PRODUCT SPECIFICATION

Product PN	**SPNCW02BG47S, SPNCW02BG47S6, SPNCW04BG47S, SPNCW04BG47S6, SPNCB04WG47S, SPNCB04WG47S6, SPNCW08BG47S, SPNCW08BG47S6, SPNCB08WG47S, SPNCB08WG47S6**	**Mod. 984**
Description	**Speed-Pack, NC Membrane, Gridded, 47mm, ST**	**Rev. 01**

Speed-Pack NC Filtration Membrane, Gridded, 47mm STL

PRODUCT DESCRIPTION

Membrane Material	Pore Size (um)	Grid Color	Sterile	Packaging	Product Code
Nitrocellulose White	0.2	Black	Yes	100/pk	SPNCW02BG47S
Nitrocellulose White	0.2	Black	Yes	600/pk	SPNCW02BG47S6
Nitrocellulose White	0.45	Black	Yes	100/pk	SPNCW04BG47S
Nitrocellulose White	0.45	Black	Yes	600/pk	SPNCW04BG47S6
Nitrocellulose Black	0.45	White	Yes	100/pk	SPNCB04WG47S
Nitrocellulose Black	0.45	White	Yes	600/pk	SPNCB04WG47S6
Nitrocellulose White	0.8	Black	Yes	100/pk	SPNCW08BG47S
Nitrocellulose White	0.8	Black	Yes	600/pk	SPNCW08BG47S6
Nitrocellulose Black	0.8	White	Yes	100/pk	SPNCB08WG47S
Nitrocellulose Black	0.8	White	Yes	600/pk	SPNCB08WG47S6

Nitrocellulose Membrane discs which are printed with 3.1 mm grids, individually pouched, and packaged in a perforated fan-folded stack. Gamma Sterilized.

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 used as filtration membranes, often used for aqueous filtration, sterility testing, gravimetric analysis, and microbiological and particulate analysis.
Primarily for use with various 47mm Membrane Dispensing systems

MATERIALS

Film: Nitrocellulose (NC), unsupported

Regulatory Documentation Required:

- ☐ Biocompatibility according ISO 10993-1
- ☐ IMDS
- ☐ Rohs, directive 2002/95/CE
- ☒ BSE/TSE, directive 2003/32/CE
- ☐ DEHP plasticizer and latex free
- ☐ Aging
- ☒ Reach 1907/2006/CE (hazardous substances regulation)
- ☐ Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)
- ☒ Conflict minerals
- ☐ USP Class VI

PRODUCT SPECIFICATION

Product PN	**SPNCW02BG47S, SPNCW02BG47S6, SPNCW04BG47S, SPNCW04BG47S6, SPNCB04WG47S, SPNCB04WG47S6, SPNCW08BG47S, SPNCW08BG47S6, SPNCB08WG47S, SPNCB08WG47S6**	**Mod. 984**
Description	**Speed-Pack, NC Membrane, Gridded, 47mm, ST**	**Rev. 01**

PRODUCT CHARACTERISTICS

Appearance/Visual:

White or Black membrane printed with black or white grids,
Individually pouched and serialized printed,
Stacked in a fan-folded format; individual pouches to be perforated

Dimensions:

Diameter (mm)	Cut Tolerance	Grid Size (mm)
47	±0.4	3.1

PRODUCT SHELF LIFE

2 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 sterile product and is Gamma sterilized.
☐ EtO
☒ Gamma (25 kGy)
☐ Autoclave (121°C)

PACKAGING

150 packs:
SPNCW02BG47S, SPNCW04BG47S, SPNCB04WG47S, SPNCW08BG47S, SPNCB08WG47S

600 packs:
SPNCW02BG47S6, SPNCW04BG47S6, SPNCB04WG47S6, SPNCW08BG47S6, SPNCB08WG47S6

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.

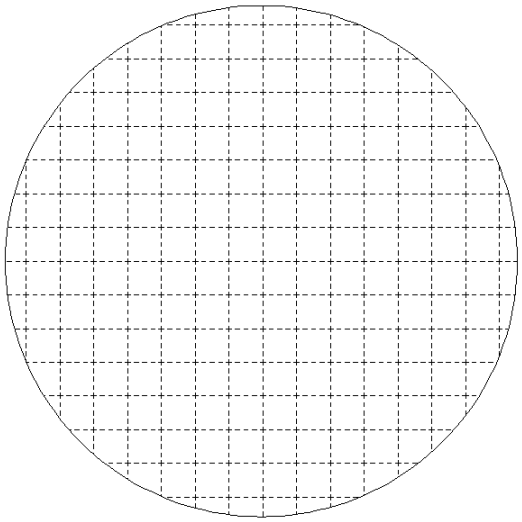
PRODUCT SPECIFICATION

Product PN	**SPNCW02BG47S, SPNCW02BG47S6, SPNCW04BG47S, SPNCW04BG47S6, SPNCB04WG47S, SPNCB04WG47S6, SPNCW08BG47S, SPNCW08BG47S6, SPNCB08WG47S, SPNCB08WG47S6**	**Mod. 984**
Description	**Speed-Pack, NC Membrane, Gridded, 47mm, ST**	**Rev. 01**

VISUAL REQUIREMENTS

Visual Inspection – 100% for the following

DASHED LINE ONLY
No Continuous Lines allowed
No Missing Grids allowed
No Double Dashed lines allowed
No Stains Allowed
No Edge damage
No Membrane Hairs



PERFORMANCE REQUIREMENTS

Acceptance Requirement				Sampling Plan
Pore Size (µm)	0.20	0.45	0.8	
Thickness (µm)	110-190	110-190	110-190	left, middle, & right every 270’
Water Flow Time (250 mL volume @ 20” Hg)	60 - 136 sec	23 - 46 sec	5 – 18 sec	left, middle, & right every 270’
Water Flow Rate (mL/min/cm^2 @ 10 psi)	12-27	35 - 70	88 - 319	left, middle, & right every 270’
Bubble Point (psi)	52-65	30 - 42	11 - 19	left, middle, & right every 270’
*GVS NC Master Roll	1232406	1232408 (WHT) 1211735 (BLK)	1232412 (WHT) 1211746 (BLK)	NA

Note: Specifications in Acceptance Requirements above done at Nitrocellulose Incoming Roll Inspection; Ref. GVS NC Master Roll #s above

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.

PRODUCT SPECIFICATION

Product PN	**SPNCW02BG47S, SPNCW02BG47S6, SPNCW04BG47S, SPNCW04BG47S6, SPNCB04WG47S, SPNCB04WG47S6, SPNCW08BG47S, SPNCW08BG47S6, SPNCB08WG47S, SPNCB08WG47S6**	**Mod. 984**
Description	**Speed-Pack, NC Membrane, Gridded, 47mm, ST**	**Rev. 01**

REVISIONS AND APPROVALS:

DATE	REV.	*REASON FOR CHANGE*	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
1/25/20	0	Initial Release	Joe DeSisto, Director, Process Engineering	Kevin Wrigley, Director, 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.