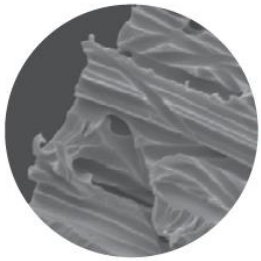
PRODUCT SPECIFICATION

Product PN	**1215618, 1215619, 1215620, 1224680, 1222026, 1221485, 1220861, 1222027, 3034261**	**Mod. 984**
Description	**0.6 µm Hydrophilic Polycarbonate Track-Etched Membrane Discs and Sheets**	**Rev. 02**

0.6 µm Hydrophilic Polycarbonate Track Etched Membrane



PORETICS PCTE Membrane

PRODUCT DESCRIPTION

0.6 µm PCTE Hydrophilic Membrane

Part Number	Geometry	Dimensions	Packaging
1215618	Disc	13 mm	100/Pk
1215619	Disc	25mm	100/Pk
1215620	Disc	47mm	100/Pk
1224680	Disc	76 mm	100/pk
1222026	Disc	90 mm	30/pk
1221485	Disc	142 mm	20/pk
1220861	Disc	293 mm	20/pk
1222027	Sheet	203 x 254 mm	30/pk
3034261	Sheet	30 x 3000 mm	1/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:

- Epifluorescence
- Observation of microorganisms
- Direct counting of microorganisms
- Water testing

MATERIALS

Film: Polycarbonate treated with wetting agent polyvinylpyrrolidone (PVP)

Regulatory Documentation Required:

☐Biocompatibility according ISO 10993-1
☐IMDS
☒Rohs, directive 2002/95/CE
☒BSE/TSE, directive 2003/32/CE
☐DEHP plasticizer and latex free
☐Aging
☒Reach 1907/2006/CE (hazardous substances regulation)
☐Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)
☒Conflict minerals
☒USP Class VI

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PRODUCT CHARACTERISTICS

- 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

Nominal Characteristics:

Attribute	Result
Thickness (um)	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 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

Product	Interior package	Exterior package
13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box
76, 90, 142, 293 mm Disc	Discs separated by blue paper	Round container
203 x 254 mm sheet	Sheets separated by blue paper	White mailer
300 x 3000 mm	Single sheet wrapped around a 3 in core	Cardboard box

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

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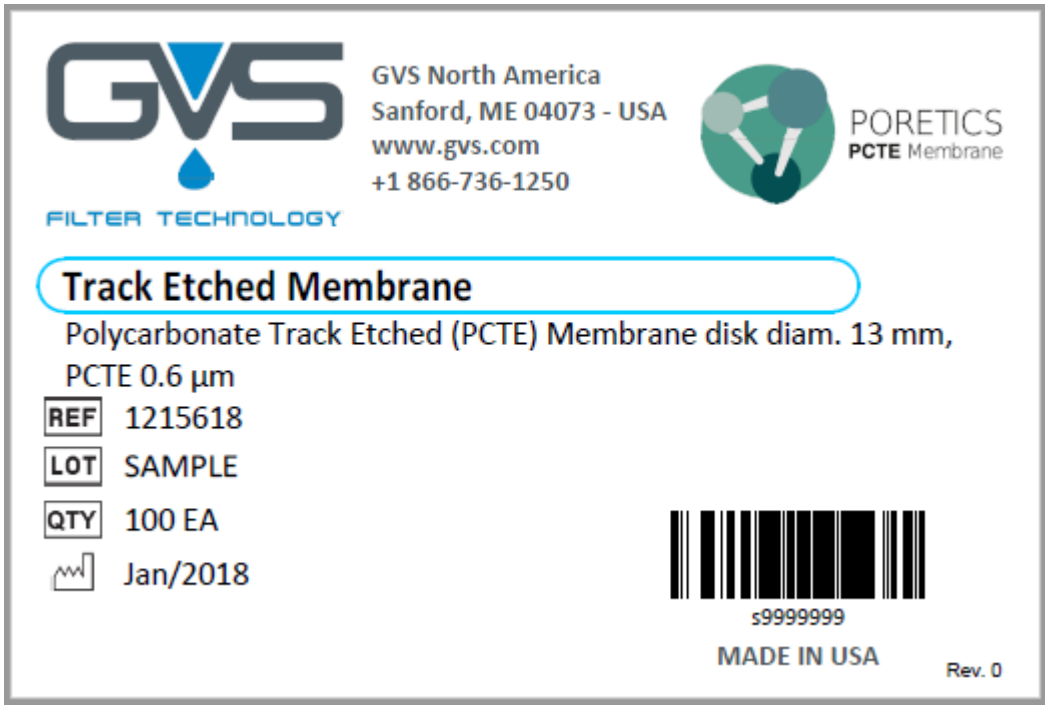
Example label below:



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)	0.48-0.60	left, middle, & right every 120m
2	Pore Density (pores/cm^2)	3.0x10E7±15%	left, middle, & right every 120m
3	Air Flow (L/min/cm^2 @ 10 psi)	≥7.5	left, middle, & right every 120m

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	4	Bubble Point (psi) (measured using IPA)	≥9	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.

REVISIONS AND APPROVALS:

DATE	REV	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
10/23/19	0	Initial Release	Yuander Ju/Director, 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.