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New Sterisart® Universal Pump



turning science into solutions



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The newest generation of the Sterisart® Universal Pump – an intelligent concept for reliable results

International pharmacopeias require the complete sterility of pharmaceutical products, such as parenteralia, 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.

The preferred method for sterility testing is the membrane filter method using a closed sterility test system, such as the new disposable sterility test system Sterisart® NF. Virtually all pharmaceutical containers and product types can be tested thanks to the wide variety of Sterisart® NF sterility test units featuring different adapter types, which Sartorius Stedim Biotech offers.

As an intelligent further development to the available 16413 peristaltic pump, Sartorius Stedim Biotech has developed the new Sterisart® Universal pump for sterility testing. This new version is a peristaltic pump 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 new Sterisart® Universal pump can be used in clean rooms, integrated into clean benches, or installed countersunk in the work area of isolators.

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.

Modular Design

The new Sterisart® Universal pump is available in two versions. The pump is designed with the idea in mind that the basic version 16419 can be upgraded later with an external control unit that has a built-in display to the high-end version 16420. 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 counter-sunk into the work areas of isolators.

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.



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



Ordering Information for the Sterisart® Universal Pump and Accessories

Sterisart® Universal pump, basic version	16419
Sterisart® Universal pump, upgraded version with display user software	16420
Ampoule tongs	16973
Holding ring for bottles	1ZG---0009
Fastening arm	1ZF---0004
Drain tubing	1ZA---0002
Ampoule breaker	1ZW---0002
Foot switch	1ZE---0033
Stand	1ZF---0013
Container for draining	1ZG---0022
Plastic sleeve for lever	1ZB---0001
Separate control unit	1EE---0008
Extension cable control unit	1EE---0009
Clamp for control unit	1ZF---0014
Wing nut	1ZF---0007
Bow	1ZS---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

Further accessories on request.

The following Sterisart® NF disposable sterility test units are available:	Order Numbers
Sterisart® NF alpha, dual-needle metal spike for closed containers (box of 10, individually sterilized with ETO; single-packed)	16466-----ACD
Sterisart® NF alpha, metal needle for open containers (box of 10, individually sterilized with ETO; single-packed)	16467-----ACD
Sterisart® NF alpha, system for medical devices with Luer lock connectors (box of 10, individually sterilized with ETO; single-packed)	16468-----ACD
Sterisart® NF gamma, dual-needle metal spike for closed containers (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16466-----GBD
Sterisart® NF gamma, metal needle for open containers (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16467-----GBD
Sterisart® NF gamma, system for medical devices with Luer or Luer lock connectors (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16468-----GBD
Sterisart® NF gamma, system with adapter for prefilled syringes (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16469-----GBD
Sterisart® NF gamma, system for slightly soluble powders in unvented vials (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16470-----GBD
Sterisart® NF gamma, system for lyophilized or freely soluble powders in unvented vials (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16475-----GBD
Sterisart® NF gamma, system with short dual-needle metal spike for closed containers (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16476-----GBD
Sterisart® NF gamma, system for liquids in plastic containers (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16477-----GBD
Sterisart® NF gamma, system for medical devices with Luer lock male connectors (box of 10, individually gamma sterilized, double-packed). Optimal for use in isolators.	16478-----GBD
Separate venting needle for ampoules, collapsible bags and vials, gamma sterilized (box of 50).	16596-----HNK

Further Sterisart® units are available on request.

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