

Steritest™ NEO Double-Packed, Gamma Sterilized Sterility Testing Device

Double packaging enhances sterility testing reliability

Sterility testing is one of the most crucial and time-consuming steps in pharmaceutical processing. Although it is a critical step, it does not have to be a difficult one. The Steritest™ NEO device simplifies every aspect of testing, from handling to traceability, to reliability, all within a closed concept system. The ease and convenience enables you to increase productivity while maintaining the highest levels of quality.

For more than four decades, we have been the market leader in sterility testing. Steritest™ NEO double-packed, gamma sterilized devices, continue to set the standard for sterility testing excellence.



Features

- Gamma sterilized and double packed for quick transfer into sterility testing environments, simplifying decontamination procedures and saving time.
- Sealed bag provides optimum decontamination of the outer bag and easy bag opening.
- Outer packaging materials ensure complete integrity of the bags during transportation, minimizing risk of piercing or damage.
- Primary blister packaging can be hung or stacked within the testing environment, minimizing the test area requirements.

Steritest™ NEO devices offer increased workflow safety, convenience and reliability to the sterility test.

Double Packed Saves Time

Steritest™ NEO devices are packed to ensure optimum cleanliness. The double packaging allows operators to open the outer bag in a clean room and bring the sterile package into a laminar flow hood or isolator environment. A tear primer on the outer bag enables gloved operators to open the outer bag easily, eliminating the use of scissors. This simplified decontamination procedure saves operator time.

Outer Bag Designed to Eliminate the Risk of Contamination

During manufacture, the bag is sealed and then trimmed to remove any potential pockets where contamination could reside. This packaging feature ensures optimum decontamination of the bag prior to introduction in a clean room.

Outer Bag Designed to keep Steritest™ NEO Devices Sterile

Unlike standard bags, which are susceptible to tears during shipping and therefore potential contamination, the new Steritest™ NEO double-packed devices outer bags are made of a thick multilayer 170 µm film (Polyamide – Polyethylene derivate). This material was

selected for its mechanical resistance. The bags are vacuum sealed and the outer box contains foam to further protect the product. Vibration tests, drop tests and shipping trials have confirmed the bags' integrity from manufacturing plant to lab.

Primary Package Simplifies Operational Steps

The Steritest™ NEO blister is made of a rigid PET shell for optimal protection during shipping and handling, a layer of which is designed to be easily peeled for opening. The shells are stackable, saving valuable space under laminar flow hoods or inside isolators. For isolator users, a hole is positioned to hang the devices prior to decontamination cycles. Catalogue and lot numbers, sterilization date and expiration date are printed on each blister for easy traceability.

Transfer of Steritest™ NEO Double-packed Devices into a Laminar Flow Hood

Unclassified Room

Bag decontamination



Bag with perfect cut sealing for an optimal decontamination.

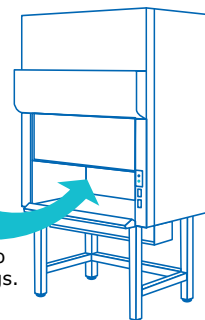
Bag Transfer

Classified Room

Bag opening and transfer of devices



Transfer of sterile devices into the LFH results in time savings.



Needle Adapter Increases Efficiency and Security

The Steritest™ NEO needle adapter enables fast and easy manipulation of drug products.

- Fits most size test vials; eliminates blockage when testing drugs in vials with thick septa
- Integrated vent eliminates the need for separate vent needle (reference TZHALV205, TZHASV205, TZHVLV205 and TZHVDV205), reducing the handling steps
- Ergonomic, non-skid design provides a secure grip for gloved operations, especially in isolators



Canister Inlet Reduces Foaming, Speeds Filtration

In the past, operators needed to reduce pump speed to minimize foam when testing protein solutions or adding media. The result was slower filtration. Now you can test faster and reduce foam with the improved canister inlet design. This feature, coupled with our high flow mixed esters of cellulose (HA) membrane, improves reliability while allowing you to maintain high pump speeds and decrease testing time.

Easy Handling

Steritest™ NEO canister tubing includes pre-installed colored clamps, eliminating the risk of error during media filling. Closing and re-opening the clamps during testing is as simple as pressing down or releasing as necessary. The 850 mm tubing length and the placement mark* offer easier set-up with ample room and precision to perform the manipulations involved in sterility testing.



* coming soon

Completely Closed for Complete Confidence

Pharmaceutical products are never exposed to the environment during the testing process with Steritest™ NEO devices. Sampling, filtration, rinsing, media addition and incubation are all conducted within a closed system. There is no need to open containers or manipulate the membrane at any time — greatly reducing the risk of adventitious contamination. Double packaging further enhances quality, so you can be assured of unmatched sterility in every step.

Quality Made Simple

We take nothing for granted. So in addition to the new quality assurance features of our Steritest™ NEO device, we also rigorously test each device during and after manufacturing.

- 100% integrity testing on every canister
- Strict physical and microbiological tests on assembled Steritest™ NEO devices prior to release from manufacturing
- Certificate of Quality provided with each system for your batch records
- Easy traceability with catalogue number, lot number and expiration date printed on each canister

Specifications

Steritest™ NEO “Blue Base” devices

For Products without Antimicrobial Agents



Canister Base Color	Blue
Canister Base Membrane	Mixed Esters of Cellulose membrane, 0.45 µm
Materials of Construction <i>Outer bag:</i>	multilayer 170 µm film (Polyamide +Polyethylene derivate)
<i>Primary blister:</i>	Shell made of PET, Cover made of Tyvek® paper
<i>Filtration Chamber (Canister):</i>	Styrene acrylonitrile
<i>Double Lumen Tubing:</i>	PVC, 850 mm length
<i>Needle:</i>	Stainless steel and polyamide 6-6
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Maximum Temperature	45 °C
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
Sterilization	Gamma irradiation

Steritest™ NEO “Red Base” devices

For Antibiotics and Products Containing Antimicrobial Agents



Canister Base Color	Red
Canister Base Membrane	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF
Materials of Construction <i>Outer bag:</i>	multilayer 170 µm film (Polyamide +Polyethylene derivate)
<i>Primary blister:</i>	Shell made of PET, Cover made of Tyvek® paper
<i>Filtration Chamber (Canister):</i>	Styrene acrylonitrile (SAN)
<i>Double Lumen Tubing:</i>	PVC, 850 mm length
<i>Needle:</i>	Stainless steel and polyamide 6-6
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Maximum Temperature	45 °C
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
Sterilization	Gamma irradiation

Steritest™ NEO devices for products without antimicrobial agents

Description	Pack size	Cat. No.
Liquids in ampoules and collapsible bags		
Steritest™ NEO device double packed	10 (2 bags of 5 devices)	TZHALA205
Liquids in large vials		
Steritest™ NEO device double packed	10 (2 bags of 5 devices)	TZHALV205
Liquids in small vials		
Steritest™ NEO device double packed	10 (2 bags of 5 devices)	TZHASV205

Steritest™ NEO devices for antibiotics and products with antimicrobial agents

Description	Pack size	Cat. No.
Antibiotics		
Steritest™ NEO device double packed	10 (2 bags of 5 devices)	TZHVAB205
Liquids in large vials		
Steritest™ NEO device double packed	10 (2 bags of 5 devices)	TZHVLV205
Liquids in small vials		
Steritest™ NEO device double packed	10 (2 bags of 5 devices)	TZHVSV205
Soluble powders in vials		
Steritest™ NEO device double packed	10 (2 bags of 5 devices)	TZHVDV205

To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645

Germany: 069 86798021

Italy: 848 845 645

Spain: 901 516 645 Option 1

Switzerland: 0848 645 645

United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Or visit: [MerckMillipore.com/offices](https://www.MerckMillipore.com/offices)

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INFORMATION**



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