

Quality Assurance Certificate

Biosart® 100 Monitor

Order no. 16402-47-06----K

Use before 10 / 2029

Lot no. 254700297

This document is to verify that the designated product was manufactured by Sartorius according to a Quality Management System that is certified for compliance with BS EN ISO 9001:2015.

Sartorius hereby declares that the designated product was manufactured to meet the published specifications for these products. Sartorius also declares that the designated products have been manufactured from approved materials of construction and comply with design and manufacturing documentation.

Sartorius certifies that the cellulose nitrate membrane filters contained in Biosart® 100 Monitor have been manufactured for use in the bacteriological analysis of potable waters, waste and natural waters and other liquids in accordance with procedures referenced in Standard Methods (recent edition) and laboratory standards for equipment and materials set forth by the U.S. Environmental Protection Agency.

The Membrane Filters are 47mm in diameter, coloured with contrasting grid.
Bacterial recovery testing has shown that the grid lines do not enhance or inhibit the growth of bacteria.
Recovery rates are determined in accordance to current ISO 7704 requirements.
The product was sterilized using a validated process in accordance with DIN EN ISO 11137 regulations.
We herewith certify that the graduation marks for all manufactured batches have a tolerance at nominal fill capacity of $\pm 5\%$.
Intermediate graduation marks have a tolerance of $\pm 10\%$ in accordance with ISO/DIN 7056 International Standards for Laboratory Plasticware Accuracy.

Specifications

Pore size
Flow rate
Thickness
Wetting time

Acceptable limits

0.45 μm
 $\geq 61 \text{ ml} / \text{cm}^2 \cdot \text{min} \cdot \text{bar}$
115-145 μm
 ≤ 10 seconds

The pore size of the 0.45 μm membrane filters is defined by retention of *Serratia marcescens* on a regular basis.

Biological Properties

Microbe Recovery (0.45 μm):
Escherichia coli ATCC 8739 $\geq 85\%$
Pseudomonas aeruginosa ATCC $\geq 85\%$

Filtration units with white and black 0.45 μm membrane were tested with microorganisms referring to the current ISO 7704. Lot specific recovery rates for these filtration units can be requested (SH_certificates@sartorius.com).
Note: For a Valid incoming goods inspection according to ISO 7704, it is necessary to test the membrane filter lot in combination with the specific agar media used. Filtration units have been irradiated to a Sterility Assurance Level (SAL) of 10⁻⁶.

28. November 2025

Date



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Site Quality Manager

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