

PRODUCT SPECIFICATION

Product PN	3000831, 1230083, 1264421, 1230084, 1230085, 1230444, 3063874, 1230086, 3097642, 1230445, 1230046	Mod. 984
Description	0.45 µm Polyethersulfone Filtration Membrane Roll Stock	Rev. 01

0.45 µm Polyethersulfone (PES) Filtration Membrane Roll Stock



PRODUCT DESCRIPTION	0.45 μm WP PES roll stock																																				
	<table><tr><th>Part Number</th><th>Roll Width</th><th>Typical Length*</th></tr><tr><td>3000831</td><td>31 in (78.7 cm), +/- 0.25 in (0.635 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>1230083</td><td>21 in (53.3 cm), +/- 0.25 in (0.635 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>1264421</td><td>20 in (50.8 cm), +/- 0.25 in (0.635 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>1230084</td><td>13 in (33 cm), +/- 0.25 in (0.635 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>1230085</td><td>12 in (30.5 cm), +/- 0.25 in (0.635 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>1230444</td><td>10 in (25.4 cm), +/- 0.25 in (0.635 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>3063874</td><td>6 in (15.2 cm), +/- 0.016 in (0.040 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>1230086</td><td>3.1 in (79 mm), +/- 0.016 in (0.040 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>3097642</td><td>1.5 in (38 mm), +/- 0.016 in (0.040 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>1230445</td><td>1.34 in (34 mm), +/- 0.016 in (0.040 cm)</td><td>500 feet (152.4 m)</td></tr><tr><td>1230446</td><td>1 in (25 mm), +/- 0.016 in (0.040 cm)</td><td>500 feet (152.4 m)</td></tr></table>	Part Number	Roll Width	Typical Length*	3000831	31 in (78.7 cm), +/- 0.25 in (0.635 cm)	500 feet (152.4 m)	1230083	21 in (53.3 cm), +/- 0.25 in (0.635 cm)	500 feet (152.4 m)	1264421	20 in (50.8 cm), +/- 0.25 in (0.635 cm)	500 feet (152.4 m)	1230084	13 in (33 cm), +/- 0.25 in (0.635 cm)	500 feet (152.4 m)	1230085	12 in (30.5 cm), +/- 0.25 in (0.635 cm)	500 feet (152.4 m)	1230444	10 in (25.4 cm), +/- 0.25 in (0.635 cm)	500 feet (152.4 m)	3063874	6 in (15.2 cm), +/- 0.016 in (0.040 cm)	500 feet (152.4 m)	1230086	3.1 in (79 mm), +/- 0.016 in (0.040 cm)	500 feet (152.4 m)	3097642	1.5 in (38 mm), +/- 0.016 in (0.040 cm)	500 feet (152.4 m)	1230445	1.34 in (34 mm), +/- 0.016 in (0.040 cm)	500 feet (152.4 m)	1230446	1 in (25 mm), +/- 0.016 in (0.040 cm)	500 feet (152.4 m)
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*Typical lengths assume ≤ 3 splices per roll and a tolerance of +/-10%																																					
MANUFACTURE NAME	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">• Protein and enzyme filtration and sterilization• Biological fluid filtration and sterilization• Pharmaceutical sterilization• Environmental water studies• Industrial water filtration• IV filters• IV drug delivery• TPN delivery																																				
MATERIALS	Film: Polyethersulfone (PES) 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)																																				

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	<input checked="" type="checkbox"/> Conflict minerals <input checked="" type="checkbox"/> USP Class VI																		
PRODUCT CHARACTERISTICS	<ul style="list-style-type: none">• White membrane on plastic cores• USP Class VI compliant• Hydrophilic• Autoclavable• Broad sealing compatibility, including, ultrasonic, heat, radio frequency and insert molding• Metals Ions, Chloride and Sulfates: Not detectable (Analytical screen by ICP)																		
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	<p>This is a non-sterile product, compatible with these sterilization techniques*:</p> <p><input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (25 kGy) <input checked="" type="checkbox"/> Autoclave (121°C) <input checked="" type="checkbox"/> eBeam</p> <p><i>*user has the responsibility to validate their process</i></p>																		
PACKAGING AND LABELING	<ul style="list-style-type: none">• Wrap the outside of the rolls with Patapar• Double bag the wrapped rolls in heat seal bags<ul style="list-style-type: none">◦ Label inside core and inside bag with part number, width, length and lot number• Insert bag into each end of core• Add Hubs to core• Add bubble wrap in box. Close, Seal, Box																		
CERTIFICATE OF COMPLIANCE	A conformity declaration will be sent to the customer for each shipment with lot number and date of manufacture. The Quality management system is in compliance with ISO 9001.																		
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions: Magnification: None Light type: Ambient</p> <table><tr><th colspan="3">Acceptance Requirement</th></tr><tr><td colspan="2">Splices per roll</td><td>≤ 3</td></tr></table>			Acceptance Requirement			Splices per roll		≤ 3										
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PERFORMANCE REQUIREMENTS	<table><tr><th colspan="3">Acceptance Requirement</th><th>Standard Test Methods</th></tr><tr><td>1</td><td>Thickness</td><td>110-150 µm</td><td>N/A</td></tr><tr><td>2</td><td>Water Flow Rate</td><td>Min 39 mL/min/cm² @ 10 psi</td><td>ASTM F 316-03 (2011)</td></tr><tr><td>3</td><td>Bubble Point</td><td>35-50 psi (2.4-3.4 bar)</td><td>ASTM F 316-03 (2011)</td></tr></table>			Acceptance Requirement			Standard Test Methods	1	Thickness	110-150 µm	N/A	2	Water Flow Rate	Min 39 mL/min/cm² @ 10 psi	ASTM F 316-03 (2011)	3	Bubble Point	35-50 psi (2.4-3.4 bar)	ASTM F 316-03 (2011)
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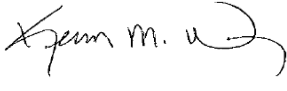

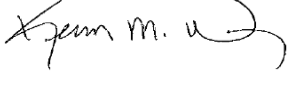
This material specification describes the properties of product above indicated.

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)
6/8/18	0	Initial Release	Gil Tavares/Process Development Engineer 	Kevin Wrigley/Director of Quality 
3/21/19	1	Corrected the splices misprint; removed support material (N/A); removed internal sampling plan (available at GVS NA by request)	Gil Tavares/Process Development Engineer 	Kevin Wrigley/Director of 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.