center; vertical-align: middle;">ISO 2859 part. 1 1<sup>st</sup> Level</td> </tr> <tr> <td style="text-align: center;">2</td> <td>           10. Mold, rust dirty.            11. Double or partially double mesh.            12. Projecting mesh, threads (not detachable).         </td> <td style="text-align: center;">0,65</td> </tr> <tr> <td style="text-align: center;">3</td> <td>           13. Embedded particulate matter &gt; 0,1 mm<sup>2</sup>.            14. Not uniform coloring.         </td> <td style="text-align: center;">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 <sup>2</sup> .	0,1	ISO 2859 part. 1 1 <sup>st</sup> 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 <sup>2</sup> . 14. Not uniform coloring.	1,5
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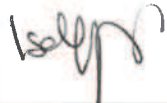
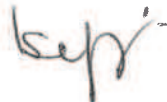
Rev. 02

**PERFORMANCE REQUIREMENTS**

Dimensional /Functional		AQL	Sampling Plan
1	External diameter 15.1 mm +/- 0.08 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 3.5 mm + 0,1 /- 0.2 mm (gauge go/no go)		
3	Mesh Tightness: 8 N force applied for 3 seconds. No mesh damage/ breakage to be observed		

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)
10/11/2017	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 	Isabella Frignani Quality Assurance Process/Product 

**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.