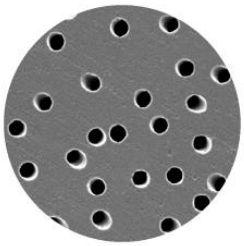
PRODUCT SPECIFICATION

Product PN	**1221387, 1221388, 1215373, 1220702, 1221389, 1222242**	**Mod. 984**
Description	**0.4µm Polyester Track-Etched Membrane Discs and Sheets**	**Rev. 02**

0.4 um Polyester Track Etched Membrane



PORETICS PETE Membrane

PRODUCT DESCRIPTION	0.4 um PETE Discs and Sheets **Part Number** / **Geometry** / **Dimensions** / **Packaging** 1222242 / Sheet / 203x254mm / 30/Pk 1221387 / Discs / 13 mm / 100/pk 1221388 / Discs / 25 mm / 100/pk 1215373 / Discs / 47 mm / 100/pk 1220702 / Discs / 90 mm / 30/pk 1221389 / 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: CustomerCareGVSLS@gvs.com Website: www.gvs.com
INTENDED USE/ APPLICATION	Typical Applications • General filtration • Removal of red blood cells from plasma • Flow control of reagents through assays • Precise filtration and pre-filtration • Air analysis • Filtration of aggressive solutions • Cellular assays and diagnostics • Trace element analysis
MATERIALS	Film: Polyester Track Etched Membrane 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
PRODUCT CHARACTERISTICS	**Nominal Characteristics:**

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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/cm^2
Specific Gravity	1.40
Leachables	Negligible
Wetting Characteristics	Naturally Hydrophilic
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

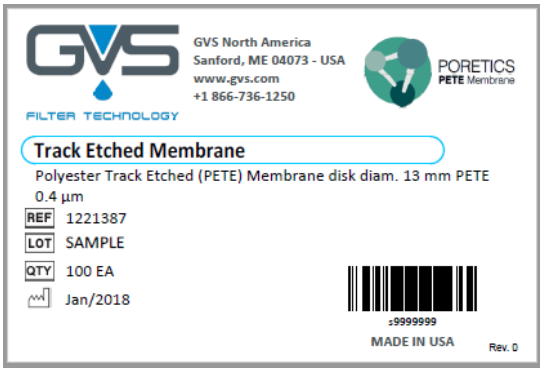
This product is compatible with these sterilization techniques:
☒EtO
☒Gamma (25 kGy)
☒Autoclave (121°C)
*Sterilization is not required

PACKAGING AND LABELING

Product	Interior package	Exterior package
13, 25, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box
90, 142, mm Disc	Discs separated by blue paper	Round container
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

Example label below:



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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

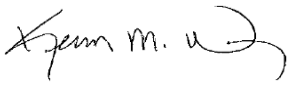
	Acceptance Requirement		Sampling Plan
1	Creases/Folds: lines which do not disappear when the membrane is placed under tension	None	100% inspection
2	Cracks: areas where the membrane is bent to the point of fracture	None	
3	Pinholes: openings or perforations in the membrane	None	
4	Tension Lines: lines 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	

PERFORMANCE REQUIREMENTS

	Acceptance Requirement	Specification	Master Roll Sampling Plan
1	Pore Size (µm)	0.32-0.40	left, middle, & right every 120m
2	Pore Density (pores/cm^2)	1.0x10E8±15%	left, middle, & right every 120m
3	Air Flow (L/min/cm^2 @ 10 psi)	≥7.5	left, middle, & right every 120m
4	Bubble Point (psi) (measured using IPA)	≥12 (0.8 bar)	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)
8/7/18	0	Initial Release	Yuander Ju/Director, Track Etch Membrane	Kevin Wrigley/Director, Quality 

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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.