

Product PN 3032875, 3032876, 3029505, 3018505, 1239465, 1235748, 3057106

Mod. 984

Description 0.03 µm Polyethersulfone Filtration Membrane Discs and Sheets

Rev. 01

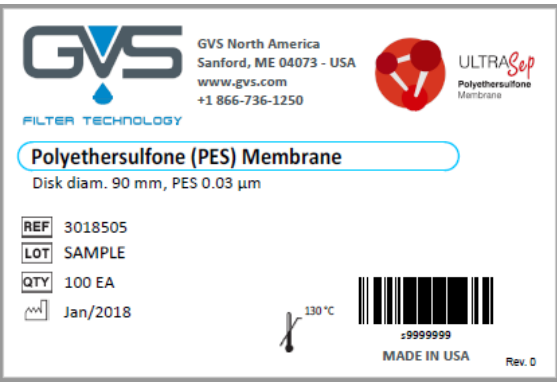
0.03 µm Polyethersulfone (PES) Filtration Membrane in Discs and Sheets



PRODUCT DESCRIPTION	0.03 µm PES Discs and Sheets			
	Part Number	Geometry	Dimensions	Packaging
	3032875	Disc	13 mm	100/Pk
	3032876	Disc	25 mm	100/Pk
	3029505	Disc	47mm	100/Pk
	3018505	Disc	90 mm	25/pk
	1239465	Sheet	150 x 50 mm	5/pk
	1235748	Sheet	200 x 200 mm	5/pk
	3057106	Sheet	30 cm x3 m	1/pk
MANUFACTURE NAME	<p>GVS North America, Inc. 63 Community Drive Sanford, ME 04073 Phone: +1.866.736.1250 Email: CustomerCareGVSLs@gvs.com Website: www.gvs.com</p>			
INTENDED USE/ APPLICATION	<p>Typical Applications:</p> <ul style="list-style-type: none"> • Protein and enzyme filtration and sterilization • Biological fluid filtration and sterilization • Pharmaceutical sterilization • Environmental water studies • Industrial water filtration • IV filters • IV drug delivery • TPN delivery 			
MATERIALS	<p>Film: Polyethersulfone (PES), supported with polyester film</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according to ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> RoHS, directive 2002/95/CE <input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE <input type="checkbox"/> DEHP plasticizer and latex free <input type="checkbox"/> Aging <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> Conflict minerals <input checked="" type="checkbox"/> USP Class VI 			

PRODUCT SPECIFICATION

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Description	0.03 µm Polyethersulfone Filtration Membrane Discs and Sheets	Rev. 01

PRODUCT CHARACTERISTICS	<ul style="list-style-type: none"> • Hydrophilic • Low Extractables • Low drug and protein binding • Superior burst strength • Lot to lot consistency 															
PRODUCT SHELF LIFE	5 years in normal storage conditions: Store the product at room temperate, in a dry place, free of dust and not exposed to direct sunlight.															
STERILIZATION	<p>This is a non-sterile product, compatible with these sterilization techniques*:</p> <p><input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (25 kGy)6.5 <input checked="" type="checkbox"/> Autoclave (121°C)</p> <p><i>*user has the responsibility to validate their process</i></p>															
PACKAGING AND LABELING	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Product</th> <th style="width: 33%;">Interior package</th> <th style="width: 33%;">Exterior package</th> </tr> </thead> <tbody> <tr> <td>13, 25, 47 mm Discs</td> <td>Discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box</td> </tr> <tr> <td>90 mm Disc</td> <td>Discs separated by blue paper</td> <td>Round container</td> </tr> <tr> <td>150 x 50 mm, 200 x 200 mm sheet</td> <td>Sheets separated by blue paper</td> <td>White mailer</td> </tr> <tr> <td>30 cm x 3 m</td> <td>Single sheet wrapped on a plastic core</td> <td>Cardboard box</td> </tr> </tbody> </table> <ul style="list-style-type: none"> • Each configuration will be labeled with: <ul style="list-style-type: none"> ○ Quantity ○ Product item code and description ○ Manufacturing date ○ Lot number ○ Storage conditions <p>Example label below:</p> <div style="text-align: center;">  </div>	Product	Interior package	Exterior package	13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	90 mm Disc	Discs separated by blue paper	Round container	150 x 50 mm, 200 x 200 mm sheet	Sheets separated by blue paper	White mailer	30 cm x 3 m	Single sheet wrapped on a plastic core	Cardboard box
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13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box														
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150 x 50 mm, 200 x 200 mm sheet	Sheets separated by blue paper	White mailer														
30 cm x 3 m	Single sheet wrapped on a plastic core	Cardboard box														
CERTIFICATE OF COMPLIANCE	A conformity declaration will be sent to the customer for each shipment with lot number and date of manufacture. The Quality management system is in compliance with ISO 9001.															



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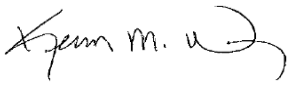
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PERFORMANCE REQUIREMENTS	Acceptance Requirement			Standard Test Method
	1	Thickness	110-150 µm	N/A
	2	Water Flow Rate	Min 3 mL/min/cm ² @ 10 psi	ASTM F 316-03 (2011)
	3	Bubble Point	90-110 psi (6.2-7.5 bar)	ASTM F 316-03 (2011)

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, and 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)
6/8/18	0	Initial Release	Gil Tavares/Process Development Engineer 	Kevin Wrigley/Director of Quality 

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.