

Quality Assurance Certificate

Minisart® High Flow

Order no. 16537-----Q
Use before 11 / 2029
Pore size 0.45 µm
Lot no. 241466103

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. The lot no. alone or lot no. with one of the following: pore size, ID no., material type, order no. are printed on top of the housing and/or Tyvek. 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

Pressure Hold Test

Flow Rate Performance

2024-11-25

Date



Dr. Anna Vreemann
Site Quality Manager

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