

Product PN 1216721, 1216719, 1215230, 1214991, 1214923, 1213643, 1222980, 1215237, 1214866,

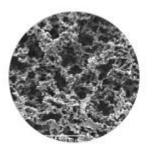
1215249, 1213145

Mod. 984

Description 0.45 µm Nitrocellulose (NC) Filtration Membrane in Discs, Sterile

Rev. 01

0.45 µm Nitrocellulose (NC) Filtration Membrane in Discs, Sterile





PRODUCT DESCRIPTION	0.45 µm Sterile Nitrocellulose (NC) Filtration membrane packaged in discs					
	Part Number	Geometry	Color	Individually Packaged	Dimensions	Packaging
	1216721	Disc	White/black grid	Without Pad	47mm	100/Pk
	1216719	Disc	Black/white grid	Without Pad	47mm	100/Pk
	1215230	Disc	White/black grid	Without Pad	47mm	200/Pk
	1214991	Disc	Black/white grid	Without Pad	47mm	200/Pk
	1214923	Disc	White/black grid	Without Pad	47mm	1000/Pk
	1213643	Disc	Black/white grid	Without Pad	47mm	1000/Pk
	1222980	Disc	White/black grid	Without Pad	50mm	1000/Pk
	1215237	Disc	White/black grid	With Pad	47mm	100/Pk
	1214866	Disc	Black/white grid	With Pad	47mm	100/Pk
	1215249	Disc	White/black grid	With Pad	47mm	1000/Pk
	1213145	Disc	Black/white grid	With Pad	47mm	1000/Pk
	Sanford, ME 04073 Phone: +1.866.736.1250 Email: CustomerCareGVSLS@gvs.com Website: www.gvs.com					
INTENDED USE/ APPLICATION	These products are sterile filtration membranes, often used for air monitoring, bioassays, aqueous filtration, gravimetric analysis with ashing technique, microbiology and particulate analysis, and cytology.					
MATERIALS	Membrane: Nitrocellulose (NC) Filtration membrane Pad (if applicable): 100% cotton paper					
	Regulatory Documentation Required: □ Biocompatibility according ISO 10993-1 □ IMDS					
	□Rohs, directive 2002/95/CE □SE/TSE, directive 2003/32/CE					
	□DEHP plasticizer and latex free					
	□Aging	actionzor and in	atox 1100			
		07/2006/CE /	hazardous substanc	es regulation)		
		· ·	•	- '	vaoroup cubotess	200)
	☐ Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) ☐ Conflict minerals					
	△ Conflict m	ıınerais				



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Rev 01

Description 0.45	5 μm Nitrocellulose (NC) F	Filtration Membrane in Discs, Steri	le Rev. 01		
	⊠USP Class VI				
PRODUCT CHARACTERISTICS	 White or black gridded membrane configured in discs with or without padHigh flow rates, fast filtration rates Uniform pore structure; consistent flow and diffusion rates Sterile 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	3 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	This is a sterile product, sterilized by Gamma Irradiation				
PACKAGING AND LABELING	QuantityProduct i	Interior package Individually sealed disc (with or without pad) on a blue paper on will be labeled with: tem code and description turing date	Exterior package Box, 5 ½" x 2 ¾ " x 3 1/8"		

- Storage conditions

Example label below:





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Rev. 01

CE	RT	IFI	CA	TE	OF
CO	MF	LI	AN	CE	

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

Light type. Ambient		
Acceptance Requirement		Sampling Plan
Gridding	Visible	
Misaligned Grid Lines	None	
Pin Hole	None	1000/ Inapportion
Poor Seal of Pack	None	100% Inspection
Cut Seal of Pack	None	
Contaminates	None	

PERFORMANCE REQUIREMENTS

	Accept	Standard Test Method	
1	Thickness	N/A	
2	Water Flow Rate	Min 34 mL/min/cm ² @ 10 psi	ASTM F 316-03 (2011)
3	Bubble Point	30-42 psi (2.0-2.8 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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 Description
 0.45 μm Nitrocellulose (NC) Filtration Membrane in Discs, Sterile
 Rev. 01

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.