PRODUCT SPECIFICATION

Product PN **FI118TERNY263** **Mod. 984** **Rev. 02**

Description Tubular filter FI118 in ABS and NY 263 µm - clear

Tubular filter FI89 in ABS NY 263 micron - clear

PRODUCT DESCRIPTION	Tubolar filter Is a non-sterile tubolar 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	**Mesh**: PA 6.6. Polyamide Monofilament (medical) **Housing:** ABS Terlux 2812 HD clear **Regulatory Documentation:** MESH - 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 HOUSING - DEHP free - Latex free −Reach 1907/2006/CE (hazardous substances regulation): conforming - Conflict minerals: conforming - BSE/TSE. Conforming **Terlux® 2812 HD is in compliance with Pharmacopoeia and Biocompatibility-Tests in Europe an United States as specified below.** However, the biocompatibility tests were recorded on tests specimens of Terlux® 2812 HD to show compatibility of the material in general. The biocompatibility-tests listed below are not part of any continuous production control. **European Pharmacopoeia:** The composition of the product complies with the requirements of the European Pharmacopoeia 5th Edition, Chap. 3.2.2. "Plastic Containers and Closures". **US Pharmacopoeia** **Biological Reactivity Tests**, USP Plastic Class VI (USP VI) **ISO 10993-5** **Biological Evaluation of Medical Devices** Part 5: Test for Cytotoxicity **DMF:** A Drug Master File (DMF) has been registered at FDA for Terlux® 2812 HD. The assigned DMF Number is 20017.

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PRODUCT CHARACTERISTIC	Total length 24,40 +/- 0,15 mm External ring diameter 16,25 +/- 0,10 mm Internal ring diameter 11,95 +/- 0,20 mm
STERILIZATION	Ethylene oxide
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^2	0,1	Sampling plan according to 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 > 2nd . 13. Dents/Scratches with plastic residual	0,65	
	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).

GVS
FILTER TECHNOLOGY

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PERFORMANCE REQUIREMENTS

Dimensional			AQL	Sampling Plan
1	External ring diameter	16,25 +/- 0,10 mm	0,1	Sampling plan according to ISO 2859 part. 1 – S3 Special inspection level.
2	Thickness of assembling ring	4 +/- 0,05 mm		
3	Total length	24,40 +/- 0,15 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)
09/11/2017	03	This revision replaces the previous rev.02. In this rev. 3 it was changed the layout of the module.	Isabella Frignani Assurance Quality Process and Product	Isabella Frignani Assurance Quality Process and Product

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.