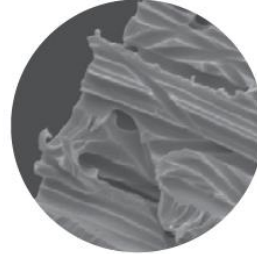




# PRODUCT SPECIFICATION

<b>Product PN</b>	1215621, 1215622, 1215623, 1215624, 1225894, 1215194, 1215309, 1222030	<b>Mod. 984</b>
<b>Description</b>	0.8 µm Hydrophilic Polycarbonate Track-Etched Membrane Discs and Sheets	<b>Rev. 02</b>

## 0.8 µm Hydrophilic Polycarbonate Track Etched Membrane



<b>PRODUCT DESCRIPTION</b>	0.8 µm PCTE Hydrophilic Membrane			
	<b>Part Number</b>	<b>Geometry</b>	<b>Dimensions</b>	<b>Packaging</b>
	1215621	Disc	13 mm	100/Pk
	1215622	Disc	25mm	100/Pk
	1215623	Disc	37mm	100/Pk
	1215624	Disc	47mm	100/Pk
	1225894	Disc	76 mm	100/pk
	1215194	Disc	90 mm	30/pk
	1215309	Disc	142 mm	20/pk
	1222030	Sheet	203 x 254 mm	30/pk
<b>MANUFACTURER</b>	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>			
<b>INTENDED USE/ APPLICATION</b>	<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>			
<b>MATERIALS</b>	Film: Polycarbonate treated with wetting agent polyvinylpyrrolidone (PVP)  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>			



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## 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:

Attribute	Result
Thickness (µm)	9-11 µm
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 temperature, 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

Product	Interior package	Exterior package
13, 25, 37, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box
76, 90, 142 mm Disc	Discs separated by blue paper	Round container
203 x 254 mm sheet	Sheets separated by blue paper	White mailer

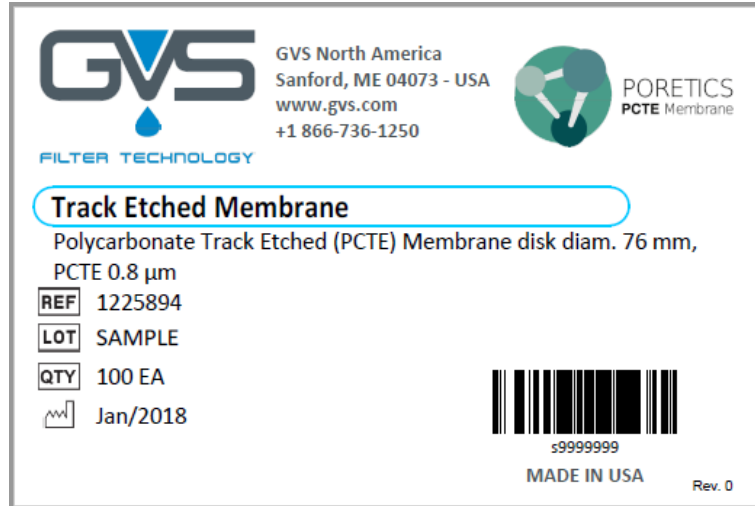
- Each configuration will be labeled with:
  - Quantity
  - Product item code and description
  - Manufacturing date
  - Lot number
  - Storage conditions



# PRODUCT SPECIFICATION

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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	

Acceptance Requirement		Specification	Master Roll Sampling Plan
1	Pore Size (µm)	0.0.64-0.80	left, middle, & right every 120m
2	Pore Density (pores/cm <sup>2</sup> )	3.0x10E7±15%	left, middle, & right every 120m
3	Air Flow (L/min/cm <sup>2</sup> @ 10 psi)	≥18	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	≥7	left, middle, & right every 120m


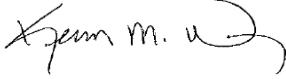
This material specification describes the properties of product above indicated.  
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



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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.