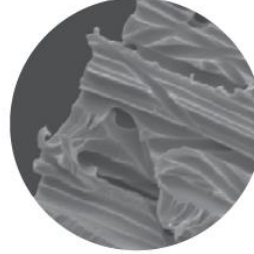




# PRODUCT SPECIFICATION

<b>Product PN</b>	1221009, 1215638, 1212661, 1267014, 1222482, 1221292, 1222088, 1220823, 3033092	<b>Mod. 984</b>
<b>Description</b>	10.0 µm Hydrophilic Polycarbonate Track-Etched Membrane Sheets	<b>Rev. 02</b>

## 10.0 um Hydrophilic Polycarbonate Track Etched Membrane Sheets



<b>PRODUCT DESCRIPTION</b>	10.0 um PCTE, treated with PVP			
	<b>Part Number</b>	<b>Geometry</b>	<b>Dimensions</b>	<b>Packaging</b>
	1221009	Disc	13 mm	100/Pk
	1215638	Disc	25mm	100/Pk
	1212661	Disc	47mm	100/Pk
	1267014	Disc	76 mm	100/pk
	1222482	Disc	90 mm	30/pk
	1221292	Disc	142 mm	20/pk
	1222088	Disc	293 mm	20/pk
	1220823	Sheet	203x254mm	30/Pk
3033092	Sheet	300x3000mm	1/Pk	
<b>MANUFACTURER</b>	<p>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></p>			
<b>INTENDED USE/ APPLICATION</b>	<p><b>Typical Applications:</b></p> <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>	<p>Film: Polycarbonate treated with wetting agent Polyvinyl Pyrolidone (PVP)</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Biocompatibility according 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>			
<b>PRODUCT CHARACTERISTICS</b>	<ul style="list-style-type: none"> <li>• Absolute pore size and density allows for precise size separation</li> <li>• Direct thickness and pore size measurements provide accurate characteristics</li> <li>• Superior strength allows for aggressive handling</li> </ul>			



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- Low protein binding ensures clean results
- Resists chemical staining to ease microscopic visualization
- Passes USP Class VI testing
- 

**Nominal Characteristics:**

Attribute	Result
Thickness (um)	9-11 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
13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic 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
300 x 3000 mm	Single sheet wrapped on a plastic core	Cardboard box

- 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:

The label includes the following information:

- GVS FILTER TECHNOLOGY** logo and contact info: GVS North America, Sanford, ME 04073 - USA, www.gvs.com, +1 866-736-1250
- PORETICS PCTE Membrane** logo
- Track Etched Membrane** title
- Polycarbonate Track Etched (PCTE) Membrane roll 300x3000 mm, PCTE 10 µm
- REF: 3033092
- LOT: SAMPLE
- QTY: 100 EA
- Jan/2018
- Barcode with number 19999999
- MADE IN USA
- Rev. 0

**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)	9.0 - 10.0	left, middle, & right every 120m
2	Pore Density (pores/cm <sup>2</sup> )	1.0x10E5±15%	left, middle, & right every 120m
3	Air Flow (L/min/cm <sup>2</sup> @ 5psi)	≥34.5	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	≥0.5	left, middle, & right every 120m


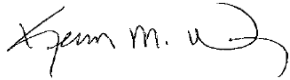
This material specification describes the properties of product above indicated.  
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



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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.