

# COMPLETE SOLUTIONS FOR COMPLETE CONFIDENCE

## with the Steritest® System



We invented the original Steritest® closed filtration system in the 1970's which changed sterility testing forever. The Steritest® NEO devices is the 4<sup>th</sup> 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
<b>For Products Without Antimicrobial Agents</b>	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	TZHADV210	TZHAMD210	TZHADA210	TZHASY210	TZHAPC210			
<b>For Products With Antimicrobial Agents</b>	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	TZHVMD210							
<b>For Antibiotics</b>											TZVC00010 + TZHVAB210 or TZHVAB205 (double packed)
<b>For products requiring Wider Chemical Compatibility</b>	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

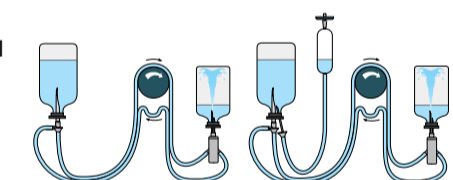
- Gamma sterilized and double packed for quick and safe transfer into sterility testing environments, simplifying decontamination procedures and saving time
- Sealed bag provides optimum decontamination of the outer bag and easy bag opening
- Outer packaging materials ensure complete integrity of the 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

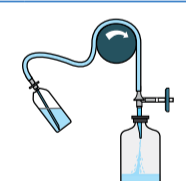


Steridilutor® NEO devices for liquids and soluble powders in vials - without expansion chamber TZV000010

Steridilutor® NEO devices for liquids and soluble powders in vials - with expansion chamber TZVC00010

#### 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/steritesto](https://SigmaAldrich.com/steritesto)

### 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 SYMBLFH01WW<sup>1</sup>

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

Steritest® Symbio FLEX SYMBFLE01WW<sup>1</sup>

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

Steritest® Symbio ISL SYMBISL01WW<sup>1</sup>

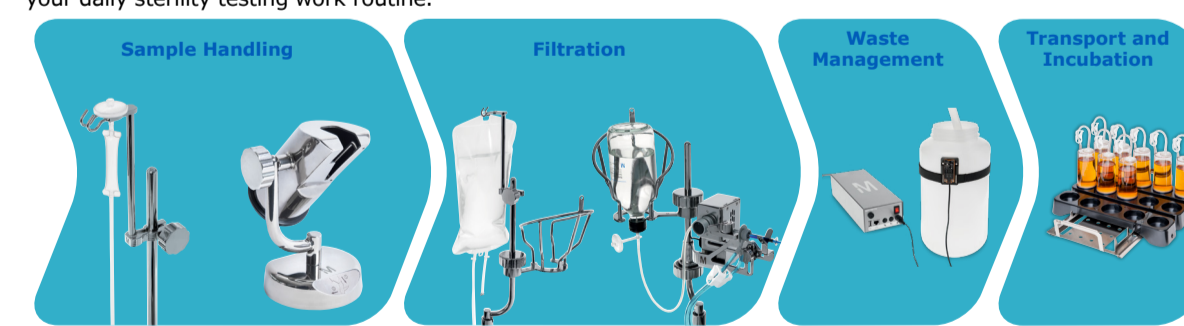
Table-integrated design for use in isolators

<sup>1</sup> Ask your local sales representative for the pump best suited for your testing environment.

Learn more on [SigmaAldrich.com/steritest-symbio](https://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](https://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
Clear Thioglycollate Medium	100 mL	Screw cap with septum	12	STBMCTM12
	100 mL	Screw cap with septum - double packed	12	STBMCTM12DP
	100 mL	Crimp cap with septum	10	1.46456.0010

#### Rinsing/Diluting Fluids

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<sup>2</sup>

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

<sup>2</sup> To be used with the Steritest® NEO green base canister TZHVSL210.

Learn more on [SigmaAldrich.com/steritest-mediafluids](https://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](https://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
- Product demo
- Certificate of attendance

#### 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 consulting services are now available remotely

Learn more on [SigmaAldrich.com/steritest-services](https://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 rinsing capability
- Service on-site or at your closest repair center
- Repair labour and parts depending on repair coverage level
- Performance report

#### Trainings

- Steritest® School<sup>3</sup>, 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)<sup>3</sup>, 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

<sup>3</sup> For availability of Steritest® School, 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 paper-based 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)

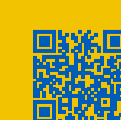
Learn more on [SigmaAldrich.com/m-trace](https://SigmaAldrich.com/m-trace)



The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.

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



# Millipore®

Preparation, Separation, Filtration & Monitoring Products