

## Certificate of Quality

### Millipak® Express 40 Filter

Catalogue Number : MPGP04001  
Lot Number : F2CB93914  
0.22 µm Rated

We certify that the product described herein meets the following criteria.

#### Good Manufacturing Practices

This product was manufactured at Millipore S.A.S., Molsheim, France which adheres to Good Manufacturing Practices guidelines. Special emphasis has been placed on cleanliness and environmental control conditions.

#### ISO® 9001/14001

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.

#### Non Fiber Releasing

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).

#### Component Materials Toxicity

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

#### Membrane Bacterial Retention

Membrane was quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of  $1 \times 10^7$  CFU/cm<sup>2</sup> using ASTM® F838-05 methodology.

#### Lot Analysis

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

This product was designed and manufactured to meet the following specifications. Performance is confirmed by testing on an audit basis.

#### Physical Tests

- **100% Integrity Testing in Manufacturing**  
Each unit must pass the Millipore SAS Integrity Test.

- **Integrity**

Samples exhibited a water bubble point equal to or greater than 56.6 psig (3903 mbarg) with air at 23°C.

- **Hydraulic Stress**

Samples maintained integrity after a forward stress to 60 psid (4.1 bard) and 45 pulses at 60 psid (4.1 bard).

- **Flow Rate and Pressure Drop**

Samples met a maximum pressure drop of 10.0 psid (689 mbard) at 0.26 gpm (2.0 L/min) per filter unit with clean water at 25°C.

- **USP oxidizable Substances**

Effluent was negative after a water flush of 200 mL.

- **Gravimetric Extractables**

The extractables level was equal to or less than 1.0 mg per filter unit after 24 hours in ASTM® Type 1 reagent-grade water at controlled room temperature.

#### Biological Tests

- **USP Bacterial Endotoxins**

A filter aqueous extraction contains less than 0.5 EU/ml as determined using the Limulus Amebocyte Lysate (LAL) test.

- **Toxicity**

This product is non-toxic per the current USP General (Mouse) Safety Test.

According to the above results, the product complies with Millipore SAS's acceptance criteria and is released.

This document has been produced electronically and is valid without a signature

Head of Biomonitoring Quality, Molsheim France

