

<b>Product PN</b>	1213774, 1213775, 1228824, 1213776, 1220671, 1213825, 1213845, 1213778, 1213779, 1213780, 1222857, 1225982	<b>Mod. 984</b>
<b>Description</b>	0.4 µm Nylon Filtration Membrane Discs and Sheets	<b>Rev. 01</b>

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



<b>PRODUCT DESCRIPTION</b>	0.4 µm Nylon Discs and Sheets			
	<b>Part Number</b>	<b>Geometry</b>	<b>Dimensions</b>	<b>Packaging</b>
	1213774	Disc	13 mm	100/Pk
	1213775	Disc	25 mm	100/Pk
	1228824	Disc	37 mm	100/Pk
	1213776	Disc	47mm	100/Pk
	1213825	Disc	47mm, black grid	100/Pk
	1220671*	Disc	47mm, white grid	1000/Pk
	1213845*	Disc	47mm, white grid	200/Pk
	1213778	Disc	90 mm	25/pk
	1213779	Disc	142 mm	25/pk
	1213780	Disc	293 mm	25/pk
	1222857	Sheet	200 x 200 mm	5/pk
	1225982	Sheet	30 cm x3 m	1/pk
	*Sterile, individually packed			
<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 ISO 10993-1</li> <li><input type="checkbox"/> IMDS</li> <li><input checked="" type="checkbox"/> Rohs, directive 2002/95/CE</li> </ul>			



# PRODUCT SPECIFICATION

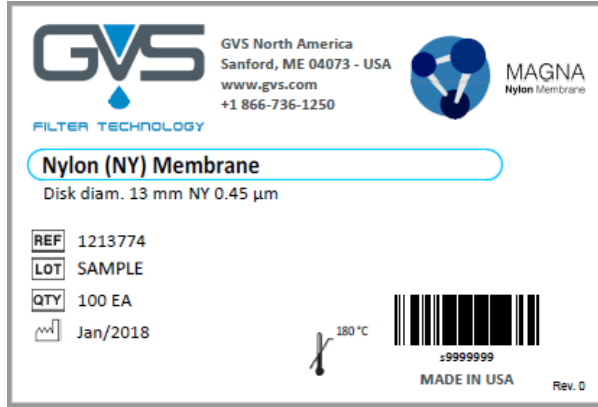
<b>Product PN</b>	1213774, 1213775, 1228824, 1213776, 1220671, 1213825, 1213845, 1213778, 1213779, 1213780, 1222857, 1225982	<b>Mod. 984</b>
<b>Description</b>	<b>0.4 µm Nylon Filtration Membrane Discs and Sheets</b>	<b>Rev. 01</b>

	<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																										
<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 temperature, in a dry place, free of dust and not exposed to direct sunlight.																										
<b>STERILIZATION</b>	This is a non-sterile product, compatible with these sterilization techniques*:  <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>PN 1213825</td> <td>Black gridded discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic box</td> </tr> <tr> <td>PN 1220671</td> <td>1000 discs individually packaged and sterile</td> <td>Cardboard box</td> </tr> <tr> <td>PN 1213845</td> <td>200 discs individually packaged and sterile</td> <td>Cardboard box</td> </tr> <tr> <td>90, 142, 293 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>			Product	Interior package	Exterior package	13, 25, 37, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box	PN 1213825	Black gridded discs separated by blue paper in a thermoformed tray	Clear/white plastic box	PN 1220671	1000 discs individually packaged and sterile	Cardboard box	PN 1213845	200 discs individually packaged and sterile	Cardboard box	90, 142, 293 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
Product	Interior package	Exterior package																									
13, 25, 37, 47 mm Discs	Discs separated by blue paper in a thermoformed tray	Clear/white plastic box																									
PN 1213825	Black gridded discs separated by blue paper in a thermoformed tray	Clear/white plastic box																									
PN 1220671	1000 discs individually packaged and sterile	Cardboard box																									
PN 1213845	200 discs individually packaged and sterile	Cardboard box																									
90, 142, 293 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																									



# PRODUCT SPECIFICATION

<b>Product PN</b>	1213774, 1213775, 1228824, 1213776, 1220671, 1213825, 1213845, 1213778, 1213779, 1213780, 1222857, 1225982	<b>Mod. 984</b>
<b>Description</b>	0.4 µm Nylon Filtration Membrane Discs and Sheets	<b>Rev. 01</b>


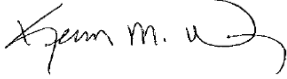


**CERTIFICATE OF COMPLIANCE** A conformity declaration will be sent to the customer for each shipment with lot number and date of manufacture. The Quality management system is in compliance with ISO 9001.

<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 18 mL/min/cm <sup>2</sup> @ 10 psi	ASTM F 316-03 (2011)
	3	Bubble Point	30-45 psi (2.0-3.1 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.

## 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 



FILTER TECHNOLOGY

# PRODUCT SPECIFICATION

<b>Product PN</b>	1213774, 1213775, 1228824, 1213776, 1220671, 1213825, 1213845, 1213778, 1213779, 1213780, 1222857, 1225982	<b>Mod. 984</b>
<b>Description</b>	0.4 µm Nylon Filtration Membrane Discs and Sheets	<b>Rev. 01</b>

## 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.*