MEMBRANE SPECIFICATION

Product PN M09G0100HxxxxE *

Mod. 984 d

Description HYDROPHOBIC, HAEMOREPELLENT 1.0 µm FORTEX MEMBRANE

Rev. 04

HYDROPHOBIC AND HAEMOREPELLENT 1.0 µm PVDF FORTEX MEMBRANES

PRODUCT DESCRIPTION	PVDF hydrophobic and haemorepellent 1.0 µm membranes cast on a nonwoven polyester support. Two-sided. Provided in rolls of different widths.
APPLICATIONS	The product is ideal for venting in medical applications.
MATERIALS COMPONENTS	Polymer: PVDF homopolymer Support: Polyester non-woven Others: Haemorepellent treatment

PRODUCT CHARACTERISTICS

Appearance/Visual:

White porous ribbons

Dimensional:

Standard Product code	Width*	Thickness	Max roll diameter	Standard length	Min length roll	Max length roll	Internal core diameter
M09G0100H0254E	25.4 mm	150 – 200 µm	220 mm	125 m	90 m	180 m	76 ± 0.8 mm
M09G0100H0340E	34.0 mm						
M09G0100H0381E	38.1 mm						
M09G0100H0787E	78.7 mm						
M09G0100H1524E	152.4 mm						
M09G0100H2540E	254.0 mm						
M09G0100H3048E	304.8 mm						
M09G0100H3302E	330.2 mm						
M09G0010H4500E	450.0 mm						

For other available widths, please contact the sales representative of your country.
The following product specification is valid also for other part numbers M09G0100**xxxx**E that do not appear in the table above.

* For width ≤ 15.5 mm : Tolerance ± 0.2 mm
  For width > 15.5 mm : Tolerance ± 0.8 mm

*** M09G0100HxxxxE, where xxxx is the width of the roll. For instance xxxx=3302 means 330.2 mm**

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Biological:

Test	Standards/ procedures of ref	Result
Bacteria filtration efficiency test (BFE) using *Staphylococcus aureus*	ASTM F2101	99%
Chemical toxicity and solvent detection	UNI EN ISO 1135-4 (Annex B) UNI EN ISO 8536-4 (Annex B)	Non toxic
Cytotoxicity-MEM elution in vitro	UNI EN ISO 10993-5 (Annex C)	Non cytototxic
Intracutaneous reactivity test	UNI EN ISO 10993-10	Non-irritant
Delayed hipersensitivity test (Guinea-pig maximization test - GPMT)	UNI EN ISO 10993-10	0% Sensitization
Acute systemic toxicity	UNI EN ISO 10993-11	Non-toxic/non-irritant
In vitro haemolysis test	UNI EN ISO 10993-4 according to Italian Pharmacopoeia	Non hemolytic
Haemocompatibility	UNI EN ISO 10993-4	Hemocompatible

Regulatory Documentation
Reg. 1907/2006/EC (REACH)
Directive 2011/65/EU (RoHS)
BPA, DEHP and Latex free
Directive 2003/32/EC (TSE-BSE)
UNI EN ISO 10993-1 (Biocompatibility)
Directive 67/546/EC and Reg.1272/2008/EC (Medical sector dangerous substances)

Physical:

Test		Result
Air Flow GVS Internal	GVS internal procedure IC303	AF ≥ 17.5 l/min on 1 cm² at 1 bar
Water Break Through	GVS internal procedure IC305	≥ 0.5 bar
Haemorepellency	GVS internal procedure IC660	Yes
Oleorepellency grade	AATCC 118-2002	≥ 3.5
Hydrorepellency grade	DuPont Teflon test	≥ 9.5

STERILIZATION COMPATIBILITY

The product is NOT provided in sterile conditions (compatible sterilization method listed below)

	Method
☑	ETO
☑	Gamma (25 kGy)
☑	Autoclave (121°C)

PRODUCT SHELF LIFE

5 years

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STORAGE	Keep the product in a closed and clean environment, away from direct light and excessive temperature and humidity conditions
PACKAGING AND LABELLING	Each roll is individually packed in a thermo-welded PE bag identified with a barcode label. A second PE bag collects all rolls with the same lot in a cardboard box. Another barcode label is applied outside the box, with reference to the cumulative quantity. Each label reports the following traceability information: - Quantity - Product description - Product date and time - Lot number (OL and 6 digits batch number to trace back to raw materials used) - Operator code An image of a barcode label is provided below as an example. 
CERTIFICATE OF COMPLIANCE	Conformity declaration is printed on every invoice with a statement according to UNI EN 10204 type 2.1. The Quality management system in compliance with ISO 9001.
VISUAL REQUIREMENTS	Visual acceptance requirements apply when inspected under below conditions: Light type: unaided eye + lamp Distance: 30 – 45 cm Timings: 5 sec per unit

	Acceptance Requirement	AQL	Sampling Plan
1	Embedded contaminations	For width≤ 20mm ->Max 2/lm For 20 mm <width≤ 60mm -> Max 5/lm For 60 mm < width ≤ 130mm ->Max 10/lm For 130 mm < width≤ 450mm ->Max 20/lm	First 3 linear meters of rolls sampled according ISO 2859 part. 1 1st Level
2	Loose contaminations		
3	Grease, stains	0 defects	
4	Splices/cross-tape for each rolls	Max 7	

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FILTER TECHNOLOGY

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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*	PREPARED BY: (name /function and signature)	CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
17/10/2019	01	New release	Brunella Merante/ R&D	Annarita Trotta/AQP	Luca Querzè/RPT

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.

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