

Millistak+® Mini

Grade 40 of  
Series CE Depth Filler  
Catalogue Number: M40CE23HH3  
Lot Number: C9JN28590

#### **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 450-835 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 0.155-0.185 inches.

##### **Basis Weight**

The basis weight of samples tested were within 870-1295 g/m<sup>2</sup>.

##### **Wet Tensile Strength**

Wet tensile strength of the samples tested was ≥ 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 Eichhart  
BioPharmaceutical Quality Manager

