



## Microfilm™ Membrane Filter

### CERTIFICATE OF QUALITY

#### 0.22 µm MCE Membrane Filter

**Part Number:** FRIMMCE4722GS

**Lot Number:** 323042176

**Expiry Date:** 2027.04.17

#### ISO 9001 Quality Standard

The product was manufactured under Membrane Solutions Quality Management System and is approved by an accredited registering body to the ISO 9001 Quality Systems Standard.

#### Good Manufacturing Practices

This product was manufactured in a Membrane Solutions Facility which adheres to FDA Device Good Manufacturing Practice standards.

#### Non-Fiber Releasing

This product was manufactured with a MCE membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3(b)(6).

#### Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications.

#### The Description of Membrane Filter

The MCE Membrane Filters are 47 mm in diameter, white and grid.

#### Lot Analysis

Each lot is tested against the following criteria:

#### Membrane Filter Analysis

Criteria	Specifications	Results
Maximum pore size of the membrane	0.22 µm as verified by bubble point and retention $10^7$ organisms/cm <sup>2</sup> Brevundimonas diminuta ATCC® 19146 challenge.	Conform
Mean membrane thickness	115±25µm	Conform
Bubble point	54±6 psi	Conform
Water flow Rate of the membrane	25±10 ml/min/cm <sup>2</sup> 100ml deionised water at 10psi vacuum at 25°C	Conform

#### Sterility Test

The sterilization method is irradiation sterilization. No growth was observed when sterilized samples were subjected to the seven day sterility test as described by USP.

#### Recovery

The membrane filter has been manufactured for use in enumeration of microorganisms by culture methods which compliance with ISO 7704:2023.

Micro-organism	Specifications	Results
<i>Staphylococcus aureus</i> ATCC® 6538	Good growth after 24h at 30-35°C	Conform
<i>Pseudomonas aeruginosa</i> ATCC® 9027	Good growth after 24h at 30-35°C	Conform
<i>Escherichia coli</i> ATCC® 8739	Good growth after 24h at 30-35°C	Conform
<i>Candida albicans</i> ATCC® 10231	Good growth after 24h at 30-35°C	Conform

Tested by:  05-07-2024

QC Technician



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