

## OptiScale® Capsule Filter with Prefiltration and Clarification Media

Polygard CN 1.2 µm Nominal Rated

Catalogue Number: SN12A47HH3

Lot Number: C9NN51380

### 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.

### 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 autoclavable 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 Eichert  
Quality Manager

Millipore and OptiScale are registered trademarks of Millipore Corporation.  
ISO is a registered trademark of The International Organization for Standardization  
P60211 Rev C 06/09