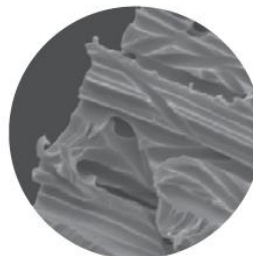


PRODUCT SPECIFICATION

Product PN	1221297	Mod. 984
Description	14.0 µm Hydrophobic Polycarbonate Track-Etched Membrane Discs	Rev. 02

14.0 µm Hydrophobic Polycarbonate Track Etched Membrane Discs







PRODUCT DESCRIPTION	14.0 um PCTE Discs, PVP Free			
	Part Number	Geometry	Dimensions	Packaging
	1221297	Disc	13 mm	100/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.			
	Nominal Characteristics:			
	Attribute		Result	
	Thickness (um)		9-11 um	
	BSA Protein Binding		5 µg/cm²	
	Max. Operating Temperature		284°F (140°C)	
Sealing Compatibility		Ultrasonic, Heat, Radio Frequency, and Insert Molding		



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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	<ul style="list-style-type: none">Primary packaging <table><tr><th>Product</th><th>Interior package</th><th>Exterior package</th></tr><tr><td>13 mm Discs</td><td>Discs separated by blue paper in a thermoformed tray</td><td>Clear/white plastic box</td></tr></table> <ul style="list-style-type: none">Each configuration will be labeled with:<ul style="list-style-type: none">QuantityProduct item code and descriptionManufacturing dateLot numberStorage conditionsLabel example <div><div><div><div><div>GVS North America</div><div>Sanford, ME 04073 - USA</div><div>www.gvs.com</div><div>+1 866-736-1250</div></div><div>PORETICS PCTE Membrane</div></div><div><div>Track Etched Membrane</div><div>Polycarbonate Track Etched (PCTE) Membrane disk diam. 13 mm, PCTE PVP-Free hydrophobic 14 µm</div><div><div>REF</div>1221297</div><div><div>LOT</div>SAMPLE</div><div><div>QTY</div>100 EA</div><div> Jan/2018</div></div><div><div><div>±9999999</div></div><div>MADE IN USA</div><div>Rev. 0</div></div></div></div>	Product	Interior package	Exterior package	13 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box								
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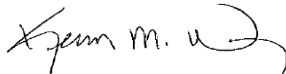
CERTIFICATE OF COMPLIANCE	A conformity declaration will be sent to the customer for each shipment with the lot number and date of manufacture. The Quality management system is in compliance with ISO 9001:2015.																										
VISUAL REQUIREMENTS	<i>Visual acceptance requirements apply when inspected under the below conditions:</i> Magnification: None Light type: Standard <table><tr><th colspan="3">Acceptance Requirement</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Creases/Folds: lines which do not disappear when the membrane is placed under tension</td><td>None</td><td rowspan="6">100% inspection</td></tr><tr><td>2</td><td>Cracks: areas where the membrane is bent to the point of fracture</td><td>None</td></tr><tr><td>3</td><td>Pinholes: openings or perforations in the membrane</td><td>None</td></tr><tr><td>4</td><td>Tension Lines: lines which disappear when the membrane is placed under tension</td><td>Max. 3 (not continuous)</td></tr><tr><td>5</td><td>Wrinkles (A): wavy surfaces which disappear when the membrane is placed under tension</td><td>Minimal</td></tr><tr><td>6</td><td>Wrinkles (B): wavy surfaces which do not disappear when the membrane is placed under tension</td><td>None</td></tr></table>				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
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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.