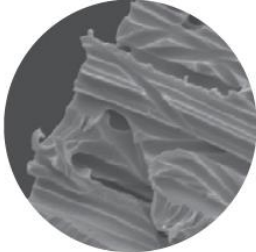




# PRODUCT SPECIFICATION

<b>Product PN</b>	1215055, 1221300, 1215044	<b>Mod. 984</b>
<b>Description</b>	12.0 µm Hydrophobic Polycarbonate Track-Etched Membrane Discs and Sheets	<b>Rev. 02</b>

**12.0 µm Hydrophobic Polycarbonate Track Etched Membrane Discs and Sheets**



<b>PRODUCT DESCRIPTION</b>	12.0 µm PCTE Discs and Sheets PVP Free			
	<b>Part Number</b>	<b>Geometry</b>	<b>Dimensions</b>	<b>Packaging</b>
	1215055	Disc	13 mm	100/Pk
	1221300	Disc	25mm	100/Pk
	1215044	Sheet	25x80	50/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  Regulatory Documentation Required: <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>	<b>Appearance/Visual:</b> Semi-translucent, thin membrane wrapped around 3" ID polypropylene (PP) cores.			



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<b>Description</b>	12.0 µm Hydrophobic Polycarbonate Track-Etched Membrane Discs and Sheets	<b>Rev. 02</b>

	<b>Nominal Characteristics:</b>																								
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<b>PRODUCT SHELF LIFE</b>	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.
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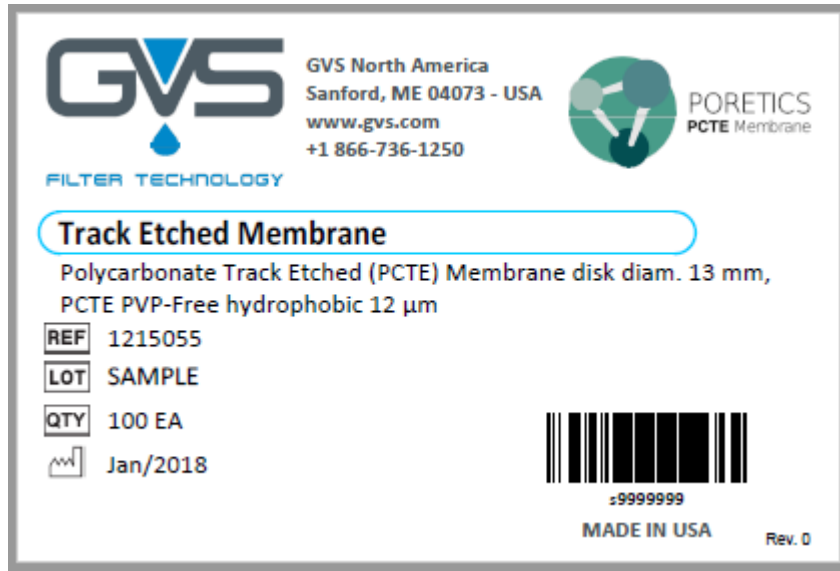
<b>STERILIZATION</b>	This product is compatible with these sterilization techniques: <input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (25 kGy) <input checked="" type="checkbox"/> Autoclave (121°C) *Sterilization is not required
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<b>PACKAGING AND LABELING</b>	<ul style="list-style-type: none"> <li>Primary packaging</li> </ul>									
	<table border="1"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>13, 25 mm Discs</td> <td>Discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box</td> </tr> <tr> <td>25x80</td> <td>Membrane separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box</td> </tr> </tbody> </table>	Product	Interior package	Exterior package	13, 25 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	25x80	Membrane separated by blue paper in a thermoformed tray	Clear/white plastic box
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<ul style="list-style-type: none"> <li>Each configuration will be labeled with:             <ul style="list-style-type: none"> <li>Quantity</li> <li>Product item code and description</li> <li>Manufacturing date</li> <li>Lot number</li> <li>Storage conditions</li> </ul> </li> <li>Label example</li> </ul>										



# PRODUCT SPECIFICATION

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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)	11.0 -12.0	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)	≥64	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	≥0.4	left, middle, & right every 120m


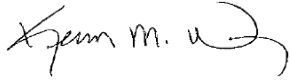
This material specification describes the properties of product above indicated.  
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



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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.