

Sterility Test Systems



Sterisart NF

Sterisart is a completely closed system for the sterility testing of pharmaceutical products. It is based on the membrane filter method, however it eliminates the procedure of manipulating the filters. By this the main risk of a secondary contamination and false positive results is also eliminated.

A peristaltic pump transfers the sample into the filtration units, and after rinsing, the filtration units are filled with media and used for incubation of the filters without any contact to the environment.

Special brochure available on request.
Order no. SLD1002-e, SLD1001-e



Technical specifications for Sterisart NF

Pore size of the Sartochem membrane filter	0.45 μm , validated acc. to HIMA for the retention of <i>Serratia marcescens</i>
Filter area	15.7 cm^2 in each Sterisart container
Flow rate (for water)	500 ml/min at 1 bar (approx. 15 psi)
Pore size of the air filters	0.2 μm PTFE, validated acc. to HIMA for the retention of <i>B. diminuta</i>
Sample container capacity	120 ml (graduation marks at 50, 75 and 100 ml)
Max. operating pressure	3 bar (approx. 44 psi) at 20 °C
Max. operating temperature	50 °C
Sterilization	ETO (ethylene oxid gas) or gamma irradiation

Technical specifications for Sterisart universal pump

Pumping performance	10–700 ml/min (dependent on the tubing)
Noise level at 1 m distance	< 45 dB (A)
Voltage	90–230 VAC (a.c. voltage)
Tolerance range acc. to VDE	–15/+10%
Frequency	47–63 Hz
Power consumption	100 W
Fuse	T 1.6 A
Ambient temperature	+10 °C – +40 °C
Protection class	IP 20
Cooling	Self-convection and fan
Dimensions	420 × 220 × 120 (W × H × D)
Weight	approx. 11 kg

Order no. for universal pump	Description
16413	Sterisart universal pump Additional accessories are available on request, such as a pump cover for Millipore sterility test units, order number 1ZG 0004.

Recommended disposable sterility test units for use with pump

Order no. for Sterisart NF	Description
16466 ACD	Sterisart NF alpha, dual-needle metal spike for closed containers (box of 10, individually sterilized with ETO; single-packed).
16467 ACD	Sterisart NF alpha, 6 cm metal needle for open containers (box of 10, individually sterilized with ETO; single-packed).
16468 ACD	Sterisart NF alpha, adapter for medical devices with luer or luer lock connectors (box of 10, individually sterilized with ETO; single-packed).
16466 GBD	Sterisart NF gamma, dual-needle metal spike for closed containers (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
16467 GBD	Sterisart NF gamma, 6 cm metal needle for open containers (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
16468 GBD	Sterisart NF gamma, Adapter for medical devices with luer or luer lock connectors (box of 10, individually gamma sterilized, double-packed, optimal for use in isolators).
Further units on request	16464ACD, 16464GBD

**Re-usable sterility test system**

Re-usable sterility test system for the sterility testing of injection and infusion solutions. The filter holders are easy to clean, dishwasher safe and autoclavable.

The system can be designed according to the needs of the user, and the membrane filter can be chosen according to requirements.

Specifications of the filter holders

Material	Glass cylinder; polypropylene base and sealing plug; anodized aluminum closing cap.
Sealing	Silicone gasket, 36/47 mm (6980573) Silicone O-ring, 40.5×3.5 mm (6980574)
Filter diameter	47 mm
Filtration area	12.5 cm ²
Capacity	16522: 85 ml (60 ml up to the mark for anaerobic incubation at a filling level of 70 mm) 16523: 130 ml (56 ml up to the mark for aerobic incubation at a level of 60 mm, 110 ml up to the mark at the 115-mm level).
Operating pressure	Vacuum only
Sterilization	Autoclaving at 121 °C

Order no. for filter holders	Description
16522	Filter holder with 85 ml capacity
16523	Filter holder with 130 ml capacity
16826	Stainless steel manifold
16696	Peristaltic pump