

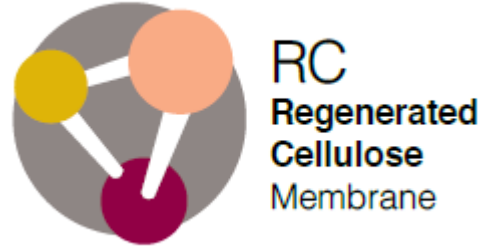
Product PN 3099757, 3099755

Mod. 984

Description Regenerated Cellulose (RC) Filtration Membrane in Discs and Sheets

Rev. 01

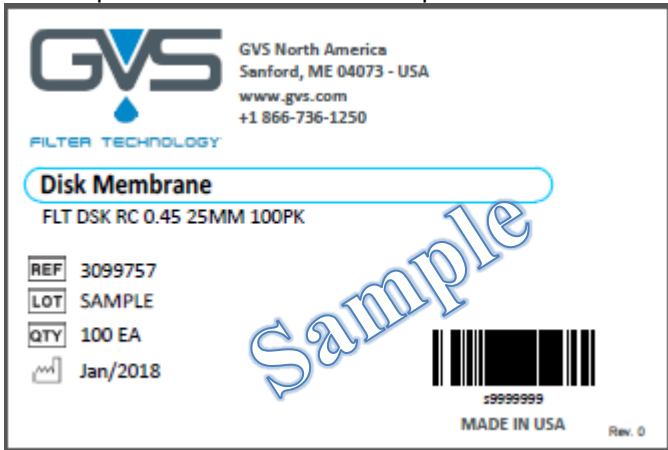
0.45 µm Regenerated Cellulose (RC) Filtration Membrane in Discs and Sheets



PRODUCT DESCRIPTION	0.45 µm Regenerated Cellulose (RC) Filtration membrane packaged in sheets and discs			
	Part Number	Geometry	Dimensions	Packaging
	3099757	Disc	25mm	100/Pk
	3099755	Disc	47mm	100/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	These products are filtration membranes, often used for protein and enzyme filtration, biological fluid sterilization, tissue culture media sterilization, and cold sterilization.			
MATERIALS	Membrane: Regenerated Cellulose (RC) Filtration membrane Regulatory Documentation Required: <input type="checkbox"/> Biocompatibility according to 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 type="checkbox"/> USP Class VI			
PRODUCT CHARACTERISTICS	Appearance/Visual: White membrane configured in discs or sheets <ul style="list-style-type: none"> • Filtration of aqueous and organic solvents • Particle removal from organic solvents of mixtures of aqueous and non-aqueous samples • Ultra-cleaning and de-gassing solvents and mobile phases for HPLC • Clarification • Protein chemistry 			

PRODUCT SPECIFICATION

Product PN	3099757, 3099755	Mod. 984
Description	Regenerated Cellulose (RC) Filtration Membrane in Discs and Sheets	Rev. 01

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"/> EtO <input checked="" type="checkbox"/> Gamma (25 kGy)													
PACKAGING AND LABELING	<ul style="list-style-type: none"> Each label reports the following traceability information: <ul style="list-style-type: none"> Quantity Product description Product date and time Lot number (OL and 6 digit batch number to trace back to raw materials used) Operator code <p>An image of a barcode label is provided below as an example:</p> 													
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	<table border="1"> <thead> <tr> <th colspan="3">Acceptance Requirement</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Thickness</td> <td>≥145 um</td> </tr> <tr> <td>2</td> <td>Water Flow Rate [ml/(min cm² bar)]</td> <td>>31</td> </tr> <tr> <td>3</td> <td>Bubble Point [bar]</td> <td>>2.4</td> </tr> </tbody> </table>		Acceptance Requirement			1	Thickness	≥145 um	2	Water Flow Rate [ml/(min cm ² bar)]	>31	3	Bubble Point [bar]	>2.4
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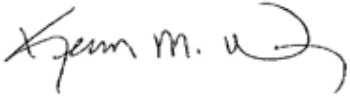

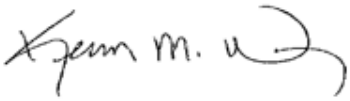
This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, and biological material requirements.



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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)
12/2/19	0	Initial Release	Joe DeSisto, Director, Process Engineering 	Kevin Wrigley/Director of Quality 
12/5/19	1	Aligned specification UOM with supplier's TDS	Joe DeSisto, Director, Process Engineering 	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.