

# Steritest® NEO Sterility Testing Devices

Convenience, Reliability and Safety

## **Sterility testing is one of the most crucial steps in pharmaceutical product release.**

Our Steritest® NEO devices simplify every aspect of testing, from handling to traceability, all within a closed concept system. The ease and convenience of this closed assembly enable you to increase productivity while maintaining the highest levels of quality and reliability. When used with the Steritest® Symbio pump and Steritest® culture media and fluids, the Steritest® system delivers unmatched sterility testing consistency.

Since 1974, we have been the market leader in sterility testing. Our Steritest® NEO devices set a new standard for excellence while maintaining all the advantages of membrane-base sealing technique.

### **Closed device for complete testing confidence**

Using Steritest® NEO devices ensures that pharmaceutical products are never exposed to the environment during the testing process. Filtering, rinsing, media transferring and incubating are all conducted within the Steritest® NEO closed system. There is no need to open the containers or manipulate the membrane at any time—greatly reducing the risk of adventitious contamination resulting in false positive results.

### **Consistent performance**

We rigorously test each device during and after manufacturing.

- 100% integrity testing on every canister
- Strict physical and microbiological tests at every step of the assembly of the Steritest® NEO device prior to release from manufacturing
- Certificate of quality provided with each system for your batch records
- Easy traceability with catalogue number, lot number, serial number and expiration date engraved on each canister
- New: 2D data matrix barcode on the label for easy data processing in a broad range of systems (ERP, LIMS, etc...)

## Benefits

- Thermo-sealing of filtration membranes in all Steritest® NEO units ensures full device integrity, efficient membrane rinsing and elimination of by-pass and false negative results
- Velax® cutting clamp, a safe and convenient way to cut the tubing. Available on each Steritest® NEO devices removing the need of scissors.
- New needle design fits the majority of test containers while maintaining a closed concept system
- Pre-installed colored clamps prevent any media transferring errors and improve your workflow
- Volume graduation on the canisters improve your workflow accuracy (addition of a 25 mL graduation)
- Pre-cut line on accessories bag to ease the opening
- Placement mark on tubing to optimize the placement in the pump head
- Engraved information on each canister and peel-and-stick box label improve traceability
- Smart Label with 2D data matrix barcode to retrieve product data (item code, batch number, shelf life, etc...). It allows an easy data processing in a broad range of systems (EPR, LIMS, etc...)

## Latest innovations

### New tool for safe & easy cutting of tubes

Thanks to the new convenient Velax® cutting clamps there is no longer a need to use scissors to disconnect the tubing.

Simply moving the cutting clamp to the right position and pressing it will easily sever the tubing with no risk to fingers or gloves.

The Velax® cutting clamps are now mounted on all Steritest® NEO devices at no extra cost and add a further safety feature to Steritest® sterility testing.

Learn more with our video on [SigmaAldrich.com/video-velax](https://www.sigmaaldrich.com/video-velax)

### New needle designs for increased safety and flexibility

New needle guard and needle protector designs increase confidence in manipulating the needle.

The two-part protective cap gives access to either a short (35 mm) or a long (60 mm) needle—select the one that works best with your sample packaging.

In addition to the multiple needle configurations, a new short (20 mm) needle is now dedicated to cartridges and small soft plastic containers. Learn more with our video on [SigmaAldrich.com/video-steritestneo-ca](https://www.sigmaaldrich.com/video-steritestneo-ca)

### For products without antimicrobial agents

The “Blue Base” Steritest® NEO devices offer the ultimate in flexibility. Perfect for use with the majority of pharmaceutical drugs that do not have antimicrobial activity, our mixed esters of cellulose HA membrane allows fast flow rates for optimum throughput performance, and reduced testing time. A range of ergonomic needles is available to meet specific drug packaging requirements as well as simplify handling for gloved operators.




### For antibiotics and products with antimicrobial agents

The “Red Base” Steritest® NEO devices, ideally suited for antibiotic sample testing, incorporate our Durapore® (PVDF) HV membrane, offering broad chemical compatibility and low binding properties. The chemical composition of the extremely thin 0.45 µm Durapore® membrane provides low antibiotic binding, which improves rinsing efficiency and reduces the risk of false negative results. The canister design ensures efficient rinsing of residual antimicrobial agents and the needle and connections minimize the risk of antibiotic residuals.

### For products requiring increased chemical compatibility

The “Green Base” Steritest® NEO devices are suited for viscous products, such as creams and ointments, which are normally diluted in a sterile solvent, such as isopropyl myristate (IPM) to improve filterability. The solvent-resistant nylon canister and the Durapore® (PVDF) HV membrane ensure a perfect chemical compatibility with IPM and other solvents. The reinforced base structure and canister connection guarantee an unmatched pressure resistance of the testing device during the whole filtration process. The “Green Base” Steritest® NEO devices are the perfect choice for testing solvents, creams, ointments and veterinary injectables.

## Specifications

Canister Base Color	Blue		Red		Green	
Canister Base Membrane	Mixed Esters of Cellulose membrane, 0.45 µm		Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF		Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF	
Materials of Construction						
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)		Styrene acrylonitrile (SAN)		Polyamide 6-6 (nylon)	
Double Lumen Tubing:	PVC, 850 mm length		PVC, 850 mm length		PVC, 850 mm length	
Needle:	Stainless steel and polyamide 6-6		Stainless steel and polyamide 6-6		Stainless steel and polyamide 6-6	
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)		120 mL (graduation marks at 25, 50, 75 and 100 mL)		120 mL (graduation marks at 25, 50, 75 and 100 mL)	
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)		300 mL/min at 690 mbar (10 psi)		300 mL/min at 690 mbar (10 psi)	
Maximum Temperature	45 °C		45 °C		45 °C	
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)		3.15 bars at 25 °C (45 psi at 77 °F)		3.15 bars at 25 °C (45 psi at 77 °F)	
Sterilization	Gamma irradiation		Gamma irradiation		Gamma irradiation	

## Ordering information

### Steritest® NEO devices for products without antimicrobial agents



Description	Pack size	Catalog number
<b>Liquids in ampoules and collapsible bags</b>		
Steritest® NEO device	10	TZHALA210
Steritest® NEO device double packed	10	TZHALA205
<b>Liquids in large vials</b>		
Steritest® NEO device	10	TZHALV210
Steritest® NEO device double packed	10	TZHALV205
<b>Liquids in small vials</b>		
Steritest® NEO device	10	TZHASV210
Steritest® NEO device double packed	10	TZHASV205
<b>Medical devices and collapsible bags</b>		
Steritest® NEO device	10	TZHAMD210
<b>Liquids in syringes</b>		
Steritest® NEO device	10	TZHASY210
<b>Liquids in plastic containers</b>		
Steritest® NEO device	10	TZHAPC210
<b>Soluble powders in ampoules</b>		
Steritest® NEO device	10	TZHADA210
<b>Soluble powders in vials</b>		
Steritest® NEO device	10	TZHADV210
<b>NEW Liquids in cartridges and small soft plastic containers</b>		
Steritest® NEO device	10	TZHACA210

### Steridilutor® NEO devices and accessories

Description	Pack size	Catalog number
<b>Steridilutor® NEO device for vials</b>		
Steridilutor® NEO device without expansion chamber	10	TZV000010
Steridilutor® NEO device with expansion chamber	10	TZVC00010
<b>Steridilutor® NEO device for liquid transfer</b>		
Steridilutor® NEO device for liquid transfer	10	TZA000010
<b>Sterile vent needles</b>		
Steritest® vent needles	25	TEFG02525

Learn more at [SigmaAldrich.com/steritestneo](https://SigmaAldrich.com/steritestneo)

### To place an order or receive technical assistance

Order/Customer Service:  
**SigmaAldrich.com/order**

Technical Service:  
**SigmaAldrich.com/techservice**

**SigmaAldrich.com/steritestneo**

### Steritest® NEO devices for antibiotics and products with antimicrobial agents



Description	Pack size	Catalog number
<b>Antibiotics</b>		
Steritest® NEO device	10	TZHVAB210
Steritest® NEO device double packed	10	TZHVAB205
<b>Powders and superpotent antibiotics</b>		
Steridilutor® NEO device with expansion chamber	10	TZVC00010
Steritest® NEO device	10	TZHVAB210
<b>Recommended accessories</b>		
Holder for Steridilutor® NEO vent chamber	1	SYMBSVB01
Steritest® vent needles	25	TEFG02525
<b>Liquids in large vial</b>		
Steritest® NEO device	10	TZHVLV210
Steritest® NEO device double packed	10	TZHVLV205
<b>Liquids in small vial</b>		
Steritest® NEO device	10	TZHSV210
Steritest® NEO device double packed	10	TZHSV205
<b>Soluble powders in vials</b>		
Steritest® NEO device	10	TZHVDV210
Steritest® NEO device double packed	10	TZHVDV205
<b>Medical devices and collapsible bags</b>		
Steritest® NEO device	10	TZHVMD210
<b>NEW Liquids in cartridges and small soft plastic containers</b>		
Steritest® NEO device	10	TZHVCA210

**Note:** For antibiotics or strong inhibitory products, the use of the TZHVAB210 filtration devices is highly recommended. Prior to the filtration step, it is recommended to dissolve and/or pool samples with the Steridilutor® NEO device.

### Steritest® NEO devices for increased chemical compatibility



Description	Pack size	Catalog number
<b>Solvents, creams, ointments, and veterinary injectables</b>		
Steritest® NEO device	10	TZHVSL210

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