

Quality Assurance Certificate

Minisart NML

Order no. 17597-----K
Use before 10 / 2017
Pore size 0.20 µm
Lot no. 41178103

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.

This product was sterilized using a validated process following DIN/EN ISO 11135 regulations.



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.

In addition Minisart is classified in class IIa of the Medical Devices Directive 93/42/EEC.

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)

07.10.2014

Date

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