



The Sterisart[®] Universal Pump

The Right Equipment
for Your Sterility Test

Simplifying Progress

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The Sterisart® Universal Pump - Convenience & Confidence Combined

An intelligent concept for reliable results

International pharmacopeias require the complete sterility of pharmaceutical products, such as parenterals, that are injected into the blood stream or that otherwise enter the body below the skin surface. As a manufacturer of such products, you are required to supply proof of the sterility of each final product batch.

Sterility testing by membrane filtration is the method of choice for all filterable sterile pharmaceuticals. The tests are typically performed using pre-sterilised, closed, single-use systems, such as the Sterisart® NF family.

Sartorius has developed the Sterisart® Universal pump for sterility testing as a successor to the 16413 peristaltic pump. The Sterisart® Universal pump is made of stainless steel, and is equipped with appropriate features for attaching a Sterisart® NF sterility test system and a sample container.

After these have been positioned and the sterility test system spike has been inserted into the sample container, the pump is started. The pump draws liquid from the sample container into the specially designed double tubing, distributing the liquid equally to both test containers of the sterility test system. In doing so, the pump builds up sufficient pressure for fast filtration through the membrane filters sealed in the base of these containers. Similarly, the pump then flushes the containers with a defined rinse liquid. Finally, the pump fills the two different culture media prescribed by the pharmacopeias into each of the two test containers for incubation and evaluation. The test containers are incubated under defined conditions and, following a prescribed time, the containers are evaluated.

The Sterisart® Universal pump can be used in clean rooms, integrated into clean benches, or installed countersunk in the work area of isolators.



Find out more

For more information, please visit
www.sartorius.com

Features



Increased Safety and Reliability

A unique motor principle has resulted in a closed pump chassis design, eliminating the need for ventilation of the motor. Therefore, the pump will not release any particles or microbes into cleanroom or isolator environments or cause turbulence in laminar-flow areas. This results in increased safety and reliability.



Rugged and Maintenance-free

As the pump chassis is made of stainless steel, it features excellent chemical compatibility with sterilants used in isolators. This, together with the unique type of motor, makes the pump highly rugged and virtually maintenance-free, considerably reducing service costs.



Compact and User-friendly

As space is often limited in isolators and clean benches, the Sterisart® Universal pump has been designed with a compact footprint and a low profile. Thanks to its user-friendly construction, it saves spaces, ensuring excellent ergonomic handling, particularly in the areas in front of and above the pump.

Despite the pump's compactness, it is easy to thread the tubing of the Sterisart® sterility test unit into the pump rotor. The special pump head design ensures excellent life of the tubing and, moreover, is easy to access for cleaning and disinfecting.



Special Software

The special software of the high-end version 16420 guides the user by individual menu prompts. For instance, two different programs can be selected currently (manual operating mode and manual operating mode with data collection). Data is input using a bar code scanner. Program-specific data, such as pump speed, time of the pumping process, etc., can additionally be manually or automatically logged. The user's special SOPs can be saved in additional programs and stored on a PC, then downloaded to the Sterisart® Universal pump so that the user can routinely recall and run these SOP programs. The complete process sequence of the sterility test can optionally be documented, for example, by a PC with special evaluation software, which facilitates the user's compliance with directives and guidelines for traceable documentation.

Of course, the Sterisart® Universal pump can also be used with other sterility test systems currently available. In this case, the alternative cover of the container for draining, order number 1ZG--0024, is required.

Overall, the operating ease of the Sterisart® Universal pump and its practical benefits save time and money, and help to ensure reliable sterility test results.



Versatile Design

The Sterisart® Universal pump is available in two versions. The name Sterisart® Universal stands for the versatility of this pump, a feature that enables one and the same pump to be integrated into clean benches as well as installed countersunk into the work areas of isolators.

Technical Specifications

Pump flow rate	70 – 650 ml/min
Power requirements	100 – 240 VAC
Frequency	50 – 60 Hz
Power consumption	100 W

Dimensions

Pump (W × D × H)	336 × 260 × 210 mm (with lever)
Pump with holding ring for bottles, container (W × D × H)	440 × 365 × 485 mm

Weight

Basic version 16419	Approx. 13.5 kg
Upgraded version 16420 with display user software	Approx. 14.6 kg

Materials

Base plate, lever, bow, rotor	Stainless steel 316L (1.4435)
Housing, connection port, housing control unit, stand, fastening arm, holder ring for bottles	Stainless steel 316 (1.4401)
Operating display	Glass
Connecting cable	PVC
Connector control unit	Tarnish chrome
Connector grommet	TPE
Container for draining, plastic sleeve for lever	PET
Seals, gaskets, adhesive	Silicone



Ordering Information

Sterisart® Universal Pump and Accessories	Order Number
Sterisart® Universal pump, basic version	16419
Sterisart® Universal pump, upgraded version with display user software	16420
Bottle holder	1ZGL--0033
Drain tubing	1ZA---0002
Ampoule breaker	1ZW---0002
Foot switch	1ZE---0033
Stand	1ZF---0013
Container for draining	1ZG---0028
Plastic sleeve for lever	1ZB---0001
Separate control unit display	1EE---0008
Extension cable control unit	1EE---0009
Clamp for control unit	1ZF---0014
Wing nut	1ZF---0007
Bow	11ZS---0005
Lever	1ZS---0002
Rotor	1ZL--0003
RJ45-cable	1ZE--0034
Serial cable	1ZE--0035
Cover for container draining (Sterisart® sterility test units)	1ZG---0023
Cover for container draining (Millipore sterility test units)	1ZG---0024
Adapter draining container for Sterisart® units on Millipore pump	1ZG---0014
Cover for electrical connectors 16419 16420	1ZDS--0001
MMC SD card reader for 16420	1ZE--0036
MMC card for 16420	1ZE--0037
External barcode scanner	1EE---0010
Transport Trolley	1ZE--0039
Communication Kit	1ZE--0040
Installation kit for isolators	1ZE--0050
Sterisart® Easy Configuration Software Drag & drop software, designed to increase process reliability for sterility testing	1Z---0004


Further accessories on request.

Sterisart® NF sterility testing solutions	Order Number
Sterisart® system for liquids in closed, large volume containers such as bottles	16466-----GBD
Sterisart® system, with septum, for liquids in closed, large volume containers such as bottles	16466-----GSD
Sterisart® CA for liquids in closed, large volume containers such as bottles	1646601-----GBD
Sterisart® system for liquids in open containers such as ampoules	16467-----GBD
Sterisart® system, with septum, for liquids in open containers such as ampoules	16467-----GSD
Sterisart® CA for liquids in open containers such as ampoules	1646701-----GBD
Sterisart® system for liquids in closed, small volume containers such as vials	16476-----GBD
Sterisart® system, with septum, for liquids in closed, small volume containers such as vials	16476-----GSD
Sterisart® system for soluble lyophilisates in closed containers such as vials	16475-----GBD
Sterisart® system, with septum, for soluble lyophilisates in closed containers such as vials	16475-----GSD
Sterisart® system, for pre-filled syringes	16469-----GBD
Sterisart® system, with septum, for pre-filled syringes	16469-----GSD
Sterisart® one-connector system for liquids in containers with a luer connector such as collapsible bags and medical devices	16468-----GBD
Sterisart® two-connector system for liquids in containers with a luer connector such as collapsible bags and medical devices	16478-----GBD
Sterisart® system for liquids in plastic containers with blow-fill seals	16477-----GBD
Sterisart® system for the dilution of liquids and poorly soluble lyophilisates in closed containers	16470-----GBD
Sterisart® system for the transfer of liquids from a closed to an open container, or vice-versa	16472-----GBD

Box of 10, gamma sterilized, double packaged. Optimal for use in all advanced aseptic processing systems.

Further Sterisart® units are available on request.




 **Find out more**
For more information, please visit
www.sartorius.com

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