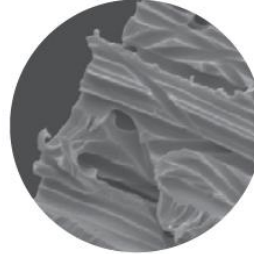




PRODUCT SPECIFICATION

Product PN	1222072, 1222073, 1215078, 1221231	Mod. 984
Description	20.0 µm Hydrophilic Polycarbonate Track-Etched Membrane Sheets	Rev. 02

20.0 um Hydrophilic Polycarbonate Track Etched Membrane Sheets



PRODUCT DESCRIPTION	20.0 um PCTE, treated with PVP			
	Part Number	Geometry	Dimensions	Packaging
	1222072	Disc	13 mm	100/Pk
	1222073	Disc	25mm	100/Pk
	1215078	Disc	47mm	100/Pk
	1221231	Sheet	203x254mm	30/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 treated with wetting agent Polyvinyl Pyrolidone (PVP) 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	<ul style="list-style-type: none"> • Absolute pore size and density allows for precise size separation • Direct thickness and pore size measurements provide accurate characteristics • Superior strength allows for aggressive handling • Low protein binding ensures clean results • Resists chemical staining to ease microscopic visualization • Passes USP Class VI testing 			



PRODUCT SPECIFICATION

Product PN	1222072, 1222073, 1215078, 1221231	Mod. 984
Description	20.0 µm Hydrophilic Polycarbonate Track-Etched Membrane Sheets	Rev. 02

Nominal Characteristics:

Attribute	Result
Thickness (µm)	9-11 µm
BSA Protein Binding	5 µg/cm ²
Max. Operating Temperature	284°F (140°C)
Sealing Compatibility	Ultrasonic, Heat, Radio Frequency, and Insert Molding
Refractive Indices	Birefringent at 1.584 and 1.625
Water Adsorption (% wt. gain 24-hr immersion)	0.24%
Residual Ash Weight Average	0.92 µg/cm ²
Leachables	Negligible
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 temperature, 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

- Primary packaging

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 sheet	Sheets separated by blue paper	White mailer

- Each configuration will be labeled with:
 - Quantity
 - Product item code and description
 - Manufacturing date
 - Lot number
 - Storage conditions



PRODUCT SPECIFICATION

Product PN	1222072, 1222073, 1215078, 1221231	Mod. 984
Description	20.0 µm Hydrophilic Polycarbonate Track-Etched Membrane Sheets	Rev. 02

Example label below:

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	

PERFORMANCE REQUIREMENTS

	Acceptance Requirement	Specification	Master Roll Sampling Plan
1	Pore Size (µm)	19.0 - 20.0	left, middle, & right every 120m
2	Pore Density (pores/cm ²)	4.0x10E4±15%	left, middle, & right every 120m
3	Air Flow (L/min/cm ² @ 5psi)	≥12	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	N/A	left, middle, & right every 120m


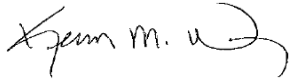
This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



PRODUCT SPECIFICATION

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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.