

COMPLETE SOLUTIONS FOR COMPLETE CONFIDENCE

with the Steritest® System

Millipore
SIGMA



We invented the original Steritest® closed filtration system in the 1970's which changed sterility testing forever. The Steritest® NEO devices is the 4th generation. We are continuously raising industry standards, and driving innovation to provide you the most secure and reliable test ever.

Select Your Steritest® NEO Device		Liquids in Ampoules or Collapsible Bags	Liquids in Cartridges and Small Soft Plastic Containers	Liquids in Large Vials	Liquids in Small Vials	Soluble Powders in Vials	Medical Devices and Collapsible Bags	Soluble Powders in Ampoules	Liquids in Syringes	Liquids in Plastic Containers	Solvents, Creams, Ointments, and Veterinary Injectables	Powders and Superpotent Antibiotics
	Filtration membranes are thermo-sealed onto the base in all Steritest® NEO units, ensuring full integrity of the device, efficient membrane rinsing and eliminating the risk of by-pass.	<ul style="list-style-type: none"> Single needle for easy access to ampoules and collapsible bags Separate vent needle 	<ul style="list-style-type: none"> Single short (20 mm) needle for easy access to cartridges and small soft plastic containers Separate vent needle 	<ul style="list-style-type: none"> Vented double needle for large glass containers with septa 	<ul style="list-style-type: none"> Vented double needle for small vials with septa 	<ul style="list-style-type: none"> Double needles for small vials with septa Vented double needle Simultaneously dissolves/dilutes the sample in sterile diluent and transfers the resulting solution to canisters 	<ul style="list-style-type: none"> Three adapters provided: male Luer, female Luer or single needle allow connection to a variety of test devices Separate vent needle 	<ul style="list-style-type: none"> Single needle for transfer into and out of ampoules Vented double needle Simultaneously dissolves/dilutes the sample in sterile diluent and transfers the resulting solution to canisters 	<ul style="list-style-type: none"> Adapter allows for sequential testing of syringe contents and needle surfaces Vented double needle 	<ul style="list-style-type: none"> Non-coring single needle minimizes blockage when piercing plastic containers Separate vent needle 	<ul style="list-style-type: none"> Single needle Separate vent needle Canister designed for testing products dissolved in solvents such as isopropyl myristate Better resistance to pressure, thanks to canister connections and reinforced base structure 	<ul style="list-style-type: none"> Tubing and needle assembly for antibiotics and products containing antimicrobial activity that require dilution or dissolution Aseptically connects the diluent or dissolution fluid to the product container for dilution Used for pooling superpotent antibiotics to reduce product-membrane contact time when product is then filtered Contains vent with expansion chamber for optimized venting Diluted product subsequently filtered with Steritest® NEO device (TZHVAB210)
For Products Without Antimicrobial Agents	Blue canister base. Mixed esters of cellulose membrane. This membrane provides an optimal filtration flow rate for standard products. Canister material: SAN (Styrene-Acrylo Nitrile).	TZHALA210 or TZHALA205 (double packed)	TZHACA210	TZHALV210 or TZHALV205 (double packed)	TZHASV210 or TZHASV205 (double packed)	TZHADV210	TZHAMD210	TZHADA210	TZHASY210	TZHAPC210		
For Products With Antimicrobial Agents	Red canister base with specific drain design. Low binding PVDF Durapore® membrane. This optimizes the rinsing of products that inhibit microbial growth. Canister material: SAN (Styrene-Acrylo Nitrile).	TZHVAB210 or TZHVAB205 (double packed)	TZHVCA210	TZHVLV210 or TZHVLV205 (double packed)	TZHVSV210 or TZHVSV205 (double packed)	TZHVVD210 or TZHVVD205 (double packed)	TZHVMD210					
For Antibiotics												TZVC00010 + TZHVAB210 or TZHVAB205 (double packed)
For products requiring Wider Chemical Compatibility	Green canister base with specific drain design. Low binding PVDF Durapore® membrane. This optimizes the rinsing of products that inhibit microbial growth. Canister material: polyamide polymer.										TZHVSL210	

Steritest® NEO Double Packed Devices

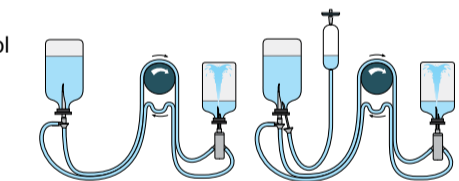
- Gamma sterilized and double packed for quick and safe transfer into sterility testing environments, simplifying decontamination procedures and saving time
- Sealed bag provides optimum decontamination of the outer bag and easy bag opening
- Outer packaging materials ensure complete integrity of the bags during transportation, minimizing risk of piercing or damage
- One box contains two bags, with five devices each



Steritest® NEO Accessories

Sample Preparation and Dilution

- Tubing and needle assembly to dissolve powders, for dilution and pool products in vials
- To be used for difficult to dissolve powders, dilution and pooling of viscous products in vials as well as antibiotics (to reduce the contact time with the filtration membrane)
- The expansion chamber vents residual vacuum or pressure from the vials without after-drip or contamination risk
- Small diameter double needle connects test product to diluent
- Diluted product subsequently filtered with suitable Steritest® NEO canisters

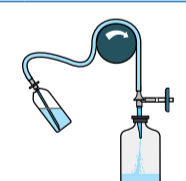


Steridilutor® NEO devices for liquids and soluble powders in vials - without expansion chamber TZV000010

Steridilutor® NEO devices for liquids and soluble powders in vials - with expansion chamber TZVC000010

Liquid Transfer

- Tubing and needle assembly for transfer of liquids from ampoules or vials to a diluent vial with septum
- Diluted products subsequently tested with suitable Steritest® NEO canister



Steridilutor® NEO devices for liquid transfer TZA000010

Sterile Vent Needles

- Single needle vented with PTFE 0.22 µm membrane
- For venting glass vials with septa and rigid plastic vials
- For venting of culture media bottles during the direct inoculation method
- For sterility and growth promotion qualification of culture media batches



Steritest® vent needles (pack of 25) TEFG02525

Steritest® sampling needle-free valve

- For planned sampling or injection into your Steritest® NEO Device
- To be installed on the canister before incubation



Steritest® sampling needle-free valve (box of 10 units, 2 valves per package) TZNFVSP20

Steritest® needle guide + needle

- For unplanned sampling or injection into your Steritest® NEO Device
- Can be installed on the canister whenever needed



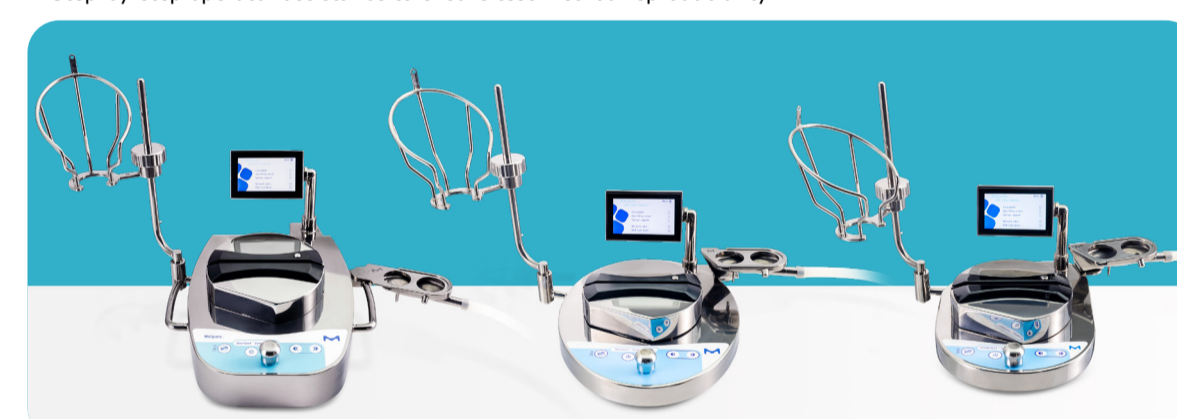
Steritest® needle guide + needle (box of 10 units) TZSPLK10

Learn more on SigmaAldrich.com/steritesteo

Pumps and Accessories

Steritest® Symbio Pumps

- Compact design to ease operations in laminar flow hoods and isolators
- Step-by-step operator assistance to ensure test method reproducibility



Steritest® Symbio LFH SYMBLFH01WW¹

Bench-top usage in laminar flow hood, biosafety cabinet, clean room or even inside an isolator

Steritest® Symbio FLEX SYMBFLE01WW¹

Versatile pump with multiple installation options in either an isolator or a laminar flow hood

Steritest® Symbio ISL SYMBISL01WW¹

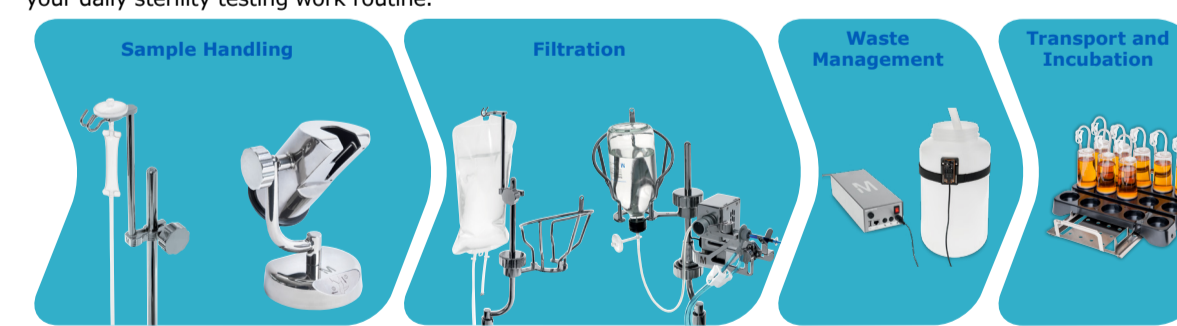
Table-integrated design for use in isolators

¹ Ask your local sales representative for the pump best suited for your testing environment.

Learn more on SigmaAldrich.com/steritest-symbio

Steritest® Symbio Pump Accessories

As sometimes little details make the difference, new Steritest® Symbio Accessories are designed to facilitate your daily sterility testing work routine.



Steritest® holder for Steridilutor® NEO vent chamber	SYMBSVB01
Steritest® glass ampoule breaker	SYMBABR01
Steritest® holder for sterile bags	SYMBSVB01
Steritest® syringe support for safe and ergonomic testing of pre-filled syringes	SYMBSYS01
Steritest® waste overfilling sensor for solid containers	SYMBWFS01
Steritest® canisters carrying tray	SYMBCAN08
Steritest® canisters carrying rack	SYMBRACK2
Steritest® pump footswitch	SYMBFSW01
Steritest® communication hub holder for hoods	SYMBCHH01
Steritest® communication hub holder for isolators	SYMBCHI01
Steritest® connection cable extension with Tri-Clover® clamp	SYMBXT01

Learn more on SigmaAldrich.com/steritest-symbioaccessories

Culture Media and Diluting/Rinsing Fluids

- Manufactured in ISO® 9001 manufacturing centers
- Formulated and tested to meet the requirements of the US, Japanese and European Pharmacopoeias



Culture Media	Volume	Closure	Qty/Pk	Ord. No.
Tryptic Soy Broth (Soybean-Casein Digest Medium)	100 mL	Screw cap with septum	12	STBMTS12
	100 mL	Screw cap with septum - double packed	12	STBMTS12DP
	100 mL	Crimp cap with septum	10	1.46317.0010
	100 mL	Screw cap with 3 mini septa	10	1.46458.0010
Fluid Thioglycollate Medium	100 mL	Screw cap with septum	12	STBMFTM12
	100 mL	Screw cap with septum - double packed	12	STBMFTM12DP
	100 mL	Crimp cap with septum	10	1.46406.0010
	100 mL	Screw cap with septum	12	STBMCTM12
Clear Thioglycollate Medium	100 mL	Screw cap with septum - double packed	12	STBMCTM12DP
	100 mL	Crimp cap with septum	10	1.46456.0010

Rinsing/Diluting Fluids	Volume	Closure	Qty/Pk	Ord. No.
USP Rinse Fluid A	900 mL	Screw cap with septum	4	STBMRFA94
	600 mL	Screw cap with septum	4	STBMRFA64
	600 mL	Crimp cap with septum	6	1.46489.0006
	300 mL	Screw cap with septum	4	STBMRFA34
	300 mL	Crimp cap with septum	6	1.46415.0006
	100 mL	Screw cap with septum	12	STBMRFA12
USP Rinse Fluid D	100 mL	Screw cap with septum - double packed	12	STBMRFA12DP
	100 mL	Crimp cap with septum	10	1.46470.0010
	300 mL	Crimp cap with septum	6	1.46483.0006
	300 mL	Screw cap with septum	4	STBMRFD34
USP Rinse Fluid K	600 mL	Screw cap with septum	4	STBMRFD64
	100 mL	Screw cap with septum	12	STBMRFK12
	300 mL	Screw cap with septum	4	STBMRFK34

Solvent ²	Volume	Closure	Qty/Pk	Ord. No.
Sterile Irradiated Isopropyl Myristate	360 mL	Red flip cap with septum	6	1.46628.0006

² To be used with the Steritest® NEO green base canister TZHVSL210.

Learn more on SigmaAldrich.com/steritest-mediafluids

Customized Culture Media for Special Applications

We offer tailor-made products that match your application needs. Choose from a variety of media formulation, formats, volume, and packaging options.

Learn more on SigmaAldrich.com/custom-media

Services and Support

Application Support

- Test Method Development & Consulting
- Customized test protocol following pharmacopoeia recommendations
- Recovery assessment performed with the relevant microorganisms
- Complete report generation
- Consulting service now available remotely

Validation Support

- Steritest® Symbio digital validation protocol SYMIQOQEP on our Val@M™ Application
- Ready-to-use protocols including installation (IQ), operational (OQ), and performance qualification (PQ) protocols
- In compliance with pharmaceutical standards and international pharmacopoeias

On-site Validation Services

- Installation
- IQ, OQ, execution of the test methods
- PQ: on-site support for implementation and execution of tests
- Requalification: ensure that your pump stays qualified
- Our validation consultation services are now available remotely

Learn more on SigmaAldrich.com/steritest-services

Service Plans

- Preventive Maintenance of Steritest® Symbio Pump
- Yearly preventive maintenance to provide reliable testing according to cGMP guidelines and ensure optimal equipment performance, such as reproducibility of filtrate volume and spitting capability
- Service on-site or at your closest repair center
- Repair labor and parts depending on repair coverage level
- Performance report

Trainings

- BEST Training³, in person or remote
- In depth theoretical training on sterility testing and applicable regulations covering:
 - Result interpretation
 - Method lifecycle
 - Product portfolio
 - Product demo
 - Certificate of attendance
- Advanced Operator Training (AOT)³, at customer site
- In-depth practical training on sterility testing covering:
 - In depth hands-on session for each participant: assembling the pump, usage, cleaning, troubleshooting and common mistakes
 - Certificate of attendance and examination form

³ For availability of BEST training, AOT and services in your geography, please contact your local sales representative.



M-Trace® Electronic Test Record Software & Mobile App

Your 21 CFR Part 11 compliant Digital QC companion for Sterility Testing & other regulated processes, for trusted and efficient data recording!

- Ensure full traceability and regulatory compliance with contemporaneous, automatic, and complete recording of data for each of your QC tests at any place of your facility
- Voice controlled data entry and electronic test record
- Increase process safety with guided QC workflows and deviation alerts
- Improve efficiency by eliminating paperbased documentation and digitizing recording and review processes
- Facilitate automated control of your Steritest® Symbio pump and advanced connectivity of your testing data to your lab IT environment (eg. LIMS)

Learn more on SigmaAldrich.com/m-trace



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For a complete overview of our Sterility Testing offer, please visit: SigmaAldrich.com/sterility-testing



Millipore®
Preparation, Separation,
Filtration & Monitoring Products