# PRODUCT SPECIFICATION

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|---|---|---|
| **Product PN** | **FI148AV29N200A00** | **Mod. 984 c** |
| **Description** | **Tubular Filter with PP frame and NY mesh 200 um** | **Rev. 03** |

## Tubular filter
## PP frame + 200 um PA mesh

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| **PRODUCT DESCRIPTION** | Non-sterile tubular filter with mesh Ny 200µm<br>Product provided in bulk packs for further manufacturing |
| **INTENDED USE / APPLICATION** | Transfusion |
| **MATERIALS** | **Mesh**: Polyamide 200 um<br>**Housing**: Polypropylene<br><br>**Regulatory Documentation Required:**<br>☑ Biocompatibility according USP VI<br>☑ Rohs, directive 2002/95/CE<br>☑ BSE/TSE, directive 2003/32/CE<br>☑ DEHP plasticizer Free and latex free<br>☑ Reach 1907/2006/CE (hazardous substances regulation)<br>☑ Conflict minerals |
| **PRODUCT SHELF LIFE** | 5 years |
| **STERILIZATION** | **STERILE :** ☐ Yes ☑ No<br><br>**SUITABLE FOR STERILIZATION : :** ☑ Ethylene oxide |
| **PACKAGING AND LABELLING** | 8.000 pcs packed in two PE bags. Bags are separately closed.<br><br>The first bar-code label is between the 2 bags.<br>The second bar-code label is stuck outside the box.<br><br>Each bag is labeled with the following traceability information:<br>- Quantity<br>- Product description<br>- Product date<br>- Lot number (OL and batch number to trace back to raw materials used)<br>- Operator code<br>Different lot of goods in one shipment are packed in a manner to prevent mix-ups.<br>Different lots in one box are separately closed and separately labeled to prevent mix-ups. |

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| **CERTIFICATE OF COMPLIANCE** | Conformity declaration is printed on every invoice and Certificate is according to UNI EN 10204 type 2.1<br>The Quality management system in compliance with ISO 9001, ISO 13485. |
| **ACCEPTABLE QUALITY LEVEL** | AQL (see table below) |
| **VISUAL REQUIREMENTS** | ***Visual acceptance requirements apply when inspected under below conditions:***<br><br>Instrument inspection with naked eye and light source<br>Distance of 300-450 mm. Timings: 5 sec per unit |

| | Acceptance Requirement | AQL | Sampling Plan |
|---|---|---|---|
| 1 | 1. Short molding<br>2. Mesh threads protruding from plastic ring (filter top area)<br>3. Short mesh, detached from the plastic support.<br>4. Broken mesh<br>5. Open mesh out of specification (uneven mesh).<br>6. Missing mesh | 0.4 | ISO 2859 part. 1<br>1st Level |
| 2 | 7. Mesh protruding out of the rib<br>8. Mesh welding out of the rib<br>9. Flashes > 0.3 mm.<br>10. Gate scar > 0.3 mm.<br>11. Loose particulate matter > 0.1 $mm^2$<br>12. Plastic infiltration on filter mesh > 2nd mesh opening<br>13. Dents/Scratches with plastic residual<br>14. Shrinkage on plastic ring (filter top area)<br>15. Burning marks<br>16. Dirty of oil, grease<br>17. Embedded particulate matter > 0.2 $mm^2$ | 1.5 | |

*Embedded Particulate Matter, loose contamination and air bubbles: according to Dirt Estimation Chart (Tappi Standard).
Characteristics listed above are statistically inspected during the manufacturing process.

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**DIMENSIONAL REQUIREMENTS**

| Acceptance Requirement | | | AQL | Sampling Plan |
|---|---|---|---|---|
| | Total height | 40.85 ± 0.15 mm | 0,1 | ISO 2859 part. 1 S3 Special Inspection Levels |
| | External diameter | 15 ± 0.15 mm | | |
| | Base height | 4 ± 0.10 mm | | |

**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) |
|---|---|---|---|---|
| 20/05/2019 | 00 | Validation of GVS Microfiltration | Paolo Carati (RP)<br>*Paolo Carati* | Sara Zaccheroni (AQ)<br>*Sara Zaccheroni* |

## *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.*