

Product PN **FI644PPNY263**

Mod. 984

Rev. 02

Description Tubular filter FI644 in PP and NY 263 micron - clear

**Tubular filter FI644 in PP
NY 263 micron - clear**



| | |
|-----------------------------------|---|
| PRODUCT DESCRIPTION | Tubular filter Is a non-sterile tubular filter with mesh 263 µm The product is provided in bulk packs for further manufacturing |
| MANUFACTURER NAME | GVS Sud S.r.l. Via Tavernole, 8 83030 Manocalzati (AV) – ITALY |
| INTENDED USE / APPLICATION | Transfusion |
| MATERIALS | <p>Mesh: PA 6.6. Polyamide Monofilament Nylon mesh 263 µm Housing: Polipropilene Purell HP371P natural</p> <p>Regulatory Documentation:</p> <p><u>MESH</u></p> <ul style="list-style-type: none"> - Test performed in compliance with USP class VI and/or ISO 10993-1. - DEHP free - Latex free - BSE/TSE free - Reach 1907/2006/CE (hazardous substances regulation): conforming - Conflict minerals: conforming <p><u>HOUSING</u></p> <ul style="list-style-type: none"> - DEHP free - Latex free - Reach 1907/2006/CE (hazardous substances regulation): conforming - Conflict minerals: conforming - Food Contact Declaration USA - Food Contact Declaration EUROPE - Test performed in compliance with USP class VI and/or ISO 10993-1. - BSE/TSE tallow derivatives used in this raw material fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3". |
| PRODUCT CHARACTERISTIC | <p>Total length 62,10 +/- 0,40 mm External ring diameter 17,25 +/- 0,10 mm Height ring diameter 7,90 +/- 0,10 mm Internal ring diameter 14,30 +/- 0,10 mm</p> |
| STERILIZATION | Ethylene oxide |

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PACKAGING AND LABELLING

8.000 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 ² | 0,1 | Sampling plan according to ISO 2859 part. 1 – 1 st 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 ² . 12. Plastic material on the filter mesh > 2 nd . 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 ² | 1,5 | |

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

PRODUCT SPECIFICATION

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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) |
|------------|------|---|---|---|
| 30/06/2017 | 04 | In this rev. 04 it was corrected the description of the raw materials | 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.