

Product PN **M09G0020HxxxxE \***

Mod. 984 d

Description **HYDROPHOBIC, HAEMOREPELLENT 0.2 µm FORTEX MEMBRANE**

Rev. 04

## HYDROPHOBIC AND HAEMOREPELLENT 0.2 µm PVDF FORTEX MEMBRANES



<b>PRODUCT DESCRIPTION</b>	PVDF hydrophobic and haemorepellent 0.2 µm membranes cast on a nonwoven polyester support. Two-sided. Provided in rolls of different widths.		
<b>APPLICATIONS</b>	The product is ideal for venting in medical applications.		
<b>MATERIALS COMPONENTS</b>	<b>Polymer:</b>	PVDF homopolymer	
	<b>Support:</b>	Polyester non-woven	
	<b>Others</b>	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
M09G0020H0254E	25.4 mm	150 – 200 µm	220 mm	125 m	90 m	180 m	76 ± 0.8 mm
M09G0020H0340E	34.0 mm						
M09G0020H0381E	38.1 mm						
M09G0020H0787E	78.7 mm						
M09G0020H1524E	152.4 mm						
M09G0020H2540E	254.0 mm						
M09G0020H3048E	304.8 mm						
M09G0020H3302E	330.2 mm						
M09G0020H4500E	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 M09G0020xxxxE 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

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	<b>Biological:</b>		
	<b>Test</b>	<b>Standards/ procedures of ref</b>	<b>Result</b>
	Bacteria filtration efficiency test (BFE) using <i>Staphylococcus aureus</i>	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 cytotoxic
	Intracutaneous reactivity test	UNI EN ISO 10993-10	Non-irritant
	Delayed hypersensitivity 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
	<b>Regulatory Documentation</b>		
	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)			
	<b>Physical:</b>		
	<b>Test</b>	<b>Result</b>	
	Air Flow GVS Internal GVS internal procedure IC303	AF ≥ 1.35 l/min on 1 cm <sup>2</sup> at 1 bar	
	Water Break Through GVS internal procedure IC305	≥ 1.8 bar	
	Haemorepellency GVS internal procedure IC660	Yes	
	Oleorepellency grade AATCC 118-2002	≥ 3.5	
Hydrorepellency grade DuPont Teflon test	≥ 9.5		
<b>STERILIZATION COMPATIBILITY</b>	The product is NOT provided in sterile conditions (compatible sterilization method listed below)		
	<input type="checkbox"/>	<b>Method</b>	
	<input checked="" type="checkbox"/>	ETO	
	<input checked="" type="checkbox"/>	Gamma (25 kGy)	
	<input checked="" type="checkbox"/>	Autoclave (121°C)	
<b>PRODUCT SHELF LIFE</b>	5 years		

\* M09G0020HxxxxE, where xxxx is the width of the roll. For instance xxxx=3302 means 330.2 mm

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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	<p>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:</p> <ul style="list-style-type: none"> <li>- Quantity</li> <li>- Product description</li> <li>- Product date and time</li> <li>- Lot number (OL and 6 digits batch number to trace back to raw materials used)</li> <li>- Operator code</li> </ul> <p>An image of a barcode label is provided below as an example.</p> <div style="text-align: center;"> </div>												
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	<p>Visual acceptance requirements apply when inspected under below conditions:          Light type: unaided eye + lamp          Distance: 30 – 45 cm          Timings: 5 sec per unit</p> <table border="1" data-bbox="343 1489 1508 1881"> <thead> <tr> <th>Acceptance Requirement</th> <th>AQL</th> <th>Sampling Plan</th> </tr> </thead> <tbody> <tr> <td>1 Embedded contaminations</td> <td>For width ≤ 20mm -&gt;Max 2/lm For 20 mm &lt; width ≤ 60mm -&gt; Max 5/lm</td> <td rowspan="4">First 3 linear meters of rolls sampled according ISO 2859 part. 1 1<sup>st</sup> Level</td> </tr> <tr> <td>2 Loose contaminations</td> <td>For 60 mm &lt; width ≤ 130mm -&gt;Max 10/lm For 130 mm &lt; width ≤ 450mm -&gt;Max 20/lm</td> </tr> <tr> <td>3 Grease, stains</td> <td>0 defects</td> </tr> <tr> <td>4 Splices/cross-tape for each rolls</td> <td>Max 7</td> </tr> </tbody> </table>	Acceptance Requirement	AQL	Sampling Plan	1 Embedded contaminations	For width ≤ 20mm ->Max 2/lm For 20 mm < width ≤ 60mm -> Max 5/lm	First 3 linear meters of rolls sampled according ISO 2859 part. 1 1 <sup>st</sup> Level	2 Loose contaminations	For 60 mm < width ≤ 130mm ->Max 10/lm For 130 mm < width ≤ 450mm ->Max 20/lm	3 Grease, stains	0 defects	4 Splices/cross-tape for each rolls	Max 7
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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.

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## 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)
19/05/2015	04	This specification is extended to all the heights available for the rolls and replaces previous rev.03 for M09G0020H0155E and rev.02 for M09G0020H0206E. Thickness of the membrane was also updated.	Sara Zaccheroni/AQP	Rinaldi Davide/ RIM	Luca Querzè/RPT
19/10/2015	05	Specified Fortex trade name in the description, membrane reversibility and layout updates.	Sara Zaccheroni/AQP	Rinaldi Davide/ RIM	Luca Querzè/RPT
01/08/2016	06	Added new widths and updated layout	Sara Zaccheroni/AQP	Rinaldi Davide/ RIM	Luca Querzè/RPT
21/08/2017	07	Returned to the original AF values range of 1,3 ÷ 5,2 l/min, on 1 cm <sup>2</sup> at 1 bar; excluded to this specification the PN M09G0020H0155E	Sara Zaccheroni/AQP	Rinaldi Davide/ RIM	Luca Querzè/RPT
17/10/2019	08	Modified the widths and updated parameters	Brunella Merante/ R&D <i>Brunella Merante</i>	Annarita Trotta/AQP <i>Annarita Trotta</i>	Luca Querzè/RPT <i>Luca Querzè</i>

### 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.