

Product PN	FM134AEPTN080A00 mesh NY 80 µm	Mod. 984
Description	DISC FILTER	Rev. 02

Disc Filter



PRODUCT DESCRIPTION	Disc Filter It's a non-sterile filter with a NY 80 µm mesh. The product is provided in bulk packs for further manufacturing.
INTENDED USE / APPLICATION	Infusion
MATERIALS	<p>Filter :</p> <ol style="list-style-type: none"> Filter Media : Nylon net 80 µm mesh Color : Natural Frame/Housing Polymer: Polypropylene Moplen EP300K Color : Natural <p>Regulatory Documentation Required Granule:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> RoHS, directive 2002/95/CE <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input checked="" type="checkbox"/> DEHP plasticizer Free <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input checked="" type="checkbox"/> Conflict minerals <input checked="" type="checkbox"/> Latex free <p>Regulatory Documentation Required Mesh:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> RoHS, directive 2002/95/CE <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input checked="" type="checkbox"/> DEHP plasticizer Free <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input checked="" type="checkbox"/> Conflict minerals <input checked="" type="checkbox"/> Latex free <p>Other <input type="checkbox"/> N/A <input type="checkbox"/> Specify:</p>
PRODUCT CHARACTERISTIC	<p>External Diameter 32,1 mm</p> <p>Filter Height 2,5 mm</p> <p>Total Weight 0,53 g</p>

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APPLICABLE STANDARDS AND REGULATIONS	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
PACKAGING AND LABELLING	10000 pcs packed in two PE begs 60 x 25 + 25 x 90 . Bags are separately closed. The first bar-code label is between the 2 bags. The second bar-code label is stuck outside the box.
CERTIFICATE OF COMPLIANCE	With each shipment, GVS SpA Customer Service will send the CoC to the Customer, based on the lot numbers and date of manufacture. 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 9001:2000, ISO 13485:2003.
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 SpA permission.
STERILIZATION	<input checked="" type="checkbox"/> EtO

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VISUAL REQUIREMENTS

Sampling plan according to ISO 2859 part. 1 – 1st Level inspection, single sampling plan, normal inspection.
Embedded Particulate Matter: according to Dirt Estimation Chart.

Visual acceptance requirements apply when inspected under below conditions:

Illumination: 1000 ± 200 lx or equivalent

Light type: Fluorescent

Magnification: unaided eye, approximately at a distance of 300-450 mm from eye.

Timing: visual for 5 sec. per unit.

Acceptance Requirement		AQL	Sampling Plan
1	Incomplete support	0.15	ISO 2859 part. 1 – 1 st Level inspection, single sampling plan, normal inspection
2	Shrinkages of material	0.15	
3	Incomplete, misplaced, missing or partially missing mesh	0.15	
4	Partially incomplete mesh (cutting not conform)	0.15	
5	Broken mesh	0.15	
6	Incorrectly positioned mesh	0.15	
7	Mesh dirty	0.15	
8	Mesh not embedded, detached	0.15	
9	Open mesh out of specification (weaving not uniform)	0.15	
10	Dent	0.15	
11	Double mesh	0.15	
12	Surmounted or folded mesh	0.15	
13	Plastic residual on the mesh	0.65	
14	Plastic material on the filter mesh > 2nd mesh opening	0.65	
15	Loose particulate matter	0.65	
16	Radial burrs > 0.2 mm	0.65	
17	Axial burrs > 0.2 mm	0.65	
18	Jutting injection gate > 0.2 mm	0.65	
19	Threads	0.65	
20	Dirty of oil, grease	0.65	
21	Rust, mold dirty	0.65	
22	Embedded particulate matter > 0.2 mm ²	0.65	
23	Colour not uniform	0.65	
24	Embedded particulate matter =< 0.2 mm ² (max 3 spot for checked area)	1.5	
25	Protruding Mesh> 1,5 mm	0.65	
26	Smash Mesh	0.15	
27	Double Mesh	0.15	
28	Burr caused by bush planted	0.15	

PERFORMANCE REQUIREMENTS

Acceptance Requirement		AQL	Sampling Plan
1	External diameter	0.15	ISO 2859 part. 1 Level S 2
2	Total height	0.15	



This material specification describes the properties of product above indicated.

This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
30/10/2017	00	First Emission – PJ534	Domenico Romondia / RP 	Isabella Frignani / AQP 

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.