

<b>Product PN</b>	1213794, 1213796, 1230356, 1213797, 1214880, 1213798, 1213799, 123800, 1222854, 1214956	<b>Mod. 984</b>
<b>Description</b>	1.2 Nylon (NY) Filtration Membrane in Discs and Sheets	<b>Rev. 01</b>

**1.2 µm Nylon (NY) Filtration Membrane in Discs and Sheets**



<b>PRODUCT DESCRIPTION</b>	1.2 µm Nylon (Ny) membrane packaged in sheets and discs			
	<b>Part Number</b>	<b>Geometry</b>	<b>Dimensions</b>	<b>Packaging</b>
	1213794	Disc	13mm	100/Pk
	1213796	Disc	25mm	100/Pk
	1230356	Disc	37mm	100/Pk
	1213797	Disc	47mm	100/Pk
	1214880	Disc	47mm, Gridded	100/Pk
	1213798	Disc	90mm	25/Pk
	1213799	Disc	142mm	25/Pk
	1213800	Disc	293mm	25/Pk
	1222854	Sheet	200x200mm	5/Pk
1214956	Sheet	30cmx3m	1/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>	These are filtration membranes, often used for sterilization and clarification of aqueous and organic solvent solutions, and HPLC sample preparation.			
<b>MATERIALS</b>	Membrane: Nylon (N66), supported with PET fabric  Regulatory Documentation Required: <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 SPECIFICATION

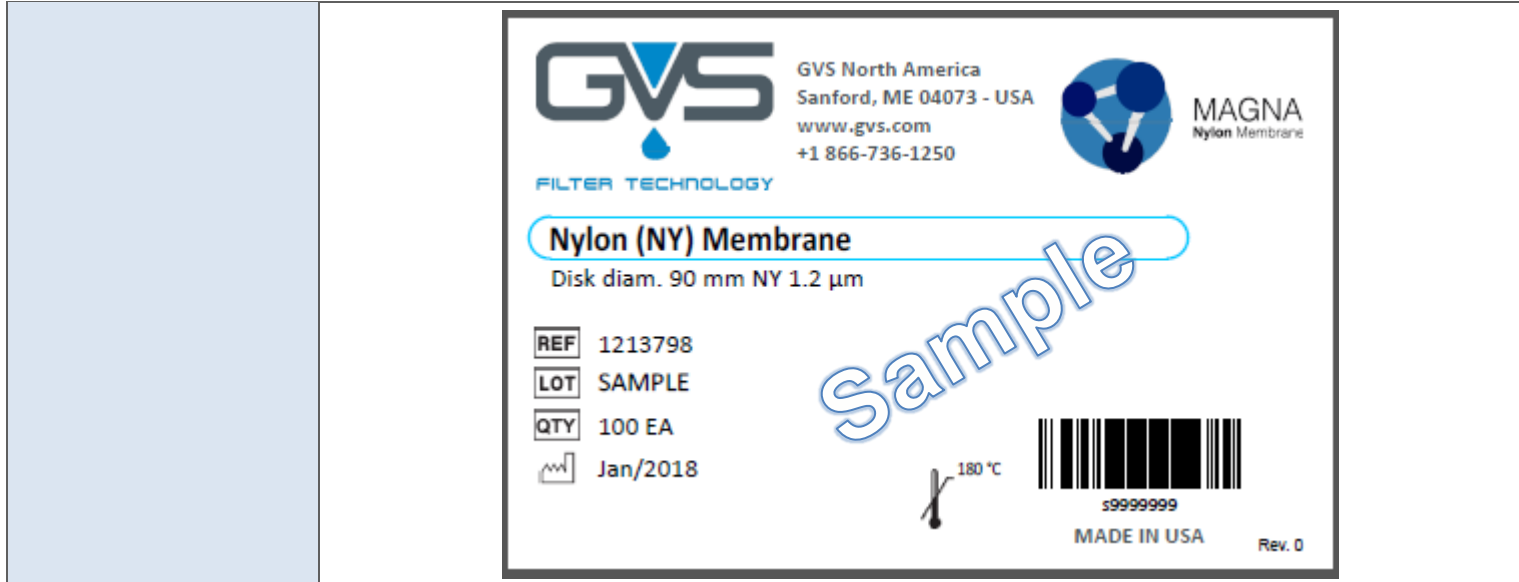
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<b>PRODUCT CHARACTERISTICS</b>	<ul style="list-style-type: none"> <li>• White membrane configured in discs or sheets</li> <li>• USP Class VI compliant</li> <li>• Hydrophilic</li> <li>• Max. operating temperature: 365°F (180°C)</li> <li>• Autoclavable</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 temperature, 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> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> EtO</li> <li><input checked="" type="checkbox"/> Gamma (25 kGy)6.5</li> <li><input checked="" type="checkbox"/> Autoclave (121°C)</li> </ul> <p><i>*user has the responsibility to validate their process</i></p>												
<b>PACKAGING AND LABELING</b>	<ul style="list-style-type: none"> <li>• Primary packaging:</li> </ul> <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, 4 5/8" x 3 1/2" x 3/4"</td> </tr> <tr> <td>90, 142, 293 mm Discs</td> <td>Discs separated by blue paper</td> <td>Size specific top and bottom</td> </tr> <tr> <td>Sheets</td> <td>Discs separated by blue paper in a zip-lock plastic pab</td> <td>Mailer 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>	Product	Interior package	Exterior package	13, 25, 37, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box, 4 5/8" x 3 1/2" x 3/4"	90, 142, 293 mm Discs	Discs separated by blue paper	Size specific top and bottom	Sheets	Discs separated by blue paper in a zip-lock plastic pab	Mailer box
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**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**  
*Visual acceptance requirements apply when inspected under below conditions:*  
Magnification: None  
Light type: Ambient

Acceptance Requirement		Sampling Plan
Creases/Folds	None	100% Inspection
Cracks	None	
Pin Holes	None	
Wrinkles	None	
Tension Lines	None	

**PERFORMANCE REQUIREMENTS**

Acceptance Requirement			Standard Test Method
1	Thickness	65-130 µm	N/A
2	Water Flow Rate	Min 51 mL/min/cm <sup>2</sup> @ 10 psi	ASTM F 316-03 (2011)
3	Bubble Point	11-22 psi (0.7-1.5 bar)	ASTM F 316-03 (2011)

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.


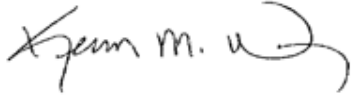


FILTER TECHNOLOGY

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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)
10/18/19	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.