



Certificate of Quality

Millipak® 0.22µm

Hydrophilic 0.22 µm rated membrane

Catalog number : MPPG002A1

Lot number : F8DA49057

Manufacturing date : 27-APR-2018

This certifies that the product described above complies with the design criteria of Millipore SAS, and has been manufactured, inspected and tested in accordance with our Quality Standard Procedures. It ensures the high standards of quality and reliability, built into our products, are consistently reached.

The product has been manufactured in a Millipore SAS facility whose quality management system is approved by an accredited registering body to the appropriate ISO 9001 Quality System Standard and ISO 14001 Environmental Management Standard. Manufacturing processes are audited on a regular basis.

All records of inspection, testing and other supporting documentation are *Controlled Documents* and cannot be copied. However, these documents are available for on-site review during audits.

100% integrity testing in Manufacturing : Each unit must pass the Millipore SAS Integrity Test and meets the requirements for the membrane integrity, the assembly of the unit and the housing.

Component materials toxicity - Component materials were tested and meet the criteria for the USP Class VI Biological Test for Plastics.

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

Membrane bacterial retention - Membrane was quantitatively retentive of a minimum challenge concentration of 1×10^7 CFU/cm² using ASTM® F838-05 methodology.



Quality assurance lot release criteria

This lot of product was statistically sampled, tested and released showing compliance to the following specifications:

- Integrity testing - Samples exhibited a water bubble point equal to or greater than 56.6 psi (3.9 bar).
- Hydraulic stress - Samples maintained integrity after a forward stress during 3 minutes to 60 psi (4.1 bar) and 45 pulses at 60 psi (4.1 bar).
- Flow rate and pressure drop - Samples exhibited a maximum pressure drop of 10.0 psi (689 mbar) at 2.0 L/min (0.53 gpm) per filter unit with clean water at 25 °C.
- Burst test - Sample housing resisted a water pressure equal to or greater than 75 psi (5.17 bar).
- USP bacterial endotoxins - A filter aqueous extraction contains less than 0.5 EU/mL (20 EU/unit) as determined using the Limulus Amebocyte Lysate (LAL) test.
- USP oxidizable substances - Effluent is negative after a water flush of 200 mL.

MILLIPORE SAS

Déborah Wild

BioMonitoring - Quality Manager