

Product PN	1213760, 1213761, 1213762, 1213763, 1213764, 1213765, 1222859, 1241477	Mod. 984
Description	0.1 µm Nylon Filtration Membrane Discs and Sheets	Rev. 01

0.1 µm Nylon (NY) Filtration Membrane Discs and Sheets



MAGNA
Nylon Membrane

PRODUCT DESCRIPTION	0.1 µm Nylon Discs and Sheets			
	Part Number	Geometry	Dimensions	Packaging
	1213760	Disc	13 mm	100/Pk
	1213761	Disc	25 mm	100/Pk
	1213762	Disc	47mm	100/Pk
	1213763	Disc	90 mm	25/pk
	1213764	Disc	142 mm	25/pk
	1231765	Disc	293 mm	25/pk
	1222859	Sheet	200 x 200 mm	5/pk
1241477	Sheet	30 cm x3 m	1/pk	
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"> • IV Filters • Oncology drug administration • Long term administration • Radiolabeled and non-radiolabeled detection systems • Northern and Southern blots (nucleic acids) • Multiple reprobings • Alkaline transfers • DNA fingerprinting • UV crosslinking 			
MATERIALS	Film: Nylon (N66), supported with PET fabric 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) <input checked="" type="checkbox"/> Conflict minerals 			



PRODUCT SPECIFICATION

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	<input checked="" type="checkbox"/> USP Class VI																	
PRODUCT CHARACTERISTICS	<ul style="list-style-type: none"> • USP Class VI compliant • Hydrophilic • Max. operating temperature: 365°F (180°C) • Autoclavable • Broad sealing compatibility, including ultrasonic, heat, radio frequency and insert molding 																	
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 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>																	
PACKAGING AND LABELING	<table border="1"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>13, 25, 47 mm Discs</td> <td>Discs separated by blue paper in a thermoformed tray</td> <td>Clear/white plastic 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>	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, 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		
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<ul style="list-style-type: none"> • Each configuration will be labeled with: <ul style="list-style-type: none"> ○ 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 lot number and date of manufacture. The Quality management system is in compliance with ISO 9001.

PERFORMANCE REQUIREMENTS	Acceptance Requirement		
	1	Thickness	65-130 µm
	2	Water Flow Rate	Min 2 mL/min/cm ² @ 10 psi
	3	Bubble Point	70-100 psi (4.8-6.8 bar)

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

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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.