PRODUCT SPECIFICATION

Product PN	**FI111CAKUN040A00**	**Mod. 984 c**
Description	**Tubular Filter with ABS frame and NY mesh 200 um**	**Rev. 03**

Tubular filter
PA 6,6 frame + 200 um PA mesh

PRODUCT DESCRIPTION	Non-sterile tubular filter with mesh Ny 40µm Product provided in bulk packs for further manufacturing
INTENDED USE / APPLICATION	Transfusion
MATERIALS	**Mesh**: Polyamide 200 um **Housing**: ABS TERLUX 6,6 **Regulatory Documentation Required:** ☑ Biocompatibility according USP VI ☑ Rohs, directive 2002/95/CE ☑ BSE/TSE, directive 2003/32/CE ☑ DEHP plasticizer Free and latex free ☑ Reach 1907/2006/CE (hazardous substances regulation) ☑ Conflict minerals
PRODUCT SHELF LIFE	5 years
STERILIZATION	**STERILE :** ☐ Yes ☑ No **SUITABLE FOR STERILIZATION : :** ☑ Ethylene oxide
PACKAGING AND LABELLING	5.000 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.

PRODUCT SPECIFICATION

Product PN	**FI111CAKUN040A00**	**Mod. 984 c**
Description	**Tubular Filter with ABS frame and NY mesh 200 um**	**Rev. 03**

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 in compliance with ISO 9001.
ACCEPTABLE QUALITY LEVEL	AQL (see table below)
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	Sampling Plan
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	ISO 2859 part. 1 1st 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 > 0,5 mm 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).
Characteristics listed above are statistically inspected during the manufacturing process.

PRODUCT SPECIFICATION

Product PN	**FI111CAKUN040A00**	**Mod. 984 c**
Description	**Tubular Filter with ABS frame and NY mesh 200 um**	**Rev. 03**

DIMENSIONAL REQUIREMENTS

Acceptance Requirement			AQL	Sampling Plan
	External diameter	15.7 +0.05 -0.10 mm	0,1	ISO 2859 part. 1 S3 Special Inspection Levels
	Base height	3.5 + 0 -0.1 mm		
	Internal diameter	11.95 ± 0.2 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)
07/05/2019	00	Validation of GVS Microfiltration	P. Carati (PM)	Sara Zaccheroni (AQ)

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.