

Product PN **FI081AAKUN040A00**

Mod. 984

Rev. 02

Description Tubular filter Ny 40µm

**Tubular filter in PA  
with mesh Ny 40µm - clear**



<b>PRODUCT DESCRIPTION</b>	Tubular filter Is a non-sterile tubular filter with mesh 40µm The product is provided in bulk packs for further manufacturing
<b>MANUFACTURER NAME</b>	GVS Sud S.r.l. Via Tavernole, 8 83030 Manocalzati (AV) – ITALY
<b>INTENDED USE / APPLICATION</b>	Transfusion
<b>MATERIALS</b>	<p><b>Mesh:</b> PA 6.6. Monofilament (medical) <b>Housing:</b> Pa Akulon K-222-D clear</p> <p><b>Regulatory Documentation:</b> <u>MESH</u> -Test performed in compliance with USP class VI and/or ISO 10993-1. -DEHP free -Latex free -BSE/TSE free</p> <p><u>HOUSING</u> -DEHP product may contain chemical substances at very low levels (less than 10 ppm) -Latex free -Food Contact Declaration USA- -Food Contact Declaration EUROPE -Test performed in compliance with USP class VI and/or ISO 10993-1. -BSE/TSE According to the recipe in the production of Akulon® K222-D (natural) Substance of animal origin. is intentionally used or added: The chemical composition of Akulon® K222-D (natural) complies with the EC Commission Decision 2000/418/EC of 29 June 2000 (including 2001/2/EC), Directive 2000/6/EC of 29 February 2000 and the "Note for Guidance on minimizing the risk of transmitting Animal Spongiform Encephalopathy", EMEA 410/01 of October 2003 concerning BSE.</p>
<b>PRODUCT CHARACTERISTIC</b>	<p>Total length 52,30 +/- 0,15 mm External ring diameter 16,26 +/- 0,10 mm Height ring diameter 4,00 +/- 0,05 mm Internal ring diameter 11,95 + 0 - 0,20 mm</p>
<b>STERILIZATION</b>	Ethylene oxide

# PRODUCT SPECIFICATION

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### PACKAGING AND LABELLING

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.

Each bag is labeled with the following traceability information:

- Quantity
- Product description
- Product date
- Lot number (OL and batch number to trace back to raw materials used)
- Operator code

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.

### CERTIFICATE OF COMPLIANCE

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.

### DRAWING

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.

### VISUAL REQUIREMENTS

**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

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 <sup>2</sup>	0,1	Sampling plan according to ISO 2859 part. 1 – 1 <sup>st</sup> General inspection Levels
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 <sup>2</sup> . 12. Plastic material on the filter mesh > 3,5mm. 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 <sup>2</sup>	1,5	

\*Embedded Particulate Matter, loose contamination and air bubbles : according to Dirt Estimation Chart (Tappi Standard).

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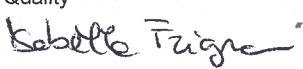

## PERFORMANCE REQUIREMENTS

Dimensional		AQL	Sampling Plan
1	External ring diameter	0,1	Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level.
2	Internal ring diameter	0,1	
3	Total length	0,1	
4	Height ring	0,1	

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)
15/03/2016	00	First immission	Isabella Frignani Process and Product Assurance Quality 	Tiziana Landi Assurance Quality 

## 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.