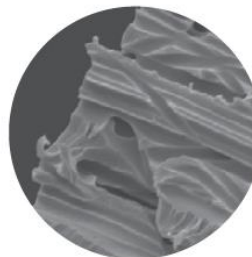


PRODUCT SPECIFICATION

Product PN	1215610, 1220694, 1215611, 1215612, 1226157, 1220891, 1215151, 1215215, 1215385, 1215118, 1239557, 3038824	Mod. 984
Description	0.2 µm Hydrophilic Polycarbonate Track-Etched Membrane Discs and Sheets	Rev. 02

0.2 µm Hydrophilic Polycarbonate Track Etched Membrane



PRODUCT DESCRIPTION	0.2 µm PCTE Hydrophilic Membrane			
	Part Number	Geometry	Dimensions	Packaging
	1215610	Disc	13 mm	100/Pk
	1220694	Disc	19 mm	100/Pk
	1215611	Disc	25mm	100/Pk
	1215612	Disc	47mm	100/Pk
	1226157*	Disc	47mm	200/Pk
	3038824	Disc	62mm	100/pk
	1220891	Disc	76 mm	100/pk
	1215151	Disc	90 mm	30/pk
	1215215	Disc	142 mm	20/pk
	1215385	Disc	293 mm	20/pk
	1215118	Sheet	203 x 254 mm	30/pk
	1239557	Sheet	300x3000 mm	1/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: • Epifluorescence • Observation of microorganisms • Direct counting of microorganisms • Water testing			
MATERIALS	Film: Polycarbonate treated with wetting agent polyvinylpyrrolidone (PVP) Regulatory Documentation Required: ☐ Biocompatibility according ISO 10993-1 ☐ IMDS ☒ Rohs, directive 2002/95/CE ☒ BSE/TSE, directive 2003/32/CE ☐ DEHP plasticizer and latex free ☐ Aging ☒ Reach 1907/2006/CE (hazardous substances regulation) ☐ Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)			



PRODUCT SPECIFICATION

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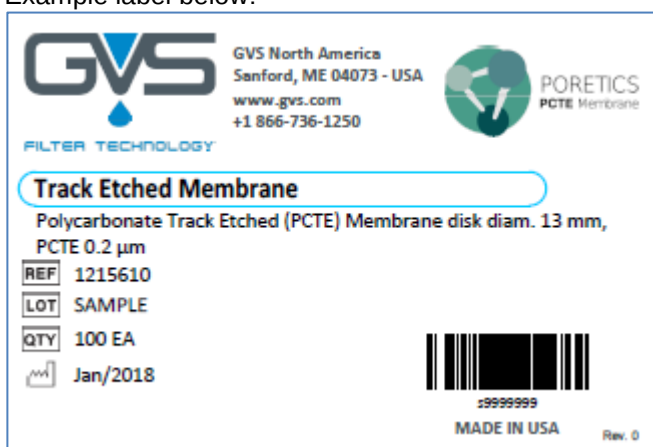
	☒ Conflict minerals ☒ USP Class VI																								
PRODUCT CHARACTERISTICS	Absolute pore size and density allows for precise size separation Direct thickness and pore size measurements provide accurate characteristics Superior strength allows for aggressive handling Low protein binding ensures clean results Resists chemical staining to ease microscopic visualization Passes USP Class VI testing Nominal Characteristics: <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>	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	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 product is compatible with these sterilization techniques: ☒ EtO ☒ Gamma (25 kGy) ☒ Autoclave (121°C) *Sterilization is not required																								
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 1226157 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><tr><td>300x3000mm sheet</td><td>Single sheet wrapped around core tube</td><td>Cardboard box</td></tr></table>	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 1226157 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	300x3000mm sheet	Single sheet wrapped around core tube	Cardboard box						
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PRODUCT SPECIFICATION

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Description	0.2 µm Hydrophilic Polycarbonate Track-Etched Membrane Discs and Sheets	Rev. 02

- Each configuration will be labeled with:
 - Quantity
 - Product item code and description
 - Manufacturing date
 - Lot number
 - Storage conditions

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	

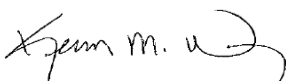


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PERFORMANCE REQUIREMENTS	Acceptance Requirement		Specification	Master Roll Sampling Plan
	1	Pore Size (µm)	0.16-0.20	left, middle, & right every 120m
	2	Pore Density (pores/cm ²)	3.0 x 10 ⁸ ± 15%	left, middle, & right every 120m
	3	Air Flow (L/min/cm ² @ 10psi)	≥ 2	left, middle, & right every 120m
	4	Bubble Point (psi) (measured using IPA)	≥ 30	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)
10/23/19	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.