



PRODUCT SPECIFICATION

Product PN	FI231ACOLP200A00	Mod. 984
Description	Tubular filter with mesh PE 200µm - DEHP FREE	Rev. 00

**Tubular filter DEHP FREE
with
mesh PE 200µm**



PART DESCRIPTION	<p>Tubular filter</p> <p>Is a non-sterile tubular filter with mesh 200µm The product is provided in bulk packs for further manufacturing</p>
MATERIALS	<p>Mesh: Polyester medical : PES 200µm Housing: PVC soft medical 7877BG-015 DEHP FREE (plasticizer TOTM)</p>
PRODUCT CHARACTERISTICS	<p>Weight : 1,42gr Total Height: 28,5mm</p>
STERILIZATION	<p>Ethylene oxide – Gamma</p>
BIOLOGICAL REQUIREMENTS	<p>FOR RAW MATERIALS USED TO PRODUCE COMPONENTS based on the available documentation from raw materials suppliers:</p> <p><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> - Latex free - BPA free - Heavy Metals compound does not contains - Conform to the declaration concerning RoHS (2011/65/EU) - DEHP are no be present at a concentration of greater than 0.1%. - BSE/TSE a tiny part of total formulation contains substances derived from tallow, but in conformity with the norms.</p>



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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 7. Total mismatch of parting lines: > 0,2mm	0,1	ISO 2859 part. 1 1 st Level
2	8. Mesh jutting out of the rib 9. Weld of filter tube out of the rib 10. Burrs > 0,3 mm 11. Jutting injection gate >0.3mm 12. Loose particulate matter > 0,1 mm ² 13. Plastic material on the filter mesh > 3mm 14. Dents/Scratches with plastic residual	0,65	
3	15. Not detachable filter mesh threads 16. Dirty of oil, grease 17. Embedded particulate matter > 0,2 mm ²	1,5	

* Embedded Particulate Matter: according to Dirt Estimation Chart (Tappi Standard).



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PERFORMANCE REQUIREMENTS

Dimensional		AQL	Sampling Plan
1	External ring diameter of assembling	0,1	ISO 2859 part. 1 1st Level
2	External ring diameter	0,1	
3	Total length	0,1	
4	Thickness of assembling 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.

REVISIONI / REVISIONS:

DATA /DATE	REV.	MODIFICA DA PRECEDENTE REVISIONE/ REASON FOR CHANGE	MODIFICATO DA / CHANGED BY (name /function and signature)	APPROVATO DA/APPROVED BY (name /function and signature)
10/02/2015	03	This revision replaces the previous rev.02. In this rev. 3 it was changed: - the layout of the module - added defect n.7	Isabella Frignani Process Quality Assurance 	Isabella Frignani Process Quality Assurance 

Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Date _____ Signature _____
(Company, Name, Function, Signature)

(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.