Data Sheet



NEW Steritest[®] NEO sterility testing devices for cartridges and small soft plastic containers

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 enables 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[®] sterility test 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 the membrane-base sealing technique.

Gain dexterity for small sample containers

The risks of injury for the operator, and the risk of damaging the isolator glove and associated loss of sterility are becoming more critical when addressing small product sample packaging like cartridges, or soft single-use plastic containers.

A new Steritest[®] NEO device was specifically designed for these applications and is now available.





New needle increases dexterity and security

The design of this new needle has been optimized to offer **dexterity and security** to the operator while piercing the small container:

- Grips on the needle guard offering a firm and secured handling of the needle adaptor
- Ridges on the needle protector for easy and safe removal of the needle cap
- Short 20 mm length needle makes the piercing of the small septum straightforward without compromising the flow rate

All these elements contribute to a more convenient and safer sampling process of these small sample containers.

This single needle is meant to be used with product samples that do not require to be vented while sampling, like cartridges or carpules or soft single-use plastic containers (e.g Blow Fill Seal).





Helping you to work smarter

The new Steritest® NEO cartridge device benefits from all the improvements of this $4^{\rm th}$ generation of sterility testing devices:

- Colored clamps to prevent filling errors when transferring the culture media
- 25 mL graduation line for accurate volume measurement
- New placement mark to position the tubing precisely in the pump head
- Easy to open pre-cut accessory bag
- Optimized identification and traceability with the new peel-off label



Steritest[®] NEO device for antibiotics with the new size-adjustable needle

Completely closed for complete confidence

Pharmaceutical products are never exposed to the environment during the testing process with Steritest[®] NEO devices. 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.

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

Specifications

Steritest® NEO "Blue Base" devices

For Products without Antimicrobial Agents

		Canister Base Color	Blue
1000	J. CER	Canister Base Membrane	Mixed Esters of Cellulose membrane, 0.45 μm
	Care	Materials of Construction	
75 50	100mL	Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Shell made of PET, Cover made of Tyvek® paper Styrene acrylonitrile PVC, 850 mm length Stainless steel and polyamide 6-6
25	- 25	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



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	Canister Base Color	Red			
	Canister Base Membrane	Low adsorption Durapore [®] membrane, 0.45 µm hydrophilic PVDF			
	Materials of Construction				
	Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Shell made of PET, Cover made of Tyvek [®] paper Styrene acrylonitrile (SAN) PVC, 850 mm length 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			

Ordering information

Description	Pack size	Cat. No.				
For products without antimicrobial agents						
Steritest [®] NEO device for liquids in cartridges	10	TZHACA210				
For antibiotics and products with antimicrobial agents						
Steritest [®] NEO device for liquids in cartridges	10	TZHVCA210				



Look at this video featuring the ease of sampling small containers in comparison to a long classical needle.



Steritest[®] NEO devices for cartridge in real size

To place an order or receive technical assistance

Order/Customer Service: SigmaAldrich.com/order

Technical Service: SigmaAldrich.com/techservice

SigmaAldrich.com/steritestneo

MilliporeSigma 400 Summit Drive Burlington, MA 01803



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