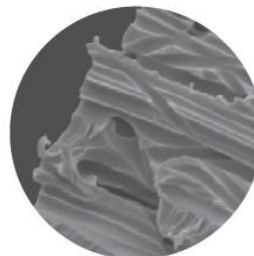


PRODUCT SPECIFICATION

Product PN	1215051, 1221746, 1222081, 1222082, 1225120, 1221331	Mod. 984
Description	5.0 µm Hydrophobic Polycarbonate Track-Etched Membrane Discs and Sheets	Rev. 02

5.0 µm Hydrophobic Polycarbonate Track Etched Membrane – Discs and Sheets



PORETICS
PCTE Membrane

PRODUCT DESCRIPTION	5.0 µm PCTE Discs and Sheets, PVP Free			
	Part Number	Geometry	Dimensions	Packaging
	1215051	Disc	13 mm	100/Pk
	1221746	Disc	25mm	100/Pk
	1222081	Disc	47mm	100/Pk
	1222082	Disc	90 mm	30/pk
	1225120	Sheet	203x254mm	100/Pk
	1221331	Sheet	25x80	50/Pk
MANUFACTURER	<p>GVS North America, Inc. 63 Community Drive Sanford, ME 04073 Phone: +1.866.736.1250 Email: CustomerCareGVSLs@gvs.com Website: www.gvs.com</p>			
INTENDED USE/ APPLICATION	<p>Typical Applications:</p> <ul style="list-style-type: none"> • Epifluorescence • Observation of microorganisms • Direct counting of microorganisms • Water testing 			
MATERIALS	<p>Film: Polycarbonate</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according to 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	<p>Appearance/Visual: Semi-translucent, thin membrane in discs and sheets</p>			



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Nominal Characteristics:

Attribute	Result
Thickness (um)	9-11 um
BSA Protein Binding	5 µg/cm ²
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/cm ²
Leachables	Negligible
Wetting Characteristics	Hydrophilic
Burst Strength Minimum	0.7 bar (10 psi)
Migration of Filter Media	0

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

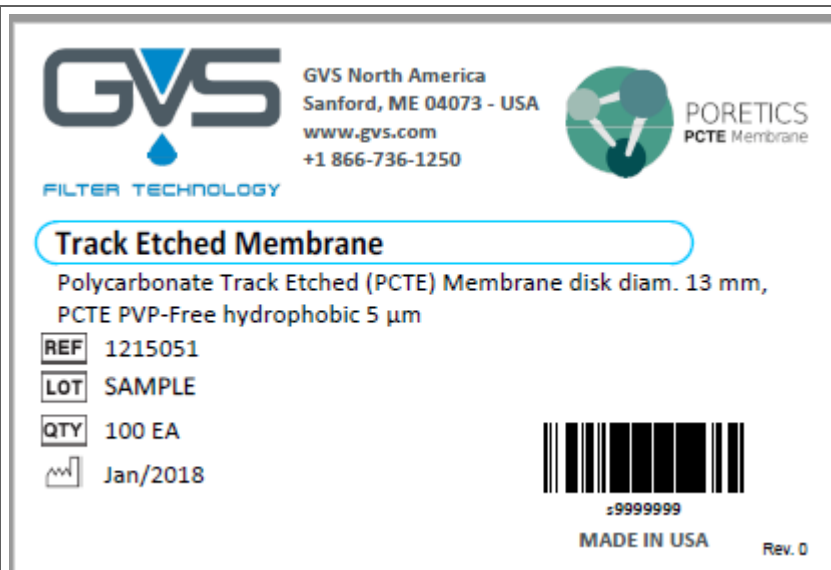
- Primary packaging

Product	Interior package	Exterior package
13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box
90 mm Disc	Discs separated by blue paper	Round container
203 x 254 mm, 19 x 42 mm sheet	Sheets separated by blue paper	White mailer
25x80	Membrane separated by blue paper in a thermoformed tray	Clear/white plastic box

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

PRODUCT SPECIFICATION

Product PN	1215051, 1221746, 1222081, 1222082, 1225120, 1221331	Mod. 984
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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 9001:2015.

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)	4.0-5.0	left, middle, & right every 120m
2	Pore Density (pores/cm ²)	4.0x10E5±15%	left, middle, & right every 120m
3	Air Flow (L/min/cm ² @ 5psi)	≥30	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	≥1.2	left, middle, & right every 120m

This material specification describes the properties of product above indicated.


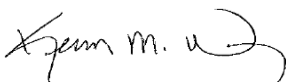
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



PRODUCT SPECIFICATION

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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)
11/22/19	0	Initial Release	Yuander Ju/ Director of 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.