

Millistak+[®] Pod Filter

Grade A1 of
Series HC Depth Filter
Catalogue Number: MA1HC10FS1
Lot Number: CP1CB25649

ISO[®] 9001 Quality Standard

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

Component Materials Toxicity

Component materials comply with the requirements of USP <88> Biological Reactivity Test for Class VI Plastics.

Indirect Food Additives

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

Pressure Equipment Directive 2014/68/EU

Devices and associated holders are designed and manufactured in accordance with the sound engineering practices (SEP) cited in Article 4(3) of 2014/68/EU.

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

With 21°C clean water at a 10 psid (690 mbard) pressure drop, samples displayed flow rates within:

Media Layer 60DE: 99.0 - 181.9 L/min/m²

Media Layer DE75: 31.6 - 58.0 L/min/m²

Integrity Tests

Pod filters were found to be integral as measured by aerosol challenge and hydrogen leak tests.

Quality Performance Criteria

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

Toxicity

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

Multiple Sterilization Cycles

Integrity was maintained after 1 autoclave cycles of 60 minutes at 123 °C.



Thomas Brackett
Supplier Quality Manager



EMD Millipore Corporation
400 Summit Drive
Burlington, MA 01803 U.S.A.

Millipore.

Certificate of Quality

The purpose of this certificate is to provide precise information on the quality and characteristics and acceptance criteria which support the high standards of quality and reliability built into our products.

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



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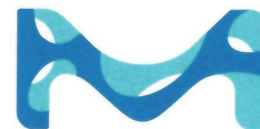
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