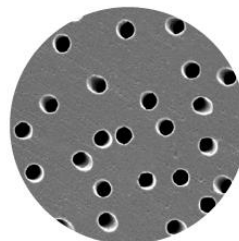




# PRODUCT SPECIFICATION

Product PN	1220969, 1221383, 1215288, 1222240, 1221385, 1220886	Mod. 984
Description	0.22 µm Polyester Track-Etched Membrane Discs and Sheets	Rev. 02

## 0.22 um Polyester Track Etched Membrane



PRODUCT DESCRIPTION	0.22 um PETE Discs and Sheets			
	Part Number	Geometry	Dimensions	Packaging
	1220886	Sheet	203x254mm	30/Pk
	1220969	Discs	13 mm	100/pk
	1221383	Discs	25 mm	100/pk
	1215288	Discs	47 mm	100/pk
	1222240	Discs	90 mm	30/pk
	1221385	Discs	142 mm*	20/pk
	*Bulk packaging available			
MANUFACTURER	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>			
INTENDED USE/ APPLICATION	Typical Applications <ul style="list-style-type: none"><li>• General filtration</li><li>• Removal of red blood cells from plasma</li><li>• Flow control of reagents through assays</li><li>• Precise filtration and pre-filtration</li><li>• Air analysis</li><li>• Filtration of aggressive solutions</li><li>• Cellular assays and diagnostics</li><li>• Trace element analysis</li></ul>			
MATERIALS	Film: Polyester Track Etched Membrane  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>			
PRODUCT CHARACTERISTICS	Nominal Characteristics:			

# PRODUCT SPECIFICATION

<b>Product PN</b>	1220969, 1221383, 1215288, 1222240, 1221385, 1220886	<b>Mod. 984</b>
<b>Description</b>	0.22 µm Polyester Track-Etched Membrane Discs and Sheets	<b>Rev. 02</b>

	<table><tr><th>Attribute</th><th>Result</th></tr><tr><td>Water Adsorption (% wt. gain 24 hr immersion)</td><td>0.24%</td></tr><tr><td>Migration of Filter Media</td><td>0</td></tr><tr><td>Autoclavable</td><td>Yes</td></tr><tr><td>Optical Properties</td><td>Semi-translucent</td></tr><tr><td>Residual Ash Weight Average</td><td>0.92 µg/cm²</td></tr><tr><td>Leachables</td><td>Negligible</td></tr><tr><td>Wetting Characteristics</td><td>Naturally Hydrophilic</td></tr><tr><td>Burst Strength Minimum</td><td>0.7 bar (10 psi)</td></tr><tr><td>Thickness</td><td>10-20 um</td></tr></table>	Attribute	Result	Water Adsorption (% wt. gain 24 hr immersion)	0.24%	Migration of Filter Media	0	Autoclavable	Yes	Optical Properties	Semi-translucent	Residual Ash Weight Average	0.92 µg/cm²	Leachables	Negligible	Wetting Characteristics	Naturally Hydrophilic	Burst Strength Minimum	0.7 bar (10 psi)	Thickness	10-20 um
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Burst Strength Minimum	0.7 bar (10 psi)																				
Thickness	10-20 um																				
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	<table><tr><th>Product</th><th>Interior package</th><th>Exterior package</th></tr><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>90, 142 mm Disc</td><td>Discs separated by blue paper</td><td>Round container</td></tr><tr><td>203 x 254 mm sheet</td><td>Sheets separated by blue paper</td><td>White mailer</td></tr></table> <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></ul> <p>Example label below:</p> <div><div><div><div><div><div></div><div></div></div><div><div></div><div></div></div><div><div></div><div></div></div></div><div><div></div><div></div></div><div><div></div><div></div></div></div><div><div></div><div></div></div><div><div></div><div></div></div></div><div><div></div><div></div></div><div><div></div><div></div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> <div><div></div><div></div></div> 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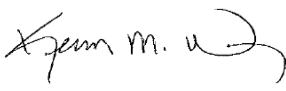
# PRODUCT SPECIFICATION

Product PN	1220969, 1221383, 1215288, 1222240, 1221385, 1220886	Mod. 984
Description	0.22 µm Polyester Track-Etched Membrane Discs and Sheets	Rev. 02

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	<i>Visual acceptance requirements apply when inspected under the below conditions:</i> 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
	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
PERFORMANCE REQUIREMENTS	Acceptance Requirement		Master Roll Sampling Plan
	1	Pore Size (µm)	0.16-0.20
	2	Pore Density (pores/cm <sup>2</sup> )	3.0x10E8±15%
	3	Air Flow (L/min/cm <sup>2</sup> @ 10 psi)	≥3
	4	Bubble Point (psi) (measured using IPA)	≥20 (1.3 bar)

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.

## REVISIONS AND APPROVALS:

DATE	REV	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
8/7/18	0	Initial Release	Yuander Ju/Director, Track Etch Membrane 	Kevin Wrigley/Director, Quality 



# PRODUCT SPECIFICATION

Product PN	1220969, 1221383, 1215288, 1222240, 1221385, 1220886	Mod. 984
Description	0.22 µm Polyester Track-Etched Membrane Discs and Sheets	Rev. 02

## 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.