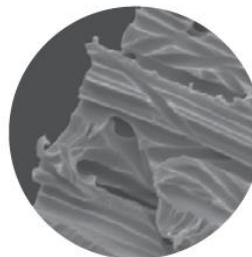


PRODUCT SPECIFICATION

Product PN	1215274, 1215613, 1215147, 1215614, 1215615, 1215617, 1226156, 3023783, 1228342, 1215303, 1215152, 1215317	Mod. 984
Description	0.4 µm Hydrophilic Polycarbonate Track-Etched Membrane Discs and Sheets	Rev. 02

0.4 µm Hydrophilic Polycarbonate Track Etched Membrane



PRODUCT DESCRIPTION	0.4 µm PCTE Hydrophilic Membrane			
	Part Number	Geometry	Dimensions	Packaging
	1215613	Disc	13 mm	100/Pk
	1215147	Disc	19 mm	100/Pk
	1215614	Disc	25mm	100/Pk
	1215615	Disc	37 mm	100/pk
	1215617	Disc	47mm	100/Pk
	1226156*	Disc	47mm	200/Pk
	3023783	Disc	62mm	100/pk
	1228342	Disc	76 mm	100/pk
	1215303	Disc	90 mm	30/pk
	1215152	Disc	142 mm	20/pk
	1215317	Disc	293 mm	20/pk
	1215274	Sheet	203 x 254 mm	30/pk
* white, sterile and single packed				
MANUFACTURER	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"> • Epifluorescence • Observation of microorganisms • Direct counting of microorganisms • Water testing 			
MATERIALS	Film: Polycarbonate treated with wetting agent polyvinylpyrrolidone (PVP) 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) 			



PRODUCT SPECIFICATION

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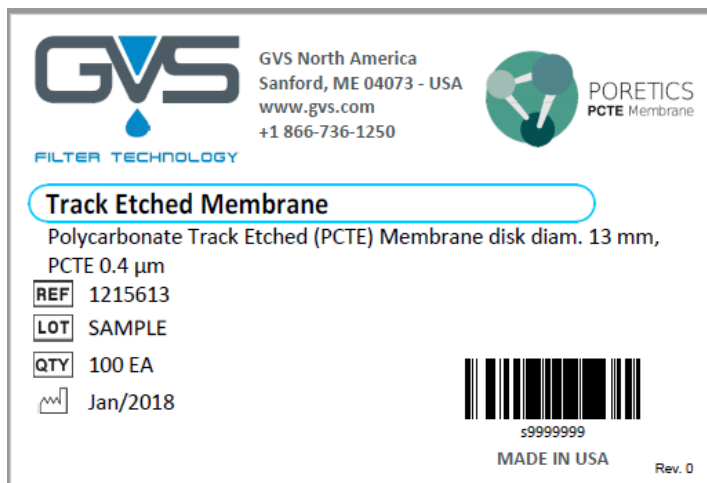
	<div><input checked="" type="checkbox"/> Conflict minerals</div> <div><input checked="" type="checkbox"/> USP Class VI</div>																								
PRODUCT CHARACTERISTICS	<div><div><div>Absolute pore size and density allows for precise size separation</div><div>Direct thickness and pore size measurements provide accurate characteristics</div><div>Superior strength allows for aggressive handling</div><div>Low protein binding ensures clean results</div><div>Resists chemical staining to ease microscopic visualization</div><div>Passes USP Class VI testing</div></div><div>Nominal Characteristics:</div><table><tr><th>Attribute</th><th>Result</th></tr><tr><td>Thickness (um)</td><td>9-11 μm</td></tr><tr><td>BSA Protein Binding</td><td>5 μg/cm²</td></tr><tr><td>Max. Operating Temperature</td><td>284°F (140°C)</td></tr><tr><td>Sealing Compatibility</td><td>Ultrasonic, Heat, Radio Frequency, and Insert Molding</td></tr><tr><td>Refractive Indices</td><td>Birefringent at 1.584 and 1.625</td></tr><tr><td>Water Adsorption (% wt. gain 24-hr immersion)</td><td>0.24%</td></tr><tr><td>Residual Ash Weight Average</td><td>0.92 μg/cm²</td></tr><tr><td>Leachables</td><td>Negligible</td></tr><tr><td>Wetting Characteristics</td><td>Hydrophilic</td></tr><tr><td>Burst Strength Minimum</td><td>0.7 bar (10 psi)</td></tr><tr><td>Migration of Filter Media</td><td>0</td></tr></table></div>	Attribute	Result	Thickness (um)	9-11 μm	BSA Protein Binding	5 μg/cm²	Max. Operating Temperature	284°F (140°C)	Sealing Compatibility	Ultrasonic, Heat, Radio Frequency, and Insert Molding	Refractive Indices	Birefringent at 1.584 and 1.625	Water Adsorption (% wt. gain 24-hr immersion)	0.24%	Residual Ash Weight Average	0.92 μg/cm²	Leachables	Negligible	Wetting Characteristics	Hydrophilic	Burst Strength Minimum	0.7 bar (10 psi)	Migration of Filter Media	0
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PRODUCT SHELF LIFE	<div>5 years in normal storage conditions:</div> <div>Store the product at room temperate, in a dry place, free of dust and not exposed to direct sunlight.</div>																								
STERILIZATION	<div>This product is compatible with these sterilization techniques:</div> <div><input checked="" type="checkbox"/> EtO</div> <div><input checked="" type="checkbox"/> Gamma (25 kGy)</div> <div><input checked="" type="checkbox"/> Autoclave (121°C)</div> <div>*Sterilization is not required</div>																								
PACKAGING AND LABELING	<table><tr><th>Product</th><th>Interior package</th><th>Exterior package</th></tr><tr><td>13, 19, 25, 37, 47, 62 mm Discs</td><td>Discs separated by blue paper in a thermoformed tray</td><td>Clear/white plastic box</td></tr><tr><td>PN 1226156 only</td><td>47 mm discs, individually packaged</td><td>Cardboard box</td></tr><tr><td>76, 90, 142, 293 mm Disc</td><td>Discs separated by blue paper</td><td>Round container</td></tr><tr><td>203 x 254 mm sheet</td><td>Sheets separated by blue paper</td><td>White mailer</td></tr></table> <div><div>Each configuration will be labeled with:</div><div><div>Quantity</div><div>Product item code and description</div><div>Manufacturing date</div><div>Lot number</div><div>Storage conditions</div></div></div>	Product	Interior package	Exterior package	13, 19, 25, 37, 47, 62 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	PN 1226156 only	47 mm discs, individually packaged	Cardboard box	76, 90, 142, 293 mm Disc	Discs separated by blue paper	Round container	203 x 254 mm sheet	Sheets separated by blue paper	White mailer									
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Example label below:



CERTIFICATE OF COMPLIANCE

A conformity declaration will be sent to the customer for each shipment with the lot number and date of manufacture. The Quality management system is in compliance with ISO 9001.

VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under the below conditions:

Magnification: None

Light type: Standard

Acceptance Requirement			Sampling Plan
1	Creases/Folds: lines which do not disappear when the membrane is placed under tension	None	100% inspection
2	Cracks: areas where the membrane is bent to the point of fracture	None	
3	Pinholes: openings or perforations in the membrane	None	
4	Tension Lines: lines which disappear when the membrane is placed under tension	Max. 3 (not continuous)	
5	Wrinkles (A): wavy surfaces which disappear when the membrane is placed under tension	Minimal	
6	Wrinkles (B): wavy surfaces which do not disappear when the membrane is placed under tension	None	

PERFORMANCE REQUIREMENTS

Acceptance Requirement		Specification	Master Roll Sampling Plan
1	Pore Size (µm)	0.32-0.4	left, middle, & right every 120m
2	Pore Density (pores/cm ²)	1.0 x 10 ⁸ ± 15%	left, middle, & right every 120m
3	Air Flow (L/min/cm ² @ 10psi)	≥ 7.5	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	≥ 12	left, middle, & right every 120m

This material specification describes the properties of product above indicated.


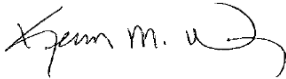
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



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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)
10/23/19	0	Initial Release	Yuander Ju/Director, TEM 	Kevin Wrigley/Director, 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.