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SISTEMAS PARA PRUEBAS DE ESTERILIDAD

Sterility Testing Systems

Sterisart® Universal Pump

International pharmacopeias require the complete sterility of pharmaceutical products 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 sterility of the final product batch.

The new Sterisart® Universal Pump is available in two versions: as a basic version, 16419, and as an upgraded version, 16420, with display and user software. The pump can be used in clean rooms, integrated into clean benches, or installed countersunk in the working surface of isolators. Its low, compact design has a space-saving footprint – a great benefit for most clean room benchtops and isolators.

Additional Features and Benefits

- Closed system – no ventilation for enhanced safety
- Rugged and maintenance-free
- Compact and ergonomic construction
- Modular design
- Pump available with special software (menu-driven prompts for operator guidance; all process sequences can be logged; barcode recognition)

Special brochures available on request.
Order no. SLD1003-e, SLD2010



Technical Specifications for Sterisart® Universal Pump

Pump flow rate [ml/min]	70–650
Power requirements [VAC]	100–240
Frequency [Hz]	50–60
Power consumption [W]	100
Dimensions W f D f H [mm]	
Pump	Approx. 336 f 260 f 210 (with lever)
Pump with holding ring for bottles, container	Approx. 440 f 365 f 485
Weight [kg]	
Basic version 16419	Approx. 13.5
Upgraded version 16420 with display and user software	Approx. 14.6

Ordering Information

Order No.	Description
16419	Sterisart® Universal pump, basic version
16420	Sterisart® Universal pump, upgraded version with display user software

Accessories

Order Number	Description
1ZE---0033	Footswitch
1ZG---0014	Adapter for Sterisart® NF units, fitting into container for draining of Millipore Equinox pump
1ZG---0025	Adapter for Sterisart® NF units, fitting into container for draining (with two slightly different diameters of the fixation-slots) of new Millipore Equinox pump
1ZE---0039	Transport trolley
1ZE---0040	Communication kit
1ZE---0050	Installation kit for isolators

Further accessories are available on request.

Sterility Testing Systems

Sterisart® NF



Sterisart® NF 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 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 brochures available on request.
Order no. SLD1002-e, SL-2019-e,
SLD2006-e, SLD2005-e, SLD2007-e,
S--2019-e, SLD2009-e, SLD2011-e

Sterisart® NF Offers the Following Features and Benefits

- Reliable, Sartochem® membrane:
 - High retention of microbes
 - Low adsorption
 - High mechanical stability
- Easy to use:
 - Pre-installed color-coded tube clamps
 - Easy-to-read graduated marks
 - Several user-friendly, practical adapters available
 - Product-|lot number identification
- Safe and protected:
 - Gas-impermeable packaging for protection against sterilants

Specifications

Technical Specifications for Sterisart® NF

Pore size of the Sartochem® membrane filter	0.45 µm, tested with <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

Ordering Information

Sterisart® NF alpha Disposable Units for Sterility Testing in Clean Rooms, Individually, Sterile Packaged, ETO-sterilized, Needles Made of Flame-sterilizable Stainless Steel, 10 Units

Type of Sample	Type of Sample Container	Description	Order No.
LVPs	Closed glass bottles with septum	Sterisart® NF alpha with long dual-needle metal spike, sterile-vented	16466-----ACD
LVPs SVPs	Open containers, i.e. glass ampoules, glass bottles collapsible bags	Sterisart® NF alpha with long needle and protective plate, inclusive sterile venting needle	16467-----ACD
LVPs SVPs	Open containers, i.e. glass ampoules, glass bottles, collapsible bags	Sterisart® NF alpha with long needle, inclusive sterile venting needle	16467-----TCD
Medical devices	Tubing systems and bags with Luer or Luer Lock connectors	Sterisart® NF alpha with Luer or Luer Lock connector, inclusive long needle and sterile venting needle	16468-----ACD

Sterisart® NF gamma Disposable Units for Sterility Testing in Isolators, Individually Sterile, Double-packaged, Gamma Irradiated, Needles Made of Flame-sterilizable Stainless Steel, 10 Units

Type of Sample	Type of Sample Container	Description	Order No.
LVPs	Closed glass bottles with septum	Sterisart® NF gamma with long dual-needle metal spike, sterile-vented	16466-----GBD
SVPs	Closed glass vials with septum	Sterisart® NF gamma with short dual-needle metal spike, sterile-vented	16476-----GBD
LVPs, SVPs, eye drops	Closed plastic containers vials ampoules, plastic containers of Blow-Fill-Seal fillings	Sterisart® NF gamma with long needle, (side opening, with solid pointed tip, non-coring), protective plate, inclusive sterile venting needle	16477-----GBD
LVPs SVPs	Open containers, (i.e. glass ampoules, glass bottles), collapsible bags	Sterisart® NF gamma with long needle and protective plate, inclusive sterile venting needle	16467-----GBD
Lyophilisates, soluble powders, liquid antibiotics	Closed glass vials with septum	Sterisart® NF gamma with two dual-needle metal spikes of different length, one is sterile-vented	16475-----GBD
Pre-filled syringes	Syringes with and without needles	Sterisart® NF gamma with syringe-adapter and long dual-needle metal spike, sterile-vented	16469-----GBD
Medical devices	Tubing systems and bags with Luer or Luer Lock connectors	Sterisart® NF gamma with Luer or Luer Lock connection, inclusive long needle and sterile venting needle	16468-----GBD
New Medical devices	Containers bags with Luer Lock male connectors	Sterisart® NF gamma with female Luer Lock connector	16478-----GBD

Sterisart® NF gamma Septum, Disposable Units for Sterility Testing in Isolators, Sterisart® NF Containers with Integrated Septum for Reliable Sample Taking during Incubation, Individually Sterile, Double-Packaged, Gamma Irradiated, Needles Made of Flame-sterilizable Stainless Steel, 10 Units

LVPs	Closed glass bottles with septum	Sterisart® NF gamma Septum with long dual-needle metal spike, sterile-vented	16466-----GSD
LVPs SVPs	Open containers, (i.e. glass ampoules, glass bottles), collapsible bags	Sterisart® NF gamma Septum with long needle and protective plate, inclusive sterile venting needle	16467-----GSD
Lyophilisates, Soluble powders, Liquid antibiotics	Closed glass vials with septum	Sterisart® NF gamma Septum with two dual-needle spikes of different length, one is sterile-vented	16475-----GSD
Pre-filled syringes	Syringes with and without needles	Sterisart® NF gamma Septum with syringe-adapter and long dual-needle metal spike, sterile-vented	16469-----GSD

Accessories

Application	Description	Order No.
Difficult-to-dissolve powders in closed glass vials with septum, non-vacuo	Sterisart® NF gamma tubing system with two dual-needle metal spikes of different length, needles made of flammable stainless steel	16470-----GBD
Sterile venting of containers with rinsing solution and nutrient media, additional sterile venting needles, equal to the inclusive needles of the Sterisart® NF units i.e. type 16467, 16468 and 16477	Needle with venting filter, 4 cm, stainless steel, individually sterile packaged, gamma-irradiated, pack size 50	16596-----HNK

Further units (16464-----ACD|GBD) on request.

