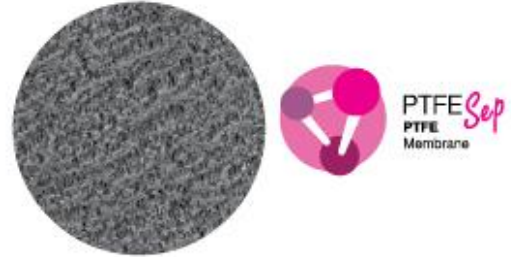


Product PN	1215491, 1215492, 1215493, 1215494, 1215495, 1215496, 1237423, 3034300	Mod. 984
Description	0.45 Polyetrafluoroethylene (PTFE) Filtration Membrane in Discs and Sheets	Rev. 01

0.45 µm Polyetrafluoroethylene (PTFE) Filtration Membrane in Discs and Sheets



PRODUCT DESCRIPTION	0.45 µm Polyetrafluoroethylene (PTFE) Filtration membrane packaged in sheets and discs			
	Part Number	Geometry	Dimensions	Packaging
	1215491	Disc	13mm	100/Pk
	1215492	Disc	25mm	100/Pk
	1215493	Disc	47mm	100/Pk
	1215494	Disc	90mm	25/Pk
	1215495	Disc	142mm	25/Pk
	1215496	Disc	293mm	25/Pk
	1237423	Sheet	200x200mm	5/Pk
	3034300	Sheet	305x305mm	50Pk
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, biological fluid sterilization, tissue culture media sterilization, and cold sterilization.			
MATERIALS	Membrane: Polyetrafluoroethylene (PTFE) Filtration membrane Regulatory Documentation Required: <input type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input 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			
PRODUCT CHARACTERISTICS	Appearance/Visual: White membrane configured in discs or sheets			

PRODUCT SPECIFICATION

Product PN 1215491, 1215492, 1215493, 1215494, 1215495, 1215496, 1237423, 3034300 **Mod. 984**

Description 0.45 Polytetrafluoroethylene (PTFE) Filtration Membrane in Discs and Sheets **Rev. 01**

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	This is a non-sterile product, compatible with these sterilization techniques: <input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (25 kGy) <input checked="" type="checkbox"/> Autoclave (121°C)													
PACKAGING AND LABELING	<ul style="list-style-type: none"> Primary packaging: <table border="1" data-bbox="386 660 1497 884"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>25, 47 mm Discs</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>90, 142, 293 mm Discs</td> <td>Discs separated by blue paper in a thermoformed tray</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> 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> 		Product	Interior package	Exterior package	25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box, 4 5/8" x 3 1/2" x 3/4"	90, 142, 293 mm Discs	Discs separated by blue paper in a thermoformed tray	Size specific top and bottom	Sheets	Discs separated by blue paper in a zip-lock plastic pab	Mailer box
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90, 142, 293 mm Discs	Discs separated by blue paper in a thermoformed tray	Size specific top and bottom												
Sheets	Discs separated by blue paper in a zip-lock plastic pab	Mailer 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.													
VISUAL REQUIREMENTS	<p><i>Visual acceptance requirements apply when inspected under below conditions:</i> Magnification: None Light type: Ambient</p> <table border="1" data-bbox="331 1848 1548 2027"> <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="4">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> </tbody> </table>		Acceptance Requirement		Sampling Plan	Creases/Folds	None	100% Inspection	Cracks	None	Pin Holes	None	Wrinkles	None
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Creases/Folds	None	100% Inspection												
Cracks	None													
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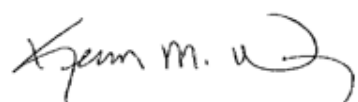
PRODUCT SPECIFICATION

Product PN	1215491, 1215492, 1215493, 1215494, 1215495, 1215496, 1237423, 3034300	Mod. 984
Description	0.45 Polytetrafluoroethylene (PTFE) Filtration Membrane in Discs and Sheets	Rev. 01

	Tension Lines	None		
PERFORMANCE REQUIREMENTS	Acceptance Requirement		Sampling Plan	
	1	Thickness	100-180 µm	left, middle, & right every 120m
	2	Flow Time (MeOH)	40-75 sec (500 mL @ 24" Hg)	left, middle, & right every 120m
	3	Bubble Point (EtOH)	9.2-14.9 psi (0.64-1.03 bar)	left, middle, & right every 120m

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)
10/22/18	0	Initial Release	Yuander Ju/Director, TEM 	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.