# MEMBRANE SPECIFICATION

**Product PN** M09G0045HxxxxE *

**Description** HYDROPHOBIC, HAEMOREPELLENT 0.45 µm FORTEX MEMBRANE

Mod. 984 d

Rev. 04

## HYDROPHOBIC AND HAEMOREPELLENT 0.45 µm PVDF FORTEX MEMBRANES

| | |
|---|---|
| PRODUCT DESCRIPTION | PVDF hydrophobic and haemorepellent 0.45 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<br>Support: Polyester non-woven<br>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 |
|---|---|---|---|---|---|---|---|
| M09G0045H0254E | 25.4 mm | 150 – 200 µm | 220 mm | 125 m | 90 m | 180 m | 76 ± 0.8 mm |
| M09G0045H0340E | 34.0 mm | | | | | | |
| M09G0045H0381E | 38.1 mm | | | | | | |
| M09G0045H0787E | 78.7 mm | | | | | | |
| M09G0045H1524E | 152.4 mm | | | | | | |
| M09G0045H2540E | 254.0 mm | | | | | | |
| M09G0045H3048E | 304.8 mm | | | | | | |
| M09G0045H3302E | 330.2 mm | | | | | | |
| M09G0045H4500E | 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 M09G0045**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



* M09G0045HxxxxE, 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)<br>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 | Haemocompatible |

| 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 ≥ 4.5 l/min on 1 cm² at 1 bar |
| Water Break Through | GVS internal procedure IC305 | ≥ 1 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

**STORAGE**

Keep the product in a closed and clean environment, away from direct light and excessive temperature and humidity conditions



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# MEMBRANE SPECIFICATION

FILTER TECHNOLOGY

**Product PN** **M09G0045HxxxxE *** Mod. 984 d

**Description** **HYDROPHOBIC, HAEMOREPELLENT 0.45 µm FORTEX MEMBRANE** Rev. 04

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

| | Acceptance Requirement | AQL | Sampling Plan |
|---|---|---|---|
| 1 | Embedded contaminations | For width≤ 20mm ->Max 2/lm<br>For 20 mm <width≤ 60mm -> Max 5/lm | First 3 linear meters of rolls sampled according ISO 2859 part. 1 1st Level |
| 2 | Loose contaminations | For 60 mm < width ≤ 130mm ->Max 10/lm<br>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.

**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) |
|---|---|---|---|---|---|
| 29/06/2015 | 01 | Added specifications for new Fortex M09G0045H1400E membrane | Sara Zaccheroni/AQP | Rinaldi Davide/RIM | Luca Querzè/RPT |
| 17/12/2015 | 02 | Alignment to other specs | Sara Zaccheroni/AQP | Rinaldi Davide/ RIM | Luca Querzè/RPT |
| 01/08/2016 | 03 | Added new widths and updated layout | Sara Zaccheroni/AQP | Rinaldi Davide/ RIM | Luca Querzè/RPT |
| 17/10/2019 | 04 | Modified the widths and updated parameters | 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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