



sartorius stedim
biotech

New Sterisart® Universal Pump



turning science **into solutions**





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.

Sales and Service Contacts

For further contacts, visit www.sartorius-stedim.com

Europe

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen

Phone +49.551.308.0
Fax +49.551.308.3289

www.sartorius-stedim.com

Sartorius Stedim Systems GmbH
Schwarzenberger Weg 73-79
34212 Melsungen

Phone +49.5661.71.3400
Fax +49.5661.71.3702

www.sartorius-stedim.com

France

Sartorius Stedim Biotech S.A.
ZI Les Paluds
Avenue de Jouques – BP 1051
13781 Aubagne Cedex

Phone +33.442.845600
Fax +33.442.845619

Sartorius Stedim France SAS
ZI Les Paluds
Avenue de Jouques – CS 71058
13781 Aubagne Cedex

Phone +33.442.845600
Fax +33.442.846545

Austria

Sartorius Stedim Austria GmbH
Franzosengraben 12
A-1030 Vienna

Phone +43.1.7965763.18
Fax +43.1.796576344

Belgium

Sartorius Stedim Belgium N.V.
Leuvensesteenweg, 248/B
1800 Vilvoorde

Phone +32.2.756.06.80
Fax +32.2.756.06.81

Denmark

Sartorius Stedim Nordic A/S
Hoerskaetten 6D, 1.
DK-2630 Taastrup

Phone +45.7023.4400
Fax +45.4630.4030

Hungary

Sartorius Stedim Hungária Kft
Kagyló u. 5
2092 Budakeszi

Phone +36.23.457.227
Fax +36.23.457.147

Italy

Sartorius Stedim Italy S.p.A.
Via dell'Antella, 76/A
50012 Antella-Bagno a Ripoli (FI)

Phone +39.055.63.40.41
Fax +39.055.63.40.526

Netherlands

Sartorius Stedim Netherlands B.V.
Edisonbaan 24
3439 MN Nieuwegein

Phone +31.30.6025080
Fax +31.30.6025099

Poland

Sartorius Stedim Poland Sp. z o.o.
ul. Wrzesinska 70
62-025 Kostrzyn

Phone +48.61.647.38.40
Fax +48.61.879.25.04

Spain

Sartorius Stedim Spain SA
C/Isabel Colbrand 10,
Oficina 70
Polígono Industrial de Fuencarral
28050 Madrid

Phone +34.90.2110935
Fax +34.91.3589623

Switzerland

Sartorius Stedim Switzerland AG
Ringstr. 24 a
8317 Tagelswangen

Phone +41.52.354.36.36
Fax +41.44.52.354.36.46

U.K.

Sartorius Stedim UK Limited
Longmead Business Park
Blenheim Road, Epsom
Surrey KT19 9 QQ

Phone +44.1372.737159
Fax +44.1372.726171

America

USA

Sartorius Stedim North America Inc.
5 Orville Drive
Bohemia, NY 11716

Toll-Free +1.800.368.7178
Fax +1.631.254.4253

Sartorius Stedim SUS Inc.
1910 Mark Court
Concord, CA 94520

Phone +1.925.689.6650
Toll Free +1.800.914.6644
Fax +1.925.689.6988

Sartorius Stedim Systems Inc.
201 South Ingram Mill Road
Springfield, MO 65802

Phone +1.417.873.9636
Fax +1.417.873.9275

Argentina

Sartorius Argentina S.A.
Int. A. Avalos 4251
B1605ECS Munro
Buenos Aires

Phone +54.11.4721.0505
Fax +54.11.4762.2333

Brazil

Sartorius do Brasil Ltda
Av. Dom Pedro I, 241
Bairro Vila Pires
Santo André
São Paulo
Cep 09110-001

Phone +55.11.4451.6226
Fax +55.11.4451.4369

Mexico

Sartorius de México S.A. de C.V.
Circuito Circunvalación Poniente No. 149
Ciudad Satélite
53100 Naucalpan, Estado de México

Phone +52.5555.62.1102
Fax +52.5555.62.2942

Asia | Pacific

Australia

Sartorius Stedim Australia Pty. Ltd.
Unit 5, 7-11 Rodeo Drive
Dandenong South Vic 3175

Phone +61.3.8762.1800
Fax +61.3.8762.1828

China

Sartorius Stedim Beijing
Representative Office
No. 33, Yu'an Road,
Airport Industrial Zone B, Shunyi District
Beijing 101300

Phone +86.10.80426516
Fax +86.10.80426580

Sartorius Stedim Shanghai
Representative Office
Room 618, Tower 1, German Centre,
Shanghai, PRC., 201203

Phone +86.21.28986393
Fax +86.21.28986392.11

Sartorius Stedim Guangzhou Office
Room 704, Broadway Plaza,
No. 233-234 Dong Feng West Road
Guangzhou 510180

Phone +86.20.8351.7921
Fax +86.20.8351.7931

India

Sartorius Stedim India Pvt. Ltd.
#69/2-69/3, Jakkasandra
Kunigal Road, Nelamangala Tq
Bangalore – 562 123

Phone +91.80.4350.5361
Fax +91.80.4350.5253

Japan

Sartorius Stedim Japan K.K.
KY Building, 8-11
Kita Shinagawa 1-chome
Shinagawa-ku
Tokyo 140-0001

Phone +81.3.3740.5407
Fax +81.3.3740.5406

Malaysia

Sartorius Stedim Malaysia Sdn. Bhd.
Lot L3-E-3B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur

Phone +60.3.8996.0622
Fax +60.3.8996.0755

Singapore

Sartorius Stedim Singapore Pte. Ltd.
1 Science Park Road,
The Capricorn, #05-08A,
Singapore Science Park 2
Singapore 117528

Phone +65.6872.3966
Fax +65.6778.2494