

DOMINIQUE DUTSCHER SAS

Sterisart® NF

Sterility Testing Made Easy and Reliable

Simplifying Progress

SARTORIUS

Sterisart® NF – Versatile and Highly Compatible

International pharmacopoeias 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 the sterility of final product batch.

The preferred method for sterility testing is the membrane filter method – any microorganisms present are concentrated on the membrane filter surfaces in the sample containers, then nutrient media are added to these containers, and the containers are incubated under the conditions specified.

The convincing solution for safe handling
The Sterisart® NF system, order number 16466--------GBD, is equipped with a dual-needle metal spike, which has been specially designed for closed sample containers. The two needles are made of metal, allowing the spike to be briefly flamed.

This feature enables you to change sample containers, while considerably minimizing the risk of contamination. Unlike plastic needles, metal needles do not snap off when tilted under pressure. This benefit together with the large protective plate on the spike not only makes it easy to pierce stoppers. The plate construction also helps prevent injury to fingers by ruling out breakage or slippage. The lengths of the dual-needles allow the same spike to be used for various types of closures.

The Sterisart® NF adapter type with the order number 16467--------GBD has been specially designed for use with open containers, such as ampoules or collapsible plastic bags that do not require venting when samples are removed. The thickness and length of the individual needle with protective plate enable samples to be drawn even from exceptionally small ampoules with narrow openings.
In addition, the length of the needle makes it easy to remove samples from plastic bags without piercing the bag itself. Last but not least, this needle can also be briefly flamed, which minimizes the risk of contamination when you change sample containers. Both Sterisart® NF types are also available as special isolator versions with the model suffixes "gamma" or "gamma Septum," which is indicated by the last letters of the order number: GBD or GSD.

The Sterisart® systems with a partitioned (i.e., septated) connector allow sterile sampling during incubation and guarantee a sterile barrier between the interior and exterior of the container during further incubation.

Both gamma versions feature a gas-tight packaging that reliably retains gas, such as H_2O_2, used for routine sterilization inside isolators. This feature simplifies validation of Sterisart systems, helping prevent false negative results that might be caused by H_2O_2 seeping into the inside of sterility test units.

Sterisart® NF systems can be used with other manufactures' pumps which have been specially designed for disposable closed sterility testing systems. This requires one of two adapters to ensure the correct seating of Sartorius NF units in the pumps of other manufacturers – adapter order number 16412--------V (for older pumps), 1ZG---0014 (for new pumps) and 1ZA---0028 (for the latest version of the pump). However, you will not need these adapters if you are using Sterisart® Universal pumps 16419 and 16420. These versatile and flexible pumps offer considerable benefits, and are ideal for use in clean rooms and clean benches as well as in isolators when installed in the working surface.

Intelligent, closed system design
Compact Sterisart® NF systems feature a closed design for sterility testing, which means they maintain a closed system during transfer and distribution of the sample into two sample containers, filtration, rinsing, the addition of nutrient media, incubation and evaluation. Therefore, this design reliably prevents secondary contamination. They are ideal for routine or sporadic sterility testing in the pharmaceutical industry. The procedure is mostly independent of the sample volume because sufficiently large total volumes of sample can be filtered through the membranes in the two sample containers.

Membranes you can benefit from
The Sartochem® regenerated cellulose membrane has been specifically developed to meet the requirements of sterility testing, in particular for extremely low adsorption characteristics and for appropriate chemical compatibility.
The cellulose acetate membrane combines high-flow rates with equally low adsorption characteristics and is chemically compatible with aqueous solutions, oils, alcohols and organic solvents. The special clamping technology used to seal the outer edges of the disk membranes to the sample containers not only holds up very well to pressure. It also enhances the membrane's low adsorption by not retaining inhibitors in such a way that could affect microbiological growth. This is very important with regard to the reliability of the test.

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Specifications

Pore size of the membrane filter	0.45 µm
Filter area	15.7 cm² in each Sterisart® container
Pore size of the air filters	0.2 µm PTFE, validated acc. to HIMA for the retention of B. diminuta
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	Gamma irradiation

Specifications subject to change without notice.

Chemical Compatibility of the Components

(24-hour contact at 20 °C)

	Sartochem® membrane	Tubing	Sterisart® containers
Aqueous solutions	C	C	C
Alcohols	C	C	C
Aliphatic hydrocarbons	C	C	C
Oils	C	C	C
Salt solutions	C	C	C
Ether	C	C	C
Weak acids	C	C	LC
Weak bases	LC	C	LC
Aromatic hydrocarbons	C	N	N
Esters	C	N	LC
Halogenated hydrocarbons	C	N	N

C = compatible, LC = limited compatibility, N = not compatible

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Ordering Information

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, with septum, for liquids in closed, large volume containers such as bottles	16466-----CA-GSD
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, with septum, for liquids in open containers such as ampoules	16467-----CA-GSD
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.

Name	Description	Quantity	Order number
Sterisart® Universal pump	Basic version: Peristaltic pump for use with sample containers in sterility testing	1	16419
Sterisart® Universal pump	Upgraded version with display	user software	1	16420
Pump adapters	For use with Sterisart® systems in the Millipore Integral and Compact pump. Please clarify pump type used.	2	16412--------V
Pump adapter	For use with Sterisart® systems in the Millipore Equinox pump. Please clarify pump type used.	1	1ZG---0014
Pump adapters	For use with Sterisart® systems in the Millipore Symbio pump. Please clarify pump type used.	2	1ZA---0028

Further Sterisart® units and accessories are available on request. Comprehensive validation support literature is available on request. Publ. No. SL-4507-e

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Status: 07 | 2025