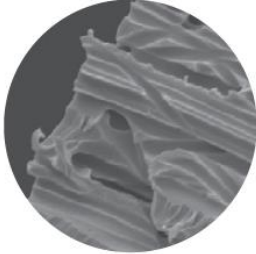




PRODUCT SPECIFICATION

Product PN	1215053, 1222089, 1220941, 1234298, 1215043	Mod. 984
Description	10.0 µm Hydrophobic Polycarbonate Track-Etched Membrane Discs and Sheets	Rev. 02

10.0 µm Hydrophobic Polycarbonate Track Etched Membrane Discs and Sheets



PRODUCT DESCRIPTION	10.0 µm PCTE Discs and Sheets, PVP Free			
	Part Number	Geometry	Dimensions	Packaging
	1215053	Disc	13 mm	100/Pk
	1222089	Disc	25mm	100/Pk
	1220941	Disc	47mm	100/Pk
	1234298	Sheet	203x254mm	100/Pk
	1215043	Sheet	25x80	50/Pk
MANUFACTURER	GVS North America, Inc. 63 Community Drive Sanford, ME 04073 Phone: +1.866.736.1250 Email: CustomerCareGVSLs@gvs.com Website: www.gvs.com			
INTENDED USE/ APPLICATION	Typical Applications: <ul style="list-style-type: none"> • Epifluorescence • Observation of microorganisms • Direct counting of microorganisms • Water testing 			
MATERIALS	Film: Polycarbonate Regulatory Documentation Required: <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according 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	Appearance/Visual: Semi-translucent, thin membrane in Discs and Sheets.			



PRODUCT SPECIFICATION

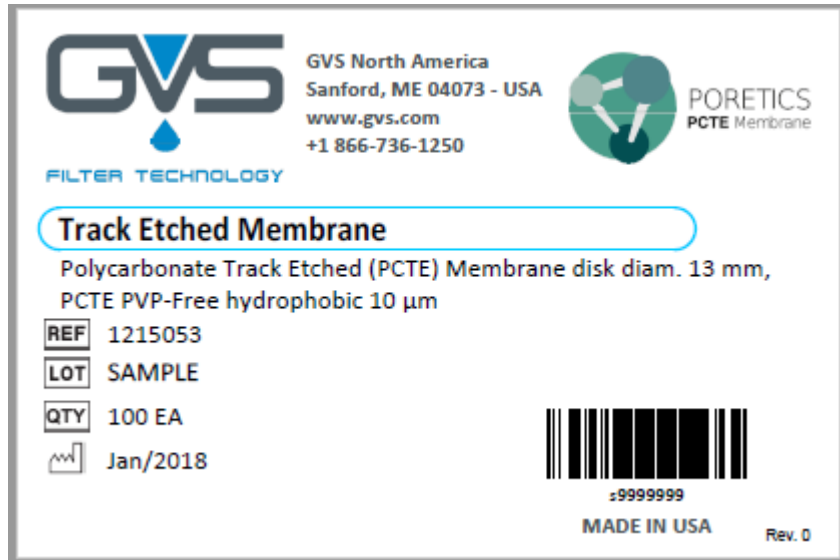
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PRODUCT SHELF LIFE	5 years in normal storage conditions: Store the product at room temperate, in a dry place, free of dust and not exposed to direct sunlight.																								
STERILIZATION	This product is compatible with these sterilization 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</td> </tr> <tr> <td>203 x 254 mm, 19 x 42 mm sheet</td> <td>Sheets separated by blue paper</td> <td>White mailer</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> <ul style="list-style-type: none"> Each configuration will be labeled with: <ul style="list-style-type: none"> Quantity Product item code and description Manufacturing date Lot number Storage conditions Label example 	Product	Interior package	Exterior package	13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	203 x 254 mm, 19 x 42 mm sheet	Sheets separated by blue paper	White mailer	25x80	Membrane separated by blue paper in a thermoformed tray	Clear/white plastic 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	Master Roll Sampling Plan
1	Pore Size (µm)	9.0 - 10.0	left, middle, & right every 120m
2	Pore Density (pores/cm ²)	1.0x10E5±15%	left, middle, & right every 120m
3	Air Flow (L/min/cm ² @ 5psi)	≥34.5	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	≥0.5	left, middle, & right every 120m

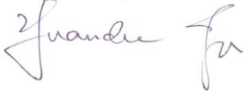
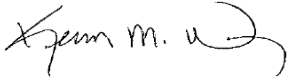
This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



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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.