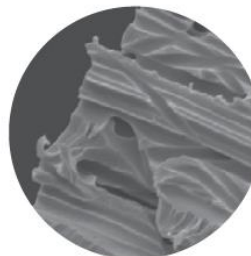


# PRODUCT SPECIFICATION

Product PN	1222037, 1222038, 1224067	Mod. 984
Description	1.0 µm Hydrophobic Polycarbonate Track-Etched Membrane Discs and Sheets	Rev. 02

## 1.0 µm Hydrophobic Polycarbonate Track Etched Membrane Discs and Sheets



PRODUCT DESCRIPTION	1.0 µm PCTE Discs and Sheets, PVP Free			
	Part Number	Geometry	Dimensions	Packaging
	1222037	Disc	25mm	100/Pk
	1222038	Disc	47mm	100/Pk
	1224067	Sheet	203x254mm	30/Pk
MANUFACTURER	GVS North America, Inc. 63 Community Drive Sanford, ME 04073 Phone: +1.866.736.1250 Email: <a href="mailto:CustomerCareGVSLs@gvs.com">CustomerCareGVSLs@gvs.com</a> Website: <a href="http://www.gvs.com">www.gvs.com</a>			
INTENDED USE/ APPLICATION	<b>Typical Applications:</b> <ul style="list-style-type: none"> <li>• Epifluorescence</li> <li>• Observation of microorganisms</li> <li>• Direct counting of microorganisms</li> <li>• Water testing</li> </ul>			
MATERIALS	Film: Polycarbonate  Regulatory Documentation Required: <ul style="list-style-type: none"> <li><input type="checkbox"/> Biocompatibility according to ISO 10993-1</li> <li><input type="checkbox"/> IMDS</li> <li><input checked="" type="checkbox"/> RoHS, directive 2002/95/CE</li> <li><input checked="" type="checkbox"/> BSE/TSE, directive 2003/32/CE</li> <li><input type="checkbox"/> DEHP plasticizer and latex free</li> <li><input type="checkbox"/> Aging</li> <li><input checked="" type="checkbox"/> REACH 1907/2006/CE (hazardous substances regulation)</li> <li><input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)</li> <li><input checked="" type="checkbox"/> Conflict minerals</li> <li><input checked="" type="checkbox"/> USP Class VI</li> </ul>			
PRODUCT CHARACTERISTICS	<b>Appearance/Visual:</b> Semi-translucent, thin membrane in discs and sheets.			



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## Nominal Characteristics:

Attribute	Result
Thickness (um)	10-12 um
BSA Protein Binding	5 µg/cm <sup>2</sup>
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 <sup>2</sup>
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

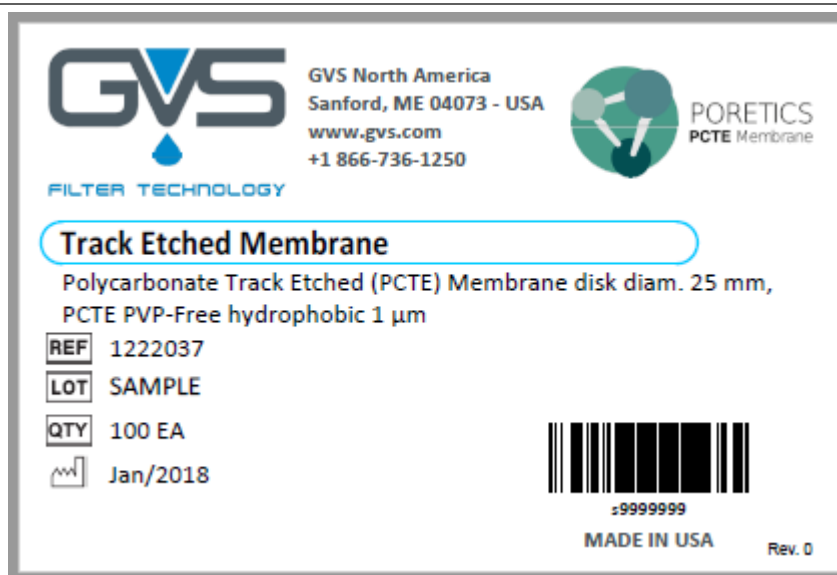
- Primary packaging

Product	Interior package	Exterior package
25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box
203 x 254 mm sheet	Sheets separated by blue paper	White mailer

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

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Product PN	1222037, 1222038, 1224067	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.

**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	

Acceptance Requirement		Specification	Master Roll Sampling Plan
1	Pore Size (µm)	0.08-1.0	left, middle, & right every 120m
2	Pore Density (pores/cm <sup>2</sup> )	2.0x10E7±15%	left, middle, & right every 120m
3	Air Flow (L/min/cm <sup>2</sup> @ 10psi)	≥20	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	≥6	left, middle, & right every 120m


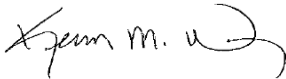
This material specification describes the properties of product above indicated.  
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



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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)
5/31/18	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.