

Quality Assurance Certificate

Minisart® PES

Order no. 1776D-----Q
Use before 10 / 2027
Pore size 0.2 µm
Lot no. 221393103

Minisart is manufactured by Sartorius in accordance with the Current Good Manufacturing Practice 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.

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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

Pressure Hold Test

Flow Rate Performance

Sterile Filtration Capability (Bacterial Challenge Test)

2022-10-27

Date



Dr. Anna Vreemann
Site Quality Manager

Manufactured by Sartorius Stedim Biotech GmbH
37070 Goettingen, Germany

Phone +49.551.308.0
Fax +49.551.308.3289

www.sartorius.com