

| Product PN | 1215376, 1215380 | Mod. 984 |
|-------------|--|----------|
| Description | 0.65 μm Nitrocellulose (NC) Filtration Membrane in Discs | Rev. 01 |

0.65 μm Nitrocellulose (NC) Filtration Membrane in Discs





| PRODUCT DESCRIPTION | 0.65 µm Nitrocell | ulose (NC) | Filtration mem | nbrane packaged | in discs | |
|------------------------------|---|--|--|--------------------|-------------------------|---------------------|
| | Part Number | Color | Gridded | Geometry | Dimensions | Packaging |
| | 1215376 | White | No | Disc | 25mm | 100/Pk. |
| | 1215380 | White | No | Disc | 47mm | 100/Pk. |
| MANUFACTURE | GVS North Amer | ica, Inc. | | | | |
| NAME | 63 Community Di Sanford, ME 040 Phone: +1.866.73 Email: Customero Website: www.gv | rive 73 36.1250 <u>CareGVSLS</u> | S@gvs.com | | | |
| INTENDED USE/ APPLICATION | These products a monitoring, and b | | filtration memb | ranes, often used | d for particle monitori | ng and removal, air |
| MATERIALS | Membrane: Nitrocellulose (NC) Filtration membrane 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 CHARACTERISTICS | High flowUniform Hydrophi | embrane co rates, fast pore structu lic | nfigured in disc filtration rates tre; consistent perature: 356°F | flow and diffusior | n rates | |



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| 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 | This is a non-sterile product, compatible with these sterilization techniques*: ⊠EtO ⊠Gamma (25 -40 kGy) ⊠Autoclave (121°C) ⊠eBeam *user has the responsibility to validate their process |
| PACKAGING AND LABELING | Primary packaging: |

| 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" |
| | | |

- Each configuration will be labeled with:
 - Quantity
 - Product item code and description 0
 - Manufacturing date 0
 - Lot number
 - Storage conditions
- An example of a label is below



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.



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| VISUA | L | |
|-------|------|-------|
| REQUI | IREM | IENTS |

Visual acceptance requirements apply when inspected under below conditions:

Magnification: None Light type: Ambient

| Acceptance | Requirement | Sampling Plan |
|---------------|-------------|-----------------|
| Creases/Folds | None | |
| Cracks | None | |
| Pin Holes | None | 100% Inspection |
| Wrinkles | None | |
| Tension Lines | None | |

PERFORMANCE REQUIREMENTS

| | Accept | Standard Test Method | |
|---|--------------------|--|----------------------|
| 1 | Thickness | 110-190 μm | N/A |
| 2 | Water Flow Rate | Min 45 mL/min/cm ² @ 10 psi | ASTM F 316-03 (2011) |
| 3 | Bubble Point | 25-42 psi (1.7-2.8 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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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 ma | aterial specification as a part of the agree | terms of delivery. | |
|---------------------|--|--------------------|--|
| Company name _ | | | |
| Approved by: _ | (Name Function) | (Cignotura) | |
| | (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.