

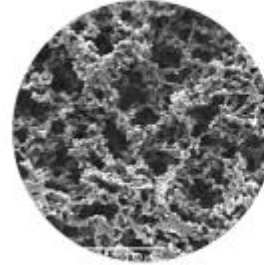
Product PN 1214527, 1214533, 1214554, 1214565

Mod. 984

Description 0.1 µm Nitrocellulose (NC) Filtration Membrane in Discs

Rev. 01

0.1 µm Nitrocellulose (NC) Filtration Membrane in Discs



PRODUCT DESCRIPTION	0.1 µm Nitrocellulose (NC) Filtration membrane packaged in discs						
	Part Number	Color	Gridded	Geometry	Dimensions	Packaging	
	1214527	White	No	Disc	25mm	100/Pk.	
	1214533	White	No	Disc	47mm	100/Pk.	
	1214554	White	No	Disc	142mm	25/Pk	
	1214565	White	No	Disc	293mm	25/Pk.	
MANUFACTURE NAME	<p>GVS North America, Inc. 63 Community Drive Sanford, ME 04073 Phone: +1.866.736.1250 Email: CustomerCareGVSLs@gvs.com Website: www.gvs.com</p>						
INTENDED USE/ APPLICATION	<p>These products are sterilizing filtration membranes, often used for air monitoring, aqueous filtration, sterility testing, gravimetric analysis with ashing technique, and microbiological and particulate analysis,.</p>						
MATERIALS	<p>Membrane: Nitrocellulose (NC) Filtration membrane</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input 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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PRODUCT CHARACTERISTICS	<ul style="list-style-type: none"> • White membrane configured in discs • High flow rates, fast filtration rates • Uniform pore structure; consistent flow and diffusion rates • Hydrophilic • Max. operating temperature: 356°F (180°C) 									
WARNINGS	Nitrocellulose membrane is highly flammable. Keep away from heat and open flame. Flash point is approximately 200°C.									
PRODUCT SHELF LIFE	5 years in normal storage conditions: Store the product at room temperature away from chemical vapors, 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> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> EtO <input checked="" type="checkbox"/> Gamma (25 - 40 kGy) <input checked="" type="checkbox"/> Autoclave (121°C) <input checked="" type="checkbox"/> eBeam <p><i>*user has the responsibility to validate their process</i></p>									
PACKAGING AND LABELING	<ul style="list-style-type: none"> • Primary packaging: <table border="1" data-bbox="386 1160 1497 1317"> <thead> <tr> <th>Product</th> <th>Interior package</th> <th>Exterior package</th> </tr> </thead> <tbody> <tr> <td>25, 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>142, 293 mm Discs</td> <td>Discs separated by blue paper</td> <td>Size specific top and bottom</td> </tr> </tbody> </table> • Each configuration will be labeled with: <ul style="list-style-type: none"> ○ Quantity ○ Product item code and description ○ Manufacturing date ○ Lot number ○ Storage conditions • An example of a label is below 	Product	Interior package	Exterior package	25, 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"	142, 293 mm Discs	Discs separated by blue paper	Size specific top and bottom
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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


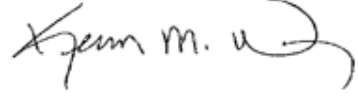
Acceptance Requirement			Standard Test Method
1	Thickness	110-190 µm	N/A
2	Water Flow Rate	Min 6 mL/min/cm ² @ 10 psi	ASTM F 316-03 (2011)
3	Bubble Point	80-110 psi (5.5-7.5 bar)	ASTM F 316-03 (2011)

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.

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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)
10/16/19	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.