



sartorius stedim
biotech

Sterisart® NF

Meet our family for sterility testing –
reliable, economical, compatible



turning science into solutions

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, 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 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 H₂O₂, used for routine sterilization inside isolators. This feature simplifies validation of Sterisart systems, helping prevent false negative results that might be caused by H₂O₂ 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 16412V (for older pumps) or 1ZE---0014 (for the latest pump versions). However, you will not need these adapters if you are using Sterisart® Universal pumps 16419 and 16420. Recently designed by

Sartorius Stedim Biotech, 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.

A membrane you can benefit from.

The Sartochem® 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 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.



Specifications

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 oxide gas) or 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

Ordering information

Name	Description	Quantity	Order number
Sterisart® NF alpha	Dual-needle metal spike for closed containers (sterilized with ETO; single-packed)	Box of 10	16466 ACD
Sterisart® NF alpha	Metal needle for open containers (sterilized with ETO; single-packed)	Box of 10	16467 ACD
Sterisart® NF gamma	Dual-needle metal spike for closed containers (gamma sterilized, double-packed, optimal for use in isolators)	Box of 10	16466 GBD
Sterisart® NF gamma	Metal needle for open containers (gamma sterilized, double-packed, optimal for use in isolators)	Box of 10	16467 GBD
Sterisart® NF gamma Septum	Dual-needle metal spike for closed containers (gamma-sterilized, double-packed, optimal for use in isolators)	Box of 10	16466 GSD
Sterisart® NF gamma Septum	Metal needle for open containers (gamma-sterilized, double-packed, optimal for use in isolators)	Box of 10	16467 GSD
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 older Millipore pumps. Please clarify pump type used.	2	16412 V
Pump adapters	For use with Sterisart® systems in newer Millipore Equinox pumps. Please clarify pump type used.	1	1ZE---0014

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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