

# PRODUCT SPECIFICATION

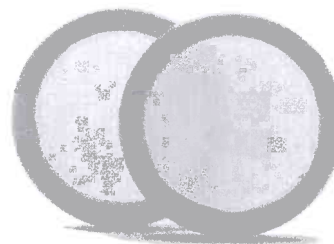
Product PN **FD229AV29N015B01 mesh NY 15µm**

Mod. 984

Rev. 02

Description **Disc filter**

**Disc filter  
for infusion set**



<b>PRODUCT DESCRIPTION</b>	Disc Filter It's a non-sterile filter with a NY 15µm mesh The product is provided in bulk packs for further manufacturing.											
<b>MANUFACTURER NAME</b>	GVS SUD S.r.l. Via Tavernole,8 - 83030 Manocalzati (Avellino) - Italy											
<b>INTENDED USE / APPLICATION</b>	Infusion											
<b>MATERIALS</b>	<table border="1" data-bbox="379 1193 1469 1417"> <thead> <tr> <th data-bbox="387 1193 555 1238">Item:</th> <th data-bbox="563 1193 1098 1238">Material:</th> <th data-bbox="1106 1193 1461 1238">Color:</th> </tr> </thead> <tbody> <tr> <td data-bbox="387 1249 555 1328">Housing</td> <td data-bbox="563 1249 1098 1328">Resin PP Purell + white colorant</td> <td data-bbox="1106 1249 1461 1328">White</td> </tr> <tr> <td data-bbox="387 1339 555 1417">Filter material</td> <td data-bbox="563 1339 1098 1417">Mesh PA 6.6 (Polyamide 6.6)</td> <td data-bbox="1106 1339 1461 1417">Natural</td> </tr> </tbody> </table> <p data-bbox="379 1440 1469 1496"><b>FOR RAW MATERIALS USED TO PRODUCE COMPONENTS</b> based on the available documentation from raw materials suppliers:</p> <p data-bbox="379 1518 1469 1552">Regulatory Documentation:</p> <ul data-bbox="467 1574 1469 1776" style="list-style-type: none"> <li>✓ Biocompatibility according ISO 10993-1</li> <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>			Item:	Material:	Color:	Housing	Resin PP Purell + white colorant	White	Filter material	Mesh PA 6.6 (Polyamide 6.6)	Natural
Item:	Material:	Color:										
Housing	Resin PP Purell + white colorant	White										
Filter material	Mesh PA 6.6 (Polyamide 6.6)	Natural										
<b>PRODUCT CHARACTERISTIC</b>	<p data-bbox="379 1821 1469 1854">Mesh: NY 15µm</p> <p data-bbox="379 1877 1469 1910">Outer diameter: 12.6 mm</p> <p data-bbox="379 1910 1469 1944">Total height: 4.0 mm</p>											

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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>	<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>
<b>DRAWING</b>	<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>



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<b>VISUAL REQUIREMENTS</b>	<p><b>Visual acceptance requirements apply when inspected under below conditions:</b>            Instrument inspection with naked eye and light source            Distance of 300-450 mm.            Timings: 5 sec per unit</p>		
	<b>Acceptance Requirement</b>		<b>AQL</b>
	1	1. Short molding 2. Missing or incomplete mesh 3. Dirty mesh 4. Broken mesh 5. Mesh opening out of specification. 6. Plastic infiltration on mesh > 0.2 mm. 7. Burrs > 0.15 mm. 8. Gate scar > 0.15 mm 9. Loose particles/contamination > 0.1 mm <sup>2</sup>	0.1
	2	10. Mold, rust dirt 11. Double or partially double mesh. 12. Mesh / threads protruding from plastic frame (not detachable).	0.65
3	13. Embedded particles/contamination > 0.1 mm <sup>2</sup> 14. Color uneven	1.5	
<p>* Embedded and loose particles/contamination: according to Dirt Estimation Chart (Tappi Standard).</p>			
<b>PERFORMANCE REQUIREMENTS</b>	<b>Dimensional / Functional</b>		<b>AQL</b>
	1	Outer diameter: 12.6 mm +/- 0.1 mm (go/no go gage)	0.1
	2	Total height: 4.0 mm +0.1/- 0.2 mm (go/no go gage)	
	3	Mesh Tightness: 8 N force applied for 3 seconds. No mesh damage/ breakage to be observed.	
<p>ISO 2859 part. 1 S3 Special inspection level, single sampling plan, normal inspection</p>			

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This material specification describes the properties of product above indicated.  
 This document contains general requirements, material description, drawing references, defect specification, biological material requirements.



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## REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
22/09/2016	00	First Issue	Raffaele Caserta Quality Assurance <i>Raffaele Caserta</i>	Raffaele Caserta Quality Assurance <i>Raffaele Caserta</i>

## 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.*