

Quality Assurance Certificate

Minisart® High Flow

Order no. 16532-----GUK
Use before 02 / 2028
Pore size 0.22 µm
Lot no. 250428103

This product was sterilized using a validated process following DIN/EN ISO 11137 regulations.

Minisart is manufactured by Sartorius in accordance with established quality standards and in a facility whose Quality Management System is certified for compliance with the DIN EN ISO 9001 Quality System Standard and DIN EN ISO 13485.

Each unit is tested 100% during manufacture for membrane and housing integrity by a leakage test under automatic conditions. Before packing each unit has been checked by visual inspection.

Minisart is biosafe according to the USP Class VI Biological tests for Plastics. It also complies with the Title 21 Code of Federal Regulations, Section 210.3(b)(6) and 211.72 for non-fiber-releasing filters.

Following 100% control, each lot has been sampled, tested and released by QA Department for the following characteristics:

Burst Pressure Test

Bubble Point Test

Endotoxine Test

Sterility

Pressure Hold Test

Flow Rate Performance

Sterile Filtration Capability (Bacterial Challenge Test)

2025-02-28

Date



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Site Quality Manager

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