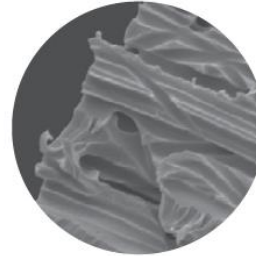




PRODUCT SPECIFICATION

Product PN	1221232, 3034567, 1215985, 1215062, 1215629, 1222070, 1222071, 1221005	Mod. 984
Description	2.0 µm Hydrophilic Polycarbonate Track-Etched Membrane Discs and Sheets	Rev. 02

2.0 µm Hydrophilic Polycarbonate Track Etched Membrane - Discs and Sheets



PRODUCT DESCRIPTION	2.0 µm PCTE Hydrophilic Membrane in Discs and Sheets			
	Part Number	Geometry	Dimensions	Packaging
	1221232	Sheet	203x254mm	30/Pk
	3034567	Sheet	300x3000mm	1/Pk
	1215985	Discs	13 mm	100/pk
	1215062	Discs	25 mm	100/pk
	1215629	Discs	47 mm	100/pk
	1222070	Discs	90 mm	30/pk
	1222071	Discs	142 mm	20/pk
1221005	Discs	293 mm	20/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 treated with wetting agent Polyvinyl Pyrrolidone (PVP)</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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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: <input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (25 kGy) <input checked="" type="checkbox"/> Autoclave (121°C) *Sterilization is not required																								
PACKAGING AND LABELING	<ul style="list-style-type: none"> Primary packaging: <table border="1"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>13, 25, 47 mm Discs</td> <td>Discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box, 4 5/8" x 3 1/2" x 3/4"</td> </tr> <tr> <td>90, 142, 293 mm Discs</td> <td>Discs separated by blue paper</td> <td>Size specific top and bottom</td> </tr> <tr> <td>203 x 254 mm sheet</td> <td>Sheets separated by blue paper</td> <td>White mailer</td> </tr> <tr> <td>300x3000mm sheet</td> <td>Single sheet wrapped around core tube</td> <td>Cardboard box</td> </tr> </tbody> </table> Each configuration will be labeled with: <ul style="list-style-type: none"> Quantity Product item code and description Manufacturing date Lot number Storage conditions An example of a label is below 	Product	Interior package	Exterior package	13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box, 4 5/8" x 3 1/2" x 3/4"	90, 142, 293 mm Discs	Discs separated by blue paper	Size specific top and bottom	203 x 254 mm sheet	Sheets separated by blue paper	White mailer	300x3000mm sheet	Single sheet wrapped around core tube	Cardboard box									
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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
1	Pore Size (µm)	1.6 - 2.0
2	Pore Density (pores/cm ²)	2.0x10E6±15%
3	Air Flow (L/min/cm ² @ 10 psi)	≥16.5
4	Bubble Point (psi) (measured using IPA)	≥3

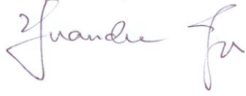
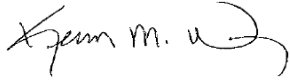
This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



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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)
12/6/19	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.