Quality Assurance Certificate

	Sterisart® NF
Order no.	16475--------GSD
Use before	04 / 2028
Lot no.	2516050035
Membrane	Regenerated Cellulose, 0.45 µm

Sartorius Stedim Biotech GmbH certifies that the product

Sterisart®

has been manufactured for use in the sterility testing procedure that is recommended in the current editions and supplements of international pharmacopoeias, e.g. EP, USP and JP. Manufacturing is performed in accordance with the applicable current Good Manufacturing Practices.
The Sartorius Stedim Biotech Quality Management System is certified for compliance with DIN EN ISO 9001.

Quality Assurance Lot Release Criteria:
The following properties of the finished (post-sterilized) device are tested by lot according to national and international standards and in house-guidelines.

Bacteria Growth Promotion Test:
The test is performed with the following test strains acc. to the current EP / USP (1-100 microorganisms per Sterisart container): Aspergillus brasiliensis ATCC 16404, Pseudomonas aeruginosa ATCC 9027, Clostridium sporogenes ATCC 19404, Staphylococcus aureus ATCC 6538, Bacillus subtilis ATCC 6633, Candida albicans ATCC 10231. The test results demonstrate that neither the materials nor the sterilization process inhibits the growth of microorganisms.

Bacteria Challenge Test:
The test is performed with Serratia marcescens ATCC 14756 and must confirm a Log Reduction Value of ≥ 7.

Each venting filter lot is tested with 10^7/cm² of Brevundimonas diminuta ATCC 19146 and must deliver a sterile filtrate in order to be released.

Physical tests:
- Visual inspection (packaging, labeling, completeness)
- Burst pressure of the containers: > 5 bar
- Equal transfer of liquid volumes: ± 10%
- Integrity of the complete system (e.g. membrane sealing, all tubing connections)

Sterility:
Each lot has met the acceptance criteria for the controlled and validated sterilization cycle (ETO and gamma irradiation).

For sterilization with ethlene oxide, spore strips (Bacillus atrophaeus, > 10^6) incorporated into a qualified process challenge device have been shown to be sterile. An additional sterility test is performed to verifiy the results of the challenge.

For sterilization by gamma irradiation, a parametric release procedure is performed on the basis of a monitoring system with dosimeters.

Further detailed information is available in the Sterisart Validation Guide.

2025-04-17

Date

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