

Product PN 1224487, 1224490, 1225883, 1225985

Mod. 984

Description 0.65 µm Polyethersulfone Filtration Membrane Discs and Sheets

Rev. 01

0.65 µm Polyethersulfone (PES) Filtration Membrane Discs and Sheets



PRODUCT DESCRIPTION	0.65 µm PES Discs and Sheets			
	Part Number	Geometry	Dimensions	Packaging
	1224487	Disc	47mm	100/Pk
	1224490	Disc	293 mm	25/pk
	1225883	Sheet	200 x 200 mm	5/pk
	1225985	Sheet	30 cm x3 m	1/pk
MANUFACTURE NAME	GVS North America, Inc. 63 Community Drive Sanford, ME 04073 Phone: +1.866.736.1250 Email: CustomerCareGVSLs@gvs.com Website: www.gvs.com			
INTENDED USE/ APPLICATION	Typical Applications: <ul style="list-style-type: none"> • Environmental water studies • Industrial water filtration • IV filters • IV drug delivery • TPN delivery 			
MATERIALS	Film: Polyethersulfone (PES), supported with polyester film Regulatory Documentation Required: <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according 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 CHARACTERISTICS	<ul style="list-style-type: none"> • USP Class VI compliant • Hydrophilic • Maximum operating temperature: 266°F (130°C) • Autoclavable • Broad sealing compatibility, including, ultrasonic, heat, radio frequency and insert molding • Metals Ions, Chloride and Sulfates: Not detectable (Analytical screen by ICP) 			
PRODUCT SHELF LIFE	5 years in normal storage conditions:			

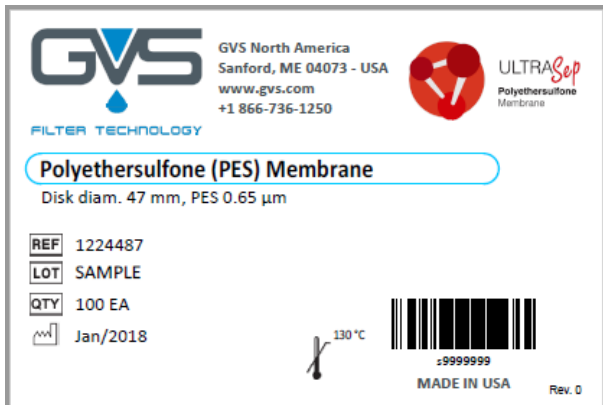
PRODUCT SPECIFICATION

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	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</p> <p><input checked="" type="checkbox"/> Gamma (25 kGy)6.5</p> <p><input checked="" type="checkbox"/> Autoclave (121°C)</p> <p><i>*user has the responsibility to validate their process</i></p>																		
PACKAGING AND LABELING	<table><tr><th>Product</th><th>Interior package</th><th>Exterior package</th></tr><tr><td>47 mm Discs</td><td>Discs separated by blue paper in a thermoformed tray</td><td>Clear/white plastic box</td></tr><tr><td>293 mm Disc</td><td>Discs separated by blue paper</td><td>Round container</td></tr><tr><td>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></table>			Product	Interior package	Exterior package	47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	293 mm Disc	Discs separated by blue paper	Round container	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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	<ul style="list-style-type: none">Each configuration will be labeled with:<ul style="list-style-type: none">QuantityProduct item code and descriptionManufacturing dateLot numberStorage conditions <p>Example label below:</p> <div></div>																		
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.																		
PERFORMANCE REQUIREMENTS	<table><tr><th colspan="3">Acceptance Requirement</th><th>Standard Test Methods</th></tr><tr><td>1</td><td>Thickness</td><td>110-150 µm</td><td>N/A</td></tr><tr><td>2</td><td>Water Flow Rate</td><td>Min 63 mL/min/cm² @ 10 psi</td><td>ASTM F 316-03 (2011)</td></tr><tr><td>3</td><td>Bubble Point</td><td>21-32 psi (1.4-2.2 bar)</td><td>ASTM F 316-03 (2011)</td></tr></table>			Acceptance Requirement			Standard Test Methods	1	Thickness	110-150 µm	N/A	2	Water Flow Rate	Min 63 mL/min/cm² @ 10 psi	ASTM F 316-03 (2011)	3	Bubble Point	21-32 psi (1.4-2.2 bar)	ASTM F 316-03 (2011)
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This material specification describes the properties of product above indicated.


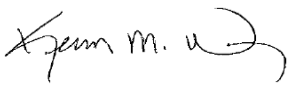
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This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.

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.