SARTORIUS

Product Datasheet

Gelatine Membrane Filters in Biosafe® Bags

Aseptic Transfer of GMF For Active Monitoring of Airborne Microorganisms With the MD8 Airscan®

Product Information

Transfer of materials into and out of different cleanroom classifications (ISO 5 – 9) normally requires numerous disinfection steps and means extra work for staff and added expense.

Despite these steps, the risk still remains that adventitious contamination can occur. It is crucial to consider this risk, especially when materials are transferred into filling lines, sterility testing isolators and blow-fill-seal machines.

Benefits

- Complete compliance with the requirements of the EU GMP Annex 1.
- Continuous monitoring of Grade A environments for a tested period of 8 hours
- Eliminate the need for routine intervention and subsequent downtime of operation
- Avoid any risk caused by routine interventions of the environmental monitoring operation
- Easy aseptic transfer of pre-sterilised consumables into barrier systems
- Economise on space; No need to by pre-load your isolator and use just one filter to capture the entire duration of operation

Gelatine Membrane Filters in Biosafe® Bags

Gelatine Membrane Filters (GMF) in Biosafe® Bags are aseptically transferred without any risk of contamination through the Biosafe® Port into the desired critical area, such as an ISO 5 – 9 cleanroom. The Biosafe® Port used in conjunction with the Biosafe® Bag is also well-suited for transferring used materials outside such facilities. At the same time, both the GMF in Biosafe® Bags and the Biosafe® Port eliminate the need for prior loading of (sterility testing) isolators and filling lines, which is expensive and takes up space inside. Instead, this combination can be quickly added afterwards without requiring an extra H_2O_2 cycle. The MD8 Airscan® is also needed to perform active monitoring of airborne microorganisms and viruses.

Critical areas in which aseptic transfer technology is used:

In the pharmaceutical | biotechnology industry:
- Cleanrooms (grades A–D; ISO classes 5 – 9)
- Sterility testing isolators
- Filling lines

In addition to the Biosafe® Bag, the Biosafe® Port is required for aseptic transfer of materials into the critical area.

Quality Control

As Sartorius is a recognized supplier of products and services for the pharmaceutical industry, product quality and safety are its number one priorities.

To meet stringent quality requirements, final 100% visual inspection of the Gelatine Membrane Filter in Biosafe® Bags is performed as one of our final quality control tests. Sterility and growth-promotion tests are carried out for each filter lot, in addition to other quality control tests.

Technical Specifications

Gelatine Membrane Filters in Biosafe® Bags	
Sterilization mode	Gamma irradiation, 25 kGy – 45 kGy
Minimum shelf life	2 years after manufacture
Product order number	17528-BFV
Packaging	▪ One Gelatine Membrane Filter (GMF) per Biosafe® Bag ▪ Each Biosafe® Bag in a sealed overpouch bag ▪ 2 bags per box

Membrane	
Filter material	Gelatine
Nom. pore size	3 µm
Behavior in water	Soluble
Filter diameter	80 mm
Effective filtration area	38.5 cm²
Humidity	Approx. 46% – 49%
Thickness	Approx. 250 µm
Ambient conditions	Max. room temperature 30°C; max. humidity 85%

Bayonet Housing	
Gelatine Membrane Filter holder	Recyclable Cyrolite®
Gelatine Membrane Filter holder bayonet	Recyclable Cyrolite®
Diameter	93 × 16 mm [3.7″ × 0.6″]

Other Materials and Data	
Overpouch bag	Polyamide | Polyethylene
Box dimensions (length × width × depth)	312 × 270 × 13.6 mm [12.3″ × 10.6″ × 0.5″]
Weight of the box including contents	905 g [~32 oz.]

Biosafe® Bag	
Film	Polyethylene | Polyamide | Polyethylene (PE | PA | PE)

Biosafe® Connector	
Plastic flange	Acrylonitrile butadiene styrene copolymer (ABS) or polycarbonate (PC)
Plastic lid	ABS or PC with integrated metal plate (stainless steel)
Pins	Made of stainless steel
Gasket	Silicone
Elastomeric band	Synthetic rubber
Plastic ring	High-density polyethylene (HDPE)

Biosafe® Port	
Main component	AISI 316L stainless steel
Components exposed to friction	Polyethylene terephthalate (PET)
Gaskets	Polyether ether ketone (PEEK)

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