

Product PN 1214193, 1214465, 1214920, 1214169, 1214759, 1223871, 1226664, 1226158

Mod. 984

Description 0.22 µm Polyethersulfone (PES) Filtration Membrane in Discs and Sheets

Rev. 00




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



PRODUCT DESCRIPTION	.22 µm Polyethersulfone (PES) membrane packaged in sheets and discs			
	Part Number	Geometry	Dimensions	Packaging
	1214193	Disc	25mm	100/Pk
	1214465	Disc	47mm	100/Pk
	1226158*	Disc	47mm	200/Pk
	1214920	Disc	90mm	25/Pk
	1214169	Disc	142mm	25/Pk
	1214759	Disc	293mm	25/Pk
	1223871	Sheet	200x200mm	5/Pk
	1226664	Sheet	30cmx3m	1/Pk
	*Sterile			
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	These products are filtration membranes, often used for protein and enzyme filtration and sterilization, biological fluid filtration and sterilization, pharmaceutical sterilization, and environmental water studies.			
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"> • White membrane in discs and sheets • USP Class VI compliant • Hydrophilic 			

PRODUCT SPECIFICATION

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	<ul style="list-style-type: none"> Maximum operating temperature: 266°F (130°C) Autoclavable Broad sealing compatibility, including, ultrasonic, heat, radio frequency and insert molding Metal Ions, Chloride and Sulfates: Not detectable (Analytical screen by ICP) 															
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>Non-sterile products are compatible with these sterilization techniques*:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (25 kGy)6.5 <input checked="" type="checkbox"/> Autoclave (121°C) <p><i>*user has the responsibility to validate their process</i></p>															
PACKAGING AND LABELING	<ul style="list-style-type: none"> Primary packaging: <table border="1" data-bbox="400 925 1513 1207"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>25, 47 mm Discs (except pn 1226158)</td> <td>Discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box, 4 5/8" x 3 1/2" x 3/4"</td> </tr> <tr> <td>Part number 1226158</td> <td>Individually packaged discs</td> <td>200 individually packaged discs per box</td> </tr> <tr> <td>90, 142, 293 mm Discs</td> <td>Discs separated by blue paper</td> <td>Size specific top and bottom</td> </tr> <tr> <td>Sheets</td> <td>Discs separated by blue paper in a zip-lock plastic pab</td> <td>Mailer box</td> </tr> </tbody> </table> <ul style="list-style-type: none"> Each configuration will be labeled with: <ul style="list-style-type: none"> o Quantity o Product item code and description o Manufacturing date o Lot number o Storage conditions <p>Example label below:</p> <div data-bbox="603 1514 1305 1984" style="border: 1px solid black; padding: 10px;">  <p>GVS North America Sanford, ME 04073 - USA www.gvs.com +1 866-736-1250</p>  <p>Polyethersulfone (PES) Membrane Disk diam. 25 mm, PES 0.22 µm</p> <p>REF 1214193 LOT SAMPLE QTY 100 EA Jan/2018</p> <p>130°C</p>  <p>s9999999 MADE IN USA Rev. 0</p> </div>	Product	Interior package	Exterior package	25, 47 mm Discs (except pn 1226158)	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box, 4 5/8" x 3 1/2" x 3/4"	Part number 1226158	Individually packaged discs	200 individually packaged discs per box	90, 142, 293 mm Discs	Discs separated by blue paper	Size specific top and bottom	Sheets	Discs separated by blue paper in a zip-lock plastic pab	Mailer box
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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.																	
VISUAL REQUIREMENTS	<p><i>Visual acceptance requirements apply when inspected under below conditions:</i> Magnification: None Light type: Ambient</p> <table border="1"> <thead> <tr> <th colspan="2">Acceptance Requirement</th> <th>Sampling Plan</th> </tr> </thead> <tbody> <tr> <td>Creases/Folds</td> <td>None</td> <td rowspan="5">100% Inspection</td> </tr> <tr> <td>Cracks</td> <td>None</td> </tr> <tr> <td>Pin Holes</td> <td>None</td> </tr> <tr> <td>Wrinkles</td> <td>None</td> </tr> <tr> <td>Tension Lines</td> <td>None</td> </tr> </tbody> </table>			Acceptance Requirement		Sampling Plan	Creases/Folds	None	100% Inspection	Cracks	None	Pin Holes	None	Wrinkles	None	Tension Lines	None	
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<p>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.</p>																		


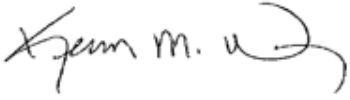

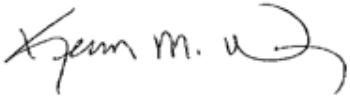


FILTER TECHNOLOGY

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REVISIONS AND APPROVALS:

DATE	REV	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
1/28/19	0	Initial Release	Gil Tavares/Development Process Engineer 	Kevin Wrigley/Director of Quality 
9/16/19	1	Added pn 1226158		

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.