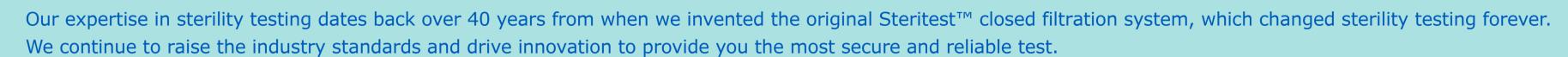
# COMPLETE SOLUTIONS FOR COMPLETE CONFIDENCE

with the Steritest™ System







For Products With Antimicrobial Agents	products. Canister material: SAN (Styrene-Acrylo Nitrile).  Red canister base with specific drain design. Low binding PVDF Durapore® membrane. This optimizes the rinsing of products that	TZHVAB210 or	TZHVCA210	TZHALV2U5 (double packed)  TZHVLV210 or  TZHVLV205 (double packed)	TZHVSV205 (double packed)  TZHVSV210 or  TZHVSV205 (double packed)	TZHVDV210 or TZHVDV205 (double packed)	TZHVMD210					
For Products Without Antimicrobial Agents	Blue canister base. Mixed esters of cellulose membrane. This membrane provides an optimal filtration flow rate for standard	TZHALA210 or TZHALA205 (double packed)	TZHACA210	TZHALV210 or TZHALV205 (double packed)	TZHASV210 or TZHASV205 (double packed)	TZHADV210	TZHAMD210	TZHADA210	TZHASY210	TZHAPC210		
Filtration membranes are therm full integrity of the device, efficient		<ul> <li>Single needle for easy access to ampoules and collapsible bags</li> <li>Separate vent needle</li> </ul>	Single short (20 mm) needle for easy access to cartridges and small soft plastic containers     Separate vent needle	Vented double needle for large glass containers with septa	Vented double needle for small vials with septa	<ul> <li>Double needles for small vials with septa</li> <li>Vented double needle</li> <li>Simultaneously dissolves/ dilutes the sample in sterile diluent and transfers the resulting solution to canisters</li> </ul>	Three adapters provided; male Luer, female Luer or single needle allow connection to a variety of test devices  Separate vent needle	<ul> <li>Single needle for transfer into and out of ampoules</li> <li>Vented double needle</li> <li>Simultaneously dissolves/ dilutes the sample in sterile diluent and transfers the resulting solution to canisters</li> </ul>	<ul> <li>Adapter allows for sequential testing of syringe contents and needle surfaces</li> <li>Vented double needle</li> </ul>	<ul> <li>Non-coring single needle minimizes blockage when piercing plastic containers</li> <li>Separate vent needle</li> </ul>	<ul> <li>Single needle</li> <li>Separate vent needle</li> <li>Canister designed for testing products dissolved in solvents such as isopropyl myristate</li> <li>Better resistance to pressure, thanks to canister connections and reinforced base structure</li> </ul>	<ul> <li>Tubing and needle assembly for antibiotics and products containing antimicrobial activity that require dilution or dissolution</li> <li>Aseptically connects the diluent or dissolution fluid to the product container for dilution</li> <li>Used for pooling superpotent antibiotics to reduce productmembrane contact time when product is then filtered</li> <li>Contains vent with expansion chamber for optimized venting</li> <li>Diluted product subsequently filtered with Steritest™ NEO device (TZHVAB210)</li> <li>Recommended Accessories: Sterile vent needles for safe transfer of liquid culture media (TEFG02525)</li> </ul>
Select Your Sterit	test™ NEO Device	Liquids in Ampoules or Collapsible Bags	Liquids in Cartridges and Small Soft Plastic Containers	Liquids in Large Vials	Liquids in Small Vials	<b>Soluble Powders in Vials</b>	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

TZVC00010 + TZHVAB210 or TZHVAB205 (double packed)

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

Sample Preparation and Dilution

time with the filtration membrane)

Steritest<sup>™</sup> vent needles (pack of 25)

For Antibiotics

## Steritest™ NEO Accessories for Dilution and Transfer

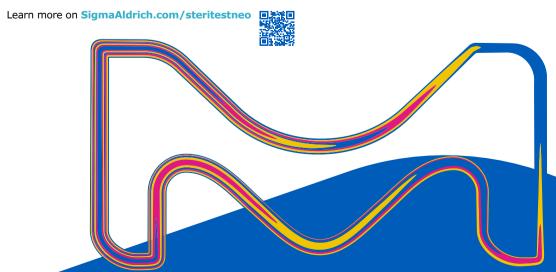
- Tubing and needle assembly to dissolve powders, for dilution and pool products in vials To be used for difficult to dissolve powders, dilution and pooling of viscous products in vials as well as antibiotics (to reduce the contact
- The expansion chamber vents residual vacuum or pressure from the vials without after-drip or contamination risk
- Small diameter double needle connects test product to diluent Diluted product subsequently filtered with suitable Steritest™ NEO canisters
- TZV000010 Steridilutor® NEO devices for liquids and soluble powders in vials - without expansion chamber Steridilutor® NEO devices for liquids and soluble powders in vials TZVC00010 - with expansion chamber
- **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 TZA000010

Steridilutor® NEO devices for liquid transfer **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 TEFG02525

Green canister base with specific drain design. Low binding PVDF Durapore® membrane. This optimizes the rinsing of products that nhibit microbial growth. Canister material: polyamide polymer.



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### 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 <sup>™</sup> Symbio LFH Bench-top usage in laminar flow hood, biosafety cabinet, clean room or even inside an isolator	SYMBLFH01WW <sup>1</sup>
Steritest™ Symbio FLEX Versatile pump with multiple installation options in either an isolator or a laminar flow hood	SYMBFLE01WW <sup>1</sup>
Steritest™ Symbio ISL Table-integrated design for use in isolators	SYMBISL01WW <sup>1</sup>
<sup>1</sup> Ask your local sales representative for the pump best suited for your testing environment.	

**Steritest™ Symbio Pump Accessories** 

Learn more on SigmaAldrich.com/steritest-symbio

Learn more on SigmaAldrich.com/steritest-symbioaccess

As sometimes little details make the difference, new Steritest™ Symbio Accessories are designed to facilitate your



ritest™ holder for ridilutor® NEO ent chamber	Steritest™ glass ampoule breaker (Stand alone)	Steritest™ holder for sterile bags	Steritest™ syringe support	St waste sens co
itest™ holde	r for Steridilutor®	NEO vent chambe	or	

Steritest™ holder for Steridilutor® NEO vent chamber	SYMBSVB01
Steritest™ glass ampoule breaker	SYMBABR01
Steritest™ holder for sterile bags	SYMBSVB01
Steritest <sup>™</sup> 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	SYMBXTC01

please visit: SigmaAldrich.com/sterility-testing

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

### 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



	Volume	Closure	Qty/Pk	Ord. No.
Tryptic Soy Broth Soybean-Casein Digest Medium)	100 mL	Screw cap with septum	12	STBMTSB12
	100 mL	Screw cap with septum – double packed	12	STBMTSB12DP
	100 mL	Crimp cap with septum	10	1.46317.0010
	100 mL	Screw cap with 3 mini septa	10	1.46458.0010
luid Thioglycollate	100 mL	Screw cap with septum	12	STBMFTM12
Medium	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

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	Contact us
	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
	100 mL	Screw cap with septum – double packed	12	STBMRFA12DF
	100 mL	Crimp cap with septum	10	1.46470.0010
USP Rinse Fluid D	300 mL	Crimp cap with septum	6	1.46483.0006
	300 mL	Screw cap with septum	4	STBMRFD34
USP Rinse Fluid K	300 mL	Screw cap with septum	4	STBMRFK34
	300 mL	Crimp cap with septum	6	Contact us

6 1.46628.0006 Sterile Irradiated 360 mL Red flip cap with septum Isopropyl Myristate

<sup>2</sup> To be used with the Steritest™ NEO green base canister TZHVSL210. Learn more on SigmaAldrich.com/steritest-mediafluids

100 mL Crimp cap with septum

### Services and Support

#### Application Support **Test Method Development & Consulting**

• Customized test protocol following pharmacopoeia recommendations

• Recovery assessment performed with the relevant microorganisms

**Validation Support** Steritest™ Symbio Pumps Validation Protocol,

European A4 format SYMBA4VP1 or US letter format SYMBLTVP1 • 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 Consultancy: On-site support for implementation of tests • Requalification: ensure that your pump stays qualified

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 splitting capability

Service on-site or at your closest repair center

 Repair labor and parts depending on service plan level Performance report

### **Trainings**

Steritest™ School<sup>3</sup> 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> In-depth practical training on sterility testing covering:

• Same as Steritest™ School or regulatory overview and product introduction • 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<sup>™</sup> School, AOT and services in your geography, please contact your local sales representative.

Learn more on SigmaAldrich.com/steritest-services



Preparation, Separation, Filtration & Monitoring Products