

**OptiScale® Capsule Filter with  
Hydrophilic Millipore  
Express® SHF Membrane**

Millipore Express SHF 0.2 µm Rated  
Catalogue Number: SGEPA47HH3  
Lot Number: C9NN48652

**Good Manufacturing Practices**

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

**ISO® 9001 Quality Standard**

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

**Indirect Food Additive**

All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.

Millipore, Millipore Express and OptiScale are registered trademarks of Millipore Corporation.  
ISO is a registered trademark of the International Standards Organization.  
P88060 Rev C 06/09

**Quality Performance Criteria**

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

**Oxidizable Substances**

Effluent meets the requirements for USP Sterile Water for Injection after a water flush of 100 mL per autoclaved capsule.

**Toxicity**

Component materials were tested and meet the criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.

This product is non-toxic per the USP <88> Safety Test with 0.9% Sodium Chloride extraction procedure.

**Multiple Sterilization Cycles**

Capsule integrity was maintained after 3 autoclave cycles of 60 minutes at 126 °C.



Peter Fichert  
Quality Manager