

Quality Assurance Certificate

Sartopore® Platinum
Sterile Midicaps®

Order no. 5495307H7--SS--A

Use before 11 / 2027

Pore size 0.45 + 0.2 µm

Lot no. 2448007103
Max. operating pressure: 5 bar/72.5 psig
Sterilization: Autoclaving at max. 134 °C,
no in-line steaming

This document certifies that the designated product was manufactured by Sartorius in conformance with established quality standards.

This product is developed, produced and distributed according to a Quality Management System that is certified for compliance with DIN/ISO 9001.

This filter capsule was sterilized using a validated process following DIN/EN ISO 17665-1 regulations, pertaining to "Sterilization of Medical Products".

This product is registered with the Food and Drug Administration (FDA). The DMF number is available upon request.

This product has passed Sartorius' inhouse tests and thus meets Sartorius' stringent quality control standards.

Integrity test values: Each membrane filter element has been individually tested for integrity by means of diffusion and bubble point testing. These tests have been performed according to the procedures stated in the corresponding Validation Guide.

For this filter element the bubble point measured was ≥ 3.5 bar/ 50.7 psi.

Diffusion rate measured for this filter was found to be ≤ 4.0 ml/min, at a test pressure of 2.5 bar/ 36 psi.

For sterilizing - grade filters, these integrity test values have been fully correlated to the ASTM F 838 Bacteria Challenge test, using a challenge level $\geq 1 \times 10^7$ CFU/cm² of *Brevundimonas diminuta*.

Biosafety: All materials of this filter element meet the requirements of the current USP Biological Reactivity tests <88> for plastics Class VI, (Systemic Injection, Intracutaneous and Implantation tests).

Non fibre releasing: This filter product complies with the title 21 of the Code of Federal Regulations (CFR), section 210.3(b)(6) and 211.72.

In addition to these main tests, the following is checked on a regular basis:

Retention of *B. diminuta*: Quantitative retention of *Brevundimonas diminuta* is checked for every 0.2 µm membrane lot. Additionally, the retention of *B. diminuta* is checked by regular sampling of all sterilizing grade filter elements.

Oxidizable Substances: The filtrate of these filter elements shows a negative reaction when tested according to the current USP.

Extractable Substances: The total amount of extractables is well below the limits established by the current USP under "Sterile Water for Injection".

Bacterial Endotoxins: An endotoxine free water extract of this filter product contains less than 0.25 EU/ml, which was determined by using the Limulus Amebocyte Lysate (LAL) test.

Particulate Matter: This product releases particulate matter in quantities well below the requirements established in the current USP in "Large Volume Injections for Single Dose Infusion".

Thermal Stability: Capsules that underwent multiple (25) autoclaving cycles at 134 °C showed no loss of integrity.

Note: Details of the methodologies used in the tests mentioned above as well as more detailed test results are given in the respective Validation Guide.

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Date



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