

## Millistak+® Mini

Grade 50 of  
Series DE Depth Filter  
Catalogue Number: M50DE23HH3  
Lot Number: C9EN05478

### Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

### ISO 9000 Quality Standard

This product was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9000 Quality Systems Standard.

### Component Materials Toxicity

Component materials were tested and meet the criteria for the USP Class VI – 70 °C Biological Test for Plastics.

### Indirect Food Additives

All component materials meet the applicable sections of the FDA Indirect Food Additive Requirements cited in 21CFR 176-186.

### Quality Assurance Lot Release Criteria

The filter material used in this manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

#### USP Bacterial Endotoxins

An aqueous extraction contained less than 0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

#### Flow Rate and Pressure Drop

Samples met the required flow rate of 212–379 L/min/m<sup>2</sup> when tested at a differential pressure of 10 psi (690 mbar) with clean water at 23 °C.

#### Thickness

Samples measured met the required thickness of 0.125–0.145 inches.

#### Basis Weight

The basis weight of samples tested were within 851–1289 g/m<sup>2</sup>.

#### Ash Content

Ash content was determined to be 49–59%.

#### Wet Tensile Strength

Wet tensile strength of the samples tested was  $\geq$  10 lb./in.

### Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

#### USP Oxidizable Substances

The effluent meets the requirements of the USP Sterile Water For Injection Oxidizable Substances Test after a water flush of 5 L per square foot of media.

#### Autoclavability

Integrity was maintained after one autoclave cycle of 60 minutes at 123 °C.



Peter Eichert  
BioPharmaceutical Quality Manager

