

ChromaSorb™ 500 mL Device

Catalogue Number: CHRFA10500
Lot Number: C9KN31872

Nominal Membrane Volume = 503 mL

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.

Component Materials Toxicity

Component materials were tested and meet the Criteria for the USP Class VI Biological Tests for Plastics.

Animal Origin Statement

All Component materials used in the manufacture of this device are either animal free or in compliance with EMEA/410/G1.

European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

Membrane BSA Capacity

Samples of the ChromaSorb membrane exhibited an average 50 mg/πl or greater BSA binding capacity at 0mM NaCl concentration.

Membrane Extractable (TOC)

Samples of the ChromaSorb membrane demonstrate $\leq 10 \mu\text{g C} / \text{cm}^2$

Device Permeability

This product was tested for permeability and demonstrated a flow rate equal to or greater than 90 LWH/psi

Device Diffusion Test

Samples of this product was tested for integrity and shown by air water diffusion to have a flow less than 10.00 cc/min at 10 psia

Device 100% Housing Integrity Test

Each ChromaSorb device has been tested for housing integrity at 30 psia and shown to be integral.

Device 100% Aerosol integrity test

Each ChromaSorb device has been aerosol tested and shown to be integral.

Quality Performance Criteria

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

Device Extractable TOC

This product was tested for TOC extractable and exhibited 0.5 ppm or less of TOC after flush post sanitization by Millig® water flush at 6.5L/min for 9 min.

Hydraulic Stress

This product was tested for hydraulic stress and exhibited integrity after pressurizing to 30 psid forward at 4-30°C and 5 psid reverse at 4-30°C.

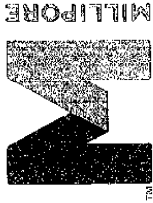
Lauren LeClair

Lauren LeClair
Quality Manager





Millipore Corporation
290 Concord Road
Billerica, MA 01821



Certificate of Quality

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

Millipore certifies that the product described within meets the following criteria.



Millipore is a registered trademark of Millipore Corporation.
The Milligo is a trademark of Millipore Corporation.
00104110PU Rev. A 02/08 07-525