

<b>Product PN</b>	1213788, 1213789, 1214881, 1213790, 3013826, 1213791, 1213792, 1213793, 1222855	<b>Mod. 984</b>
<b>Description</b>	0.8 µm Nylon Filtration Membrane Discs and Sheets	<b>Rev. 01</b>

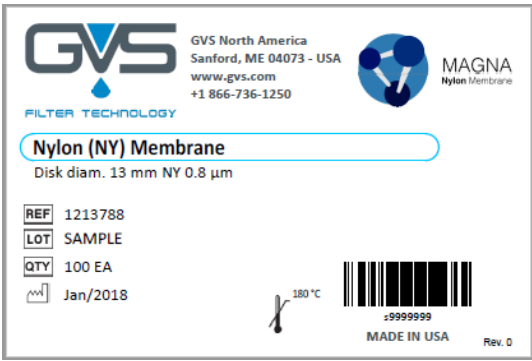
## 0.8 µm Nylon (NY) Filtration Membrane Discs and Sheets



<b>PRODUCT DESCRIPTION</b>	0.8 µm Nylon Discs and Sheets			
	<b>Part Number</b>	<b>Geometry</b>	<b>Dimensions</b>	<b>Packaging</b>
	1213788	Disc	13 mm	100/Pk
	1213789	Disc	25 mm	100/Pk
	1214881	Disc	37 mm	100/Pk
	1213790	Disc	47mm	100/Pk
	3013826	Disc	47mm, gridded	100/Pk
	1213791	Disc	90 mm	25/pk
	1213792	Disc	142 mm	25/pk
	1213793	Disc	293 mm	25/pk
1222855	Sheet	200 x 200 mm	5/pk	
<b>MANUFACTURE NAME</b>	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>			
<b>INTENDED USE/ APPLICATION</b>	Typical Applications: <ul style="list-style-type: none"> <li>• IV Filters</li> <li>• Oncology drug administration</li> <li>• Long term administration</li> <li>• Radiolabeled and non-radiolabeled detection systems</li> <li>• Northern and Southern blots (nucleic acids)</li> <li>• Multiple reprobings</li> <li>• Alkaline transfers</li> <li>• DNA fingerprinting</li> <li>• UV crosslinking</li> </ul>			
<b>MATERIALS</b>	Film: Nylon (N66), supported with PET fabric  Regulatory Documentation Required: <ul style="list-style-type: none"> <li><input type="checkbox"/> Biocompatibility according to 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> </ul>			

# PRODUCT SPECIFICATION

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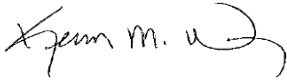
	<input checked="" type="checkbox"/> Conflict minerals <input checked="" type="checkbox"/> USP Class VI																		
<b>PRODUCT CHARACTERISTICS</b>	<ul style="list-style-type: none"> <li>USP Class VI compliant</li> <li>Hydrophilic</li> <li>Max. operating temperature: 365°F (180°C)</li> <li>Autoclavable</li> <li>Broad sealing compatibility, including ultrasonic, heat, radio frequency and insert molding</li> </ul>																		
<b>PRODUCT SHELF LIFE</b>	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.																		
<b>STERILIZATION</b>	<p>This is a non-sterile product, compatible with these sterilization techniques*:</p> <input checked="" type="checkbox"/> Gamma (25 kGy)6.5 <input checked="" type="checkbox"/> Autoclave (121°C) <input checked="" type="checkbox"/> eBeam																		
	<i>*user has the responsibility to validate their process</i>																		
<b>PACKAGING AND LABELING</b>	<table border="1"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>13, 25, 37, 47 mm Discs</td> <td>Discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box</td> </tr> <tr> <td>47 mm, gridded</td> <td>Gridded 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>200 x 200 mm sheet</td> <td>Sheets separated by blue paper</td> <td>White mailer</td> </tr> <tr> <td>30 cm x 3 m</td> <td>Single sheet wrapped on a plastic core</td> <td>Cardboard box</td> </tr> </tbody> </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 style="border: 1px solid black; padding: 10px; width: fit-content; margin: 10px auto;">  </div>	Product	Interior package	Exterior package	13, 25, 37, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	47 mm, gridded	Gridded discs separated by blue paper in a thermoformed tray	Clear/white plastic box	90, 142 mm Disc	Discs separated by blue paper	Round container	200 x 200 mm sheet	Sheets separated by blue paper	White mailer	30 cm x 3 m	Single sheet wrapped on a plastic core	Cardboard box
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<b>CERTIFICATE OF COMPLIANCE</b>	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.			
<b>PERFORMANCE REQUIREMENTS</b>	<b>Acceptance Requirement</b>		<b>Standard Test Method</b>	
	1	Thickness	65-130 µm	N/A
	2	Water Flow Rate	Min 43 mL/min/cm <sup>2</sup> @ 10 psi	ASTM F 316-03 (2011)
	3	Bubble Point	13-28 psi (0.8-1.9 bar)	ASTM F 316-03 (2011)
<p>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.</p>				

## 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 

## 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.