

For reliable sterility testing

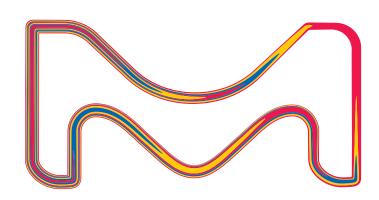
TRUST THE PIONEERS

Complete sterility testing solutions for complete confidence.

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

Millipore®

Preparation, Separation, Filtration & Monitoring Products



Sterility testing is an essential part of validation for products manufactured according to GMP purporting to be sterile.

Configure your Steritest™ system to fit your sample, packaging, and controlled testing environment needs. Our large variety of devices and pumps, along with sterile culture media and rinsing fluids can help you to stay compliant, whether you use membrane filtration or direct inoculation methods.



Workflow

History

Steritest™ NEO Filtration Device

Culture Media & Rinsing Fluids

Story of the Steritest™ system invention

Peristaltic Steritest™
Symbio Pump

Smart Accessories

Services & Training





EASY WORKFLOW In a 6-step procedure



Media Transfer

Reading

Place Steritest™ NEO device tubing in pump head* and push button to automatically close the pump head cover.

* New placement mark on the tubing for precise pump head positioning





EASY WORKFLOW In a 6-step procedure

Test Preparation Filter Pre-wetting

Sample Filtration Device Rinsing Media Transfer

Reading



Pre-wet the Steritest™ NEO device to optimize filtration, conditioning the membrane.



Workflow

EASY WORKFLOW In a 6-step procedure

Test Preparation Filter Pre-wetting

Sample Filtration

Device Rinsing Media Transfer

Reading



An equal amount of the product will be filtered into each canister through the sterile Steritest™ NEO tubing.





EASY WORKFLOW In a 6-step procedure

Test Preparation Filter Pre-wetting

Sample Filtration Device Rinsing

Media Transfer

Reading



Rinse product from both canisters.



Workflow

EASY WORKFLOW In a 6-step procedure

Test Preparation Filter Pre-wetting

Sample Filtration Device Rinsing Media Transfer

Reading



Pump media into each canister separately, using clamps to divert media to a single canister.



Workflow

EASY WORKFLOW In a 6-step procedure

Test Preparation Filter Pre-wetting

Sample Filtration Device Rinsing Media Transfer

Reading

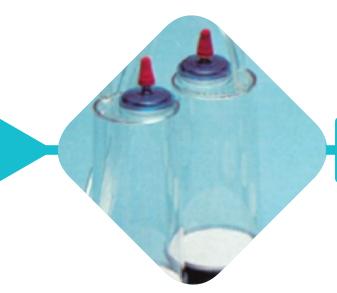


Incubate and examine the Steritest™ NEO canisters for growth in accordance with the appropriate pharmacopoeias.



History

Sterility Testing OUR PIONEERING HISTORY



1975 First Steritest™ unit



1985
New sealing technique & MCE membrane



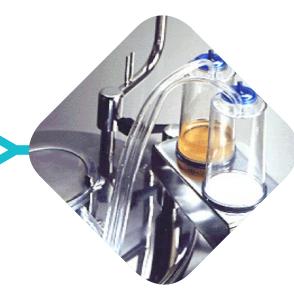
1986 PVDF Membrane



1988 Steritest™ Compact Pump



1994 Steritest™ device for oily samples



1994 Steritest™ Integral Pump



2004 Steritest™ Equinox Pumps



2018 & 2019 Steritest™ NEO Device



2016 Complete range of Steritest™ accessories



2014 Steritest™ Symbio Pumps



2012
Double packed media



2012
More choice of media & fluids



2010 New media & fluid bottles



2005 Steritest™ EZ Devices



1975

The first Steritest™ device is launched by Millipore Corporation



- A closed filtration device prevents external contamination (false positive results).
- The cellulose filter membrane with hydrophobic edge is pinched between canister top and base.
- The needle allows to sample the product out of the sterile vial the same way as the nurse or doctor would take the product out with a syringe.



1935

The Steritest™ device with welded canister and MCE membrane (Blue base)



Sealing Technique:

- Membrane heat sealing on base
- Ultrasonic welding of top on base

Avoids:

- Capillary diffusion of inhibitory products on the edges
- Usage of hydrophobic edge



History

1986

The Steritest™ device with PVDF membrane (Red base)



- The PVDF (Polyvinylidene fluoride) filter has low binding properties.
- The red base device is recommended to test products containing antibiotics or preservatives.
- Optimized filter support improves membrane rinsing.
- The ultrasonic welding prevents antibiotic diffusion on the membrane edge.



History

1988

The Steritest™ Compact pump



The flat design improves ergonomics in laminar flow hoods.



1994

The Steritest™ Integral pump



The pump is integrated inside the isolator table, is compatible with decontamination gases – vaporized hydrogen peroxide (VHP), and





History

1994

The Steritest™ device for oily samples (Green base)



- The canister material (grilamid) is compatible with a wide range of solvents, especially IPM (Isopropyl myristate) used to dilute creams, ointments, and veterinary vaccines.
- The tubing is inserted inside the canister chimney for highest resistance to pressure created by viscous products.



2004

The Steritest™ Equinox pumps



- The automatic pump head closing improves operator safety.
- The pressure sensors alert the operator if pressure increases inside the canisters.
- The "Automatic Mode" displays the test methods on the screen.



History

2005

The Steritest™ EZ devices



- Pre-assembled clamps
- Longer tubing
- Black line on tubing to differentiate canisters
- Lot number and expiry date etched on each canister
- Improved needle adapters
- Winged red and yellow plugs for easier handling





2010

New culture media and rinsing fluids bottles



- A large and rimless septum allows easy piercing and prevents decontamination agents entering while piercing.
- No risk of false positives and false negative results.





2010

The double-packed culture media and rinsing fluids



- Double Tyvek® bag and bottle surface sterilized by ethylene oxide, including septum and protective cap.
- 2-step unpacking prevents false positives and false negatives caused by improper decontamination procedures.



History

2012

More choice of culture media and rinsing fluids



- New lid types
- Wide range of bottle sizes
 (from 9 mL tube to 1 L bottles)
- Customization possibilities



History

2014

The Steritest™ Symbio pumps





2016

Complete range of Steritest™ accessories

Streamline your workflow and increase safety with smart accessories.

Sample Handling



SYMBSVB01
Steritest™ Holder
for Steridilutor®
NEO Vent Chamber



SYMBABR01 Steritest™ Glass Ampoule Breaker

Filtration



SYMBSVB01
Steritest™ Holder
for Sterile Bags



SYMBSYS01
Steritest™ Syringe
Support

Waste Management



SYMBWFS01
Steritest™ Waste
Overfilling Sensor
for Solid Containers

Transport and Incubation



SYMBCAN08
Steritest™ Canister
carrying trays
and SYMBRACK2
Steritest™ Rack



2018 & 2019

The Steritest™ NEO devices



Let us introduce the fourth generation of Steritest™ devices. Created to improve your workflow safety, reliability and convenience.

Evolution of safety

EVOLUTION OF CONVENIENCE

EVOLUTION OF RELIABILITY



Benefits

New Features

Video - New Features

Video - New Devices

Specifications

Regulations

Double Packed

Ordering Information

Complete Sterility Testing Offer

Our Steritest™ NEO devices simplify every aspect of testing, from handling to traceability, all within a closed 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, specific accessories and high quality culture media and rinsing fluids, the Steritest™ sterility test system offers an optimized and fully regulatory compliant testing process (USP <71>, EU Pharmacopoeia < 2.6.1> and JP Pharmacopoeia < 4.06>).

TRUST THE DIDNEERS

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 our thermo-sealed filtration membrane assembly.





Benefits

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Complete Sterility Testing Offer

Benefits

- Filtration membranes are thermo sealed onto the base for all of our Steritest™ NEO units. This ensures full integrity of the device and efficient membrane rinsing while eliminating the risk of by-pass
- Quality: 100% integrity testing and visual checks on every canister, along with strict physical and microbiological tests at every step
- Ergonomically designed needles fit the majority of test containers while maintaining a closed concept system
- Pre-installed colored clamps prevent any media filling errors and improve your workflow
- Canister design reduces foaming, enabling faster filtration

- Engraved information on each canister and peel-and-stick box label optimize traceability
- Volume graduation on the canisters improve your workflow accuracy (addition of a 25 mL graduation mark)
- Pre-cut line on accessory bag to ease the opening
- Placement mark on tubing to ease the placement in the pump head





Benefits

New Features

Video - New Features

Video - New Devices

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Complete Sterility Testing Offer

New features of the 4th generation of Steritest™ devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY



Feel flexible: protective caps for long needles are now in 2 parts

The protective cap in 2 parts gives access to either a short (35 mm) or a long (60 mm) needle designed to fit your sample packaging configuration.

Color-coded protectors help you to differentiate the needle type once covered.



CLICK TO ENLARGE

Feel calm: a brand new short needle for small sample containers

Experience dexterity with the new 20 mm length needle when piercing cartridges or small soft plastic containers, without compromising the flow rate.



CLICK TO ENLARGE

Feel free: upgraded accessory bag

Simplified opening of the accessory bag improves your workflow convenience thanks to the pre-cut line.



Feel comfortable: new placement mark

Be sure to place the Steritest™ NEO tube in the pump head precisely by using the new placement mark.



Benefits

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New features of the 4th generation of Steritest™ devices

EVOLUTION OF CONVENIENCE

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Feel flexible: protective caps for long needles are now in 2 parts giving access to a short or long needle







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EVOLUTION OF CONVENIENCE

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Feel calm: a brand new short needle for small sample containers









Benefits

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EVOLUTION OF CONVENIENCE

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Feel free: easy to open accessory bag







Benefits

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Feel comfortable: new placement mark optimizing the position of the tube in the pump head







Benefits

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New features of the 4th generation of Steritest™ devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY



Feel confident: colored clamps

Prevent any filling errors and improve your workflow clarity, thanks to the pre-installed colored clamps and the existing blackline for accurate media filling.



Feel safer: new designed needle guard and needle protector

Grips on the guard and ridges on the protector improve the confidence in needle manipulation.



Benefits

New Features

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Video - New Devices

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New features of the 4th generation of Steritest™ devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY

Feel confident: colored clamps









Benefits

New Features

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Video - New Devices

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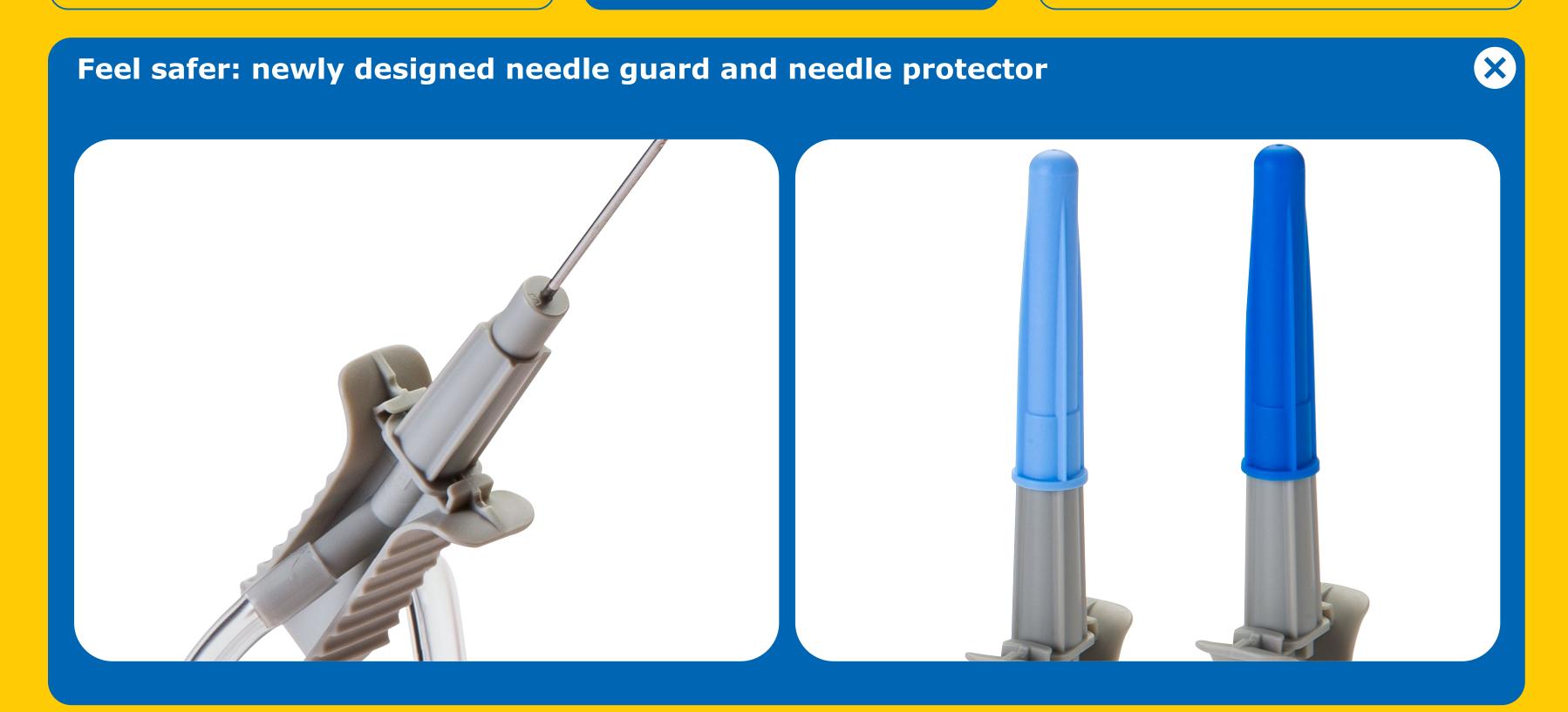
Complete Sterility Testing Offer

New features of the 4th generation of Steritest™ devices

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EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY





Benefits

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Testing Offer

New features of the 4th generation of Steritest™ devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY



Feel peaceful: optimized identification and traceability

Clear packaging identification: The selection of the appropriate box of Steritest™ NEO devices is facilitated thanks to the new designed label using color coding linked to canister base color and using a needle/application drawing.



CLICK TO ENLARGE

1D bar code associated to critical information and peel-and-stick label to place in a lab notebook for accurate tracking.



Feel sure: volume graduation on the canisters

Be precise and improve your workflow accuracy through the addition of a 25 mL graduation line and volume engraved in the Steritest™ NEO canisters.



Benefits

New Features

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Video - New Devices

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Complete Sterility Testing Offer

New features of the 4th generation of Steritest™ devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY

Feel peaceful: optimized identification and traceability



Devices for liquids in amposites
Statistics Translation
REF TRAILATIO
TRAILATIO
30-JUN-1020









Benefits

New Features

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New features of the 4th generation of Steritest™ devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY











Benefits

New Features

Video - New Features

Video - New Devices

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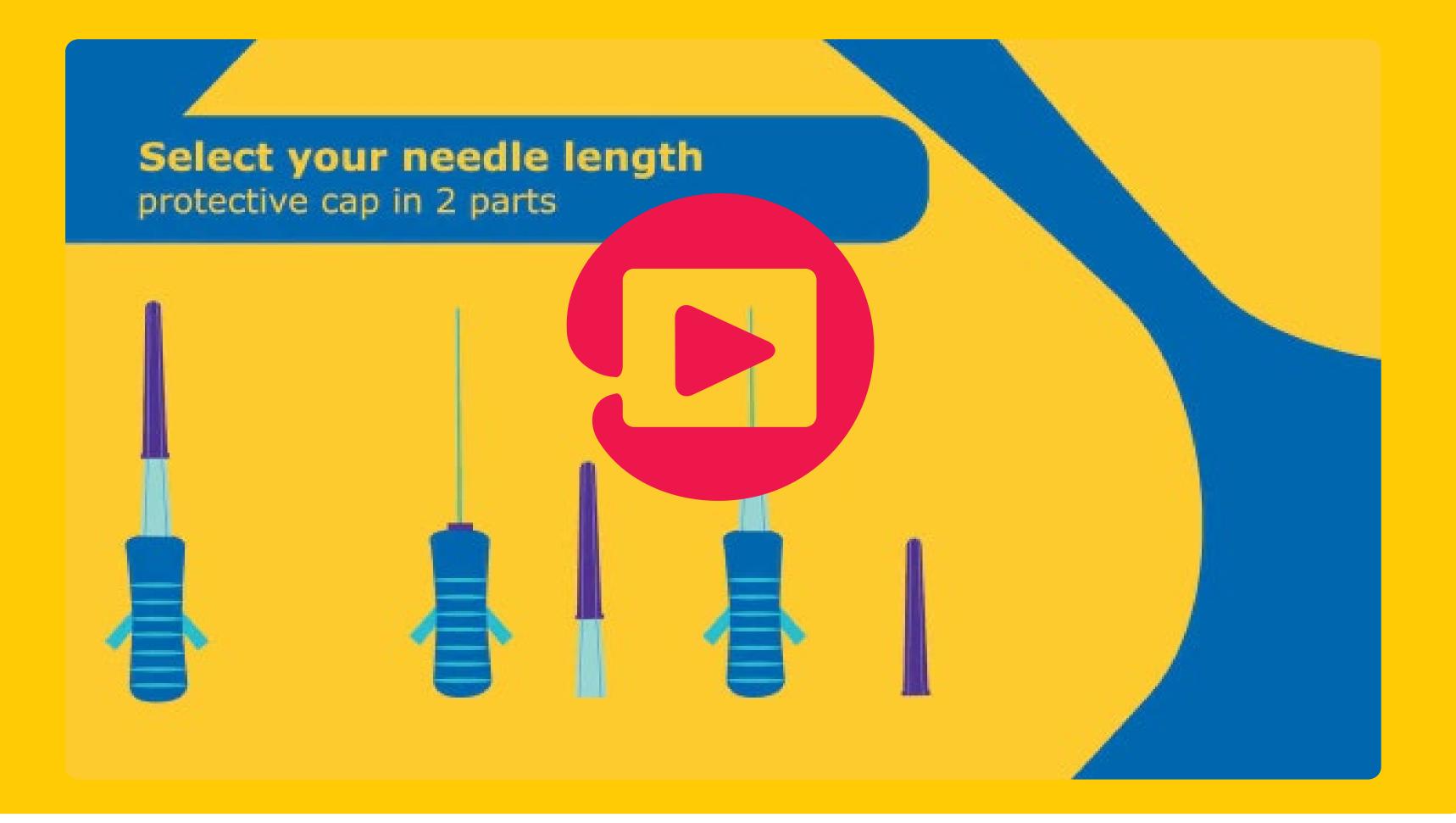
Regulations

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Complete Sterility
Testing Offer

VideoSteritest™ NEO devices: new features





Benefits

New Features

Video - New Features

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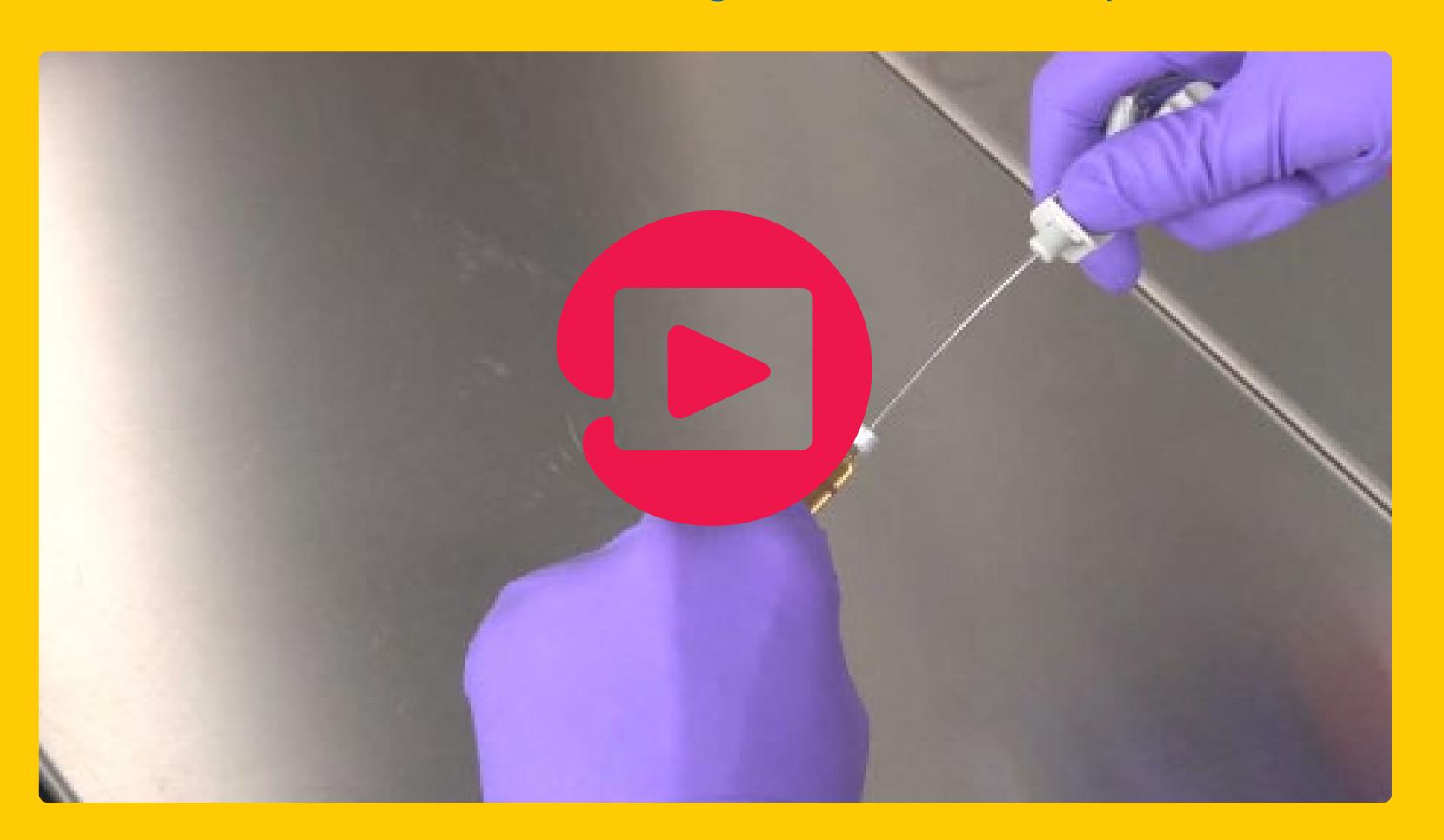
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Ordering Information

Complete Sterility
Testing Offer

Video

Steritest™ NEO devices for cartridges and small soft plastic containers





Benefits

New Features

Video - New Features

Video - New Devices

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Double Packed

Ordering Information

Complete Sterility Testing Offer

Specifications

Steritest™ NEO "Blue Base" devices

for antibiotics, products WITH antimicrobial agents and medical devices



Blue Mixed Esters of Cellulose (HA) membrane, 0.45 µm

3.15 bars at 25 °C (45 psi at 77 °F)

Click here

Filtration Chamber (Canister): Styrene acrylonitrile PVC, 850 mm length Stainless steel and polyamide 6-6

Sample Container Capacity 120 mL (graduation marks at 25, 50, 75 and 100 mL)

Gamma irradiation

45 °C

Minimum Flow Rate (for water) 300 mL/min at 690 mbar (10 psi)

Maximum Temperature

Canister Base Color

Canister Base Membrane

Materials of Construction

Double Lumen Tubing:

Maximum Operating Pressure

Sterilization

Needle:

Ordering Information

Steritest™ NEO "Red Base" devices

for products WITHOUT antimicrobial agents and medical devices



Red Low adsorption Durapore® membrane

(HV), 0.45 μm hydrophilic PVDF

Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6

120 mL (graduation marks at 25, 50, 75 and 100 mL)

300 mL/min at 690 mbar (10 psi)

45 °C

3.15 bars at 25 °C (45 psi at 77 °F)

Gamma irradiation

Click here

Steritest™ NEO "Green Base" devices

for products dissolved in solvents requiring increased chemical compatibility



Green

Low adsorption Durapore® membrane (HV), 0.45 μm hydrophilic PVDF

polyamide 6-6 (nylon) PVC, 850 mm length Stainless steel and polyamide 6-6

120 mL (graduation marks at 25, 50, 75 and 100 mL)

300 mL/min at 690 mbar (10 psi)

45 °C

3.15 bars at 25 °C (45 psi at 77 °F)

Gamma irradiation

Click here



Benefits

New Features

Video - New Features

Video - New Devices

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Complete Sterility
Testing Offer

Regulations and Industry benchmark

Regulations

Closed Environment

Consistent Performance

Certificates of Quality

Documented Qualification





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The membrane filtration sterility test is the regulatory method of choice for filterable pharmaceutical products, as cited in the USP <71>, EU Pharmacopoeia <2.6.1> and JP Pharmacopoeia <4.06>.



Benefits

New Features

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Closed Environment

Using Steritest™ NEO devices ensures that pharmaceutical products are never exposed to the environment during the testing process. Sampling, filtering, rinsing, media transfer and incubation are all conducted within the Steritest™ NEO closed system.

Minimize false positives: closed Steritest™ NEO filtration devices reduce the risk of false positive results avoiding a costly investigation or possible batch loss. There are no open containers or membrane manipulations, decreasing the risk of adventitious contamination.

Reduce false negatives: Steritest™ NEO filtration devices are the right answer to the danger that false negative results pose to patients. Through specific membranes, unique sealing technology and optimized device design, the unit allows efficient elimination of bacteriostatic, fungistatic or bactericidal agents.



Benefits

New Features

Video - New Features

Video - New Devices

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Regulations and Industry benchmark

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Documented Qualification

Consistent Performance

- We rigorously test each device during and after manufacturing.
- 100% integrity testing on every canister
- 100% visual check 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



Benefits

New Features

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Documented Qualification

Certificates of Quality

Each Steritest™ NEO device is subjected to rigorous in-process and release quality checks including 100% membrane and canister integrity tests as well as intense physical and microbiological testing. The detailed Certificates of Quality are available for download from our website.



Benefits

New Features

Video - New Features

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Documented Qualification

Documented Qualification

We have compiled comprehensive Steritest™ Qualification Reports (available upon request) that confirms Steritest™ NEO device performance.



Benefits

New Features

Video - New Features

Video - New Devices

Specifications

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Double Packed

Ordering Information

Steritest™ NEO Double-Packed,Gamma Sterilized Sterility Testing Device

FEATURES

- Gamma sterilized and double packed for quick 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.
- Primary blister packaging can be hung or stacked within the testing environment, minimizing the test area requirements.

DOUBLE PACKAGING SAVES TIME

Learn more



Complete Sterility Testing Offer



Benefits

New Features

Video - New Features

Video - New Devices

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Double Packed

Ordering Information

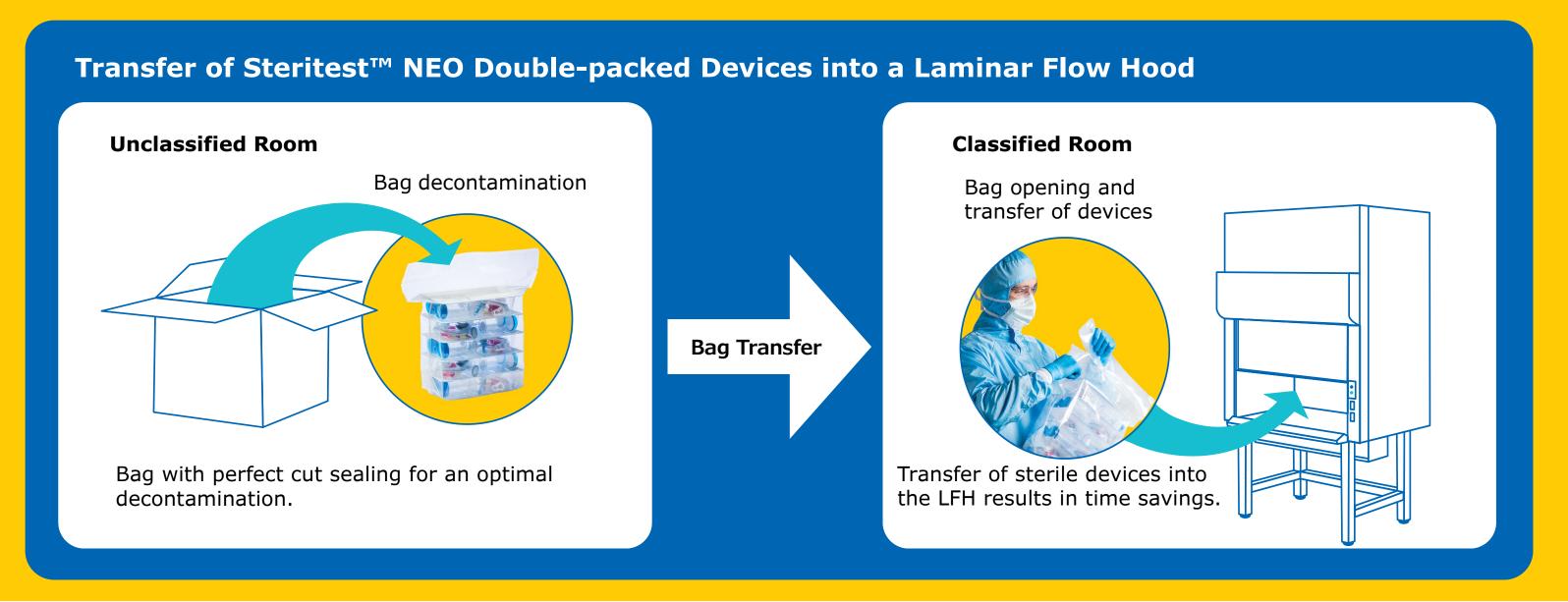
Complete Sterility Testing Offer

Steritest™ NEO Double-Packed,Gamma Sterilized Sterility Testing Device

DOUBLE DACKAGING SAVES TIME

Steritest™ NEO devices are packed to ensure optimum cleanliness. The double packaging allows operators to open the outer bag in a clean room and bring the sterile package into a laminar flow hood or isolator environment. A tear primer on the outer bag enables gloved operators to open the outer bag easily, eliminating the use of scissors.

This simplified decontamination procedure saves operator time by reducing cleaning steps.





Benefits

New Features

Video - New Features

Video - New Devices

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Double Packed

Ordering Information

Complete Sterility Testing Offer

Ordering Information

Steritest™ NEO "Red Base" devices for antibiotics, products WITH

antimicrobial agents and medical devices.

Perfect for antibiotic sample testing, this device incorporates our HV Durapore® (PVDF) membrane, offering broad chemical compatibility and low binding properties.

and medical devices

Perfect for the majority of pharmaceutical drugs

for products WITHOUT antimicrobial agents

Steritest™ NEO "Blue Base" devices

that do not have antimicrobial activity, our HA mixed cellulose esters membrane allows fast flow rates for optimum throughput performance.

Ordering Table

Steritest™ NEO "Green Base" devices for products dissolved in solvents requiring increased chemical compatibility

Perfect for viscous products, such as creams and ointments, which are normally diluted in a sterile solvent, such as isopropyl myristate (IPM) to improve filterability.

Ordering Table

Ordering Table

Accessories for sample preparation and dilution.

Tubing and needle assembly to dissolve powders, or for the transfer of liquids, or sterile vent needles

Ordering Table



Benefits

New Features

Video - New Features

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Double Packed

Ordering Information

Complete Sterility
Testing Offer

Ordering Information

Steritest™ NEO "Blue Base" Devices

for products WITHOUT antimicrobial agents and medical devices





Application	Product #	More Information	Add to Cart
Steritest™ NEO Devices for Liquids in Ampoules	TZHALA210		
Steritest™ NEO Devices for Liquids in Ampoules DP	TZHALA205		
Steritest™ NEO Devices for Liquids in Collapsible Bags	TZHALA210		
Steritest™ NEO Devices for Liquids in Collapsible Bags DP	TZHALA205		
Steritest™ NEO Devices for Liquids in Large Vials	TZHALV210		
Steritest™ NEO Devices for Liquids in Large Vials DP	TZHALV205		
Steritest™ NEO Devices for Liquids in Small Vials	TZHASV210		
Steritest™ NEO Devices for Liquids in Small Vials DP	TZHASV205		
Steritest™ NEO Devices for Soluble Powders in Vials	TZHADV210		
Steritest™ NEO Devices for Soluble Powders in Ampoules	TZHADA210		
Steritest™ NEO Devices for Medical Devices and Collapsible Bags	TZHAMD210		
Steritest™ NEO Devices for Liquids in Syringes	TZHASY210		
Steritest™ NEO Devices for Liquids in Plastic Containers	TZHAPC210		
NEW Steritest™ NEO Devices for Liquids in Cartridges	TZHACA210		

DP = Double Packed



Benefits

New Features

Video - New Features

Video - New Devices

Specifications

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Double Packed

Ordering Information

Complete Sterility Testing Offer

Ordering Information

Steritest™ NEO "Blue Base" Devices

for products WITHOUT antimicrobial agents and medical devices





X

Application Product # More Information Add to Cart

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Solubl

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

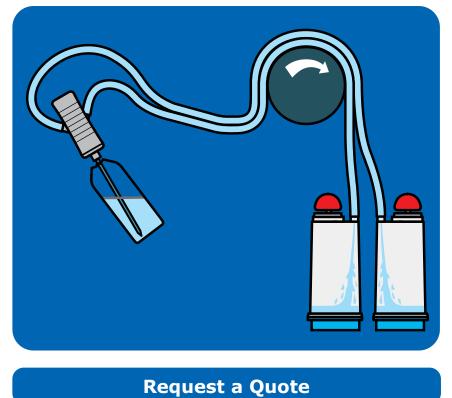
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Ampoules (TZHALA210)



Separate vent needle

Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm
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
Order Now	





Benefits

New Features

Video - New Features

Video - New Devices

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Double Packed

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Complete Sterility Testing Offer

Ordering Information

Steritest™ NEO "Blue Base" Devices

for products WITHOUT antimicrobial agents and medical devices





Add to Cart

X

Application

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

NEW Steritest™ NEO Devices for

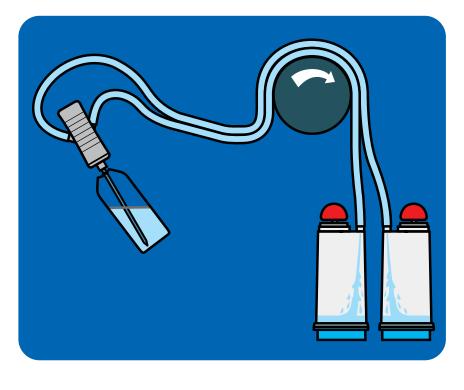
Steritest™ NEO Devices for Liquids in Ampoules -Double-Packed (TZHALA205)



Product #

- Single needle for easy access to ampoules
- Separate vent needle
- Double-packed for quick transfer into sterility testing environments

Order Now	
Sterilization	Gamma irradiation
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
Maximum Temperature	45 °C
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Materials of Construction Outer bag: Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Multilayer 170 µm film (Polyamide + Polyethylene derivate) Shell made of PET, Cover made of Tyvek® paper Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6
Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 μm



More

Information



Benefits

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Steritest™ NEO Devices for Liquid

Steritest™ NEO "Blue Base" Devices

for products WITHOUT antimicrobial agents and medical devices





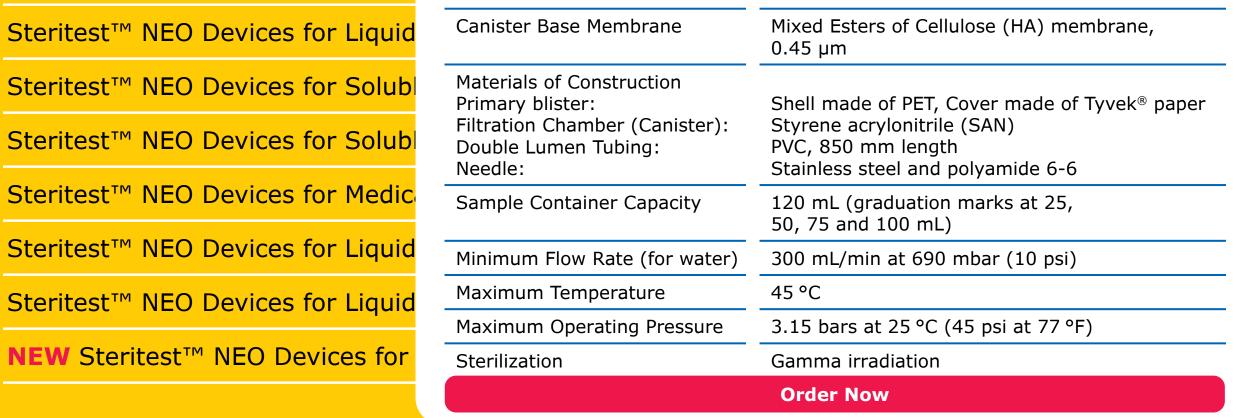
More Product # **Add to Cart Application Information**

Steritest™ NEO Devices for Liquid **Steritest™ NEO Devices for Liquids** Steritest™ NEO Devices for Liquid Steritest™ NEO Devices for Liquid

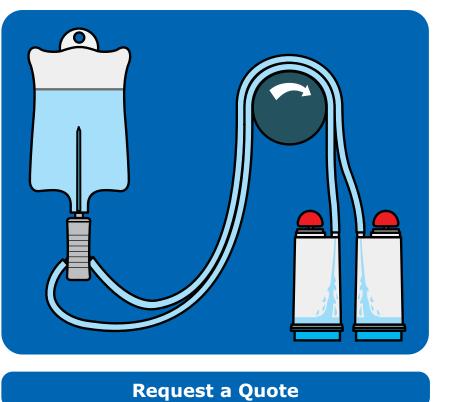


Separate vent needle

in Collapsible Bags (TZHALA210)









Benefits

New Features

Video - New Features

Video - New Devices

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Regulations

Double Packed

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Steritest™ NEO "Blue Base" Devices

for products WITHOUT antimicrobial agents and medical devices





Application

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Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Solubl

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

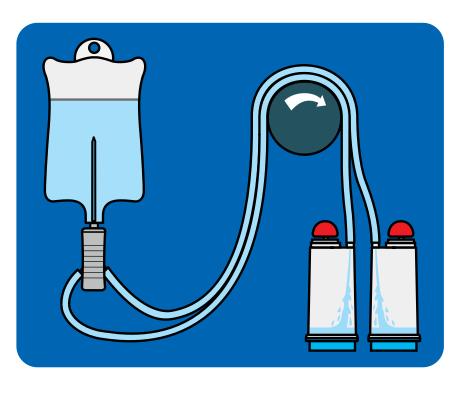
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Collapsible Bags - Double-Packed (TZHALA205)



- Separate vent needle
- Double-packed for quick transfer into sterility testing environments

	Order Now
Sterilization	Gamma irradiation
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
Maximum Temperature	45 °C
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Materials of Construction Outer bag: Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Multilayer 170 µm film (Polyamide + Polyethylene derivate) Shell made of PET, Cover made of Tyvek® paper Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6
Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 μm





Benefits

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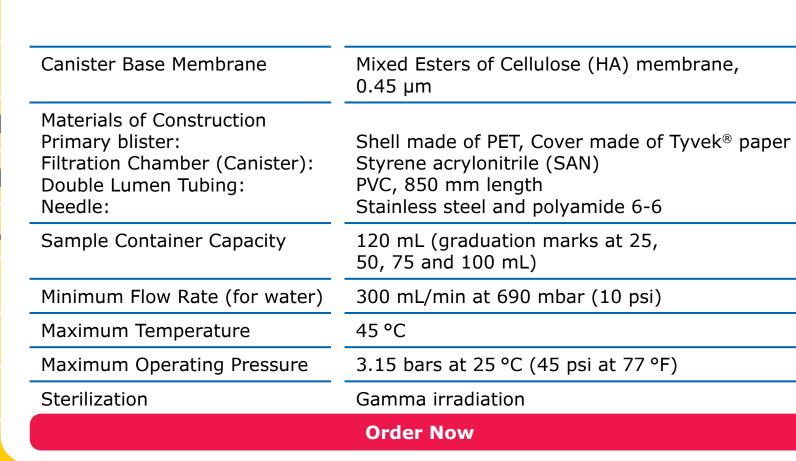
Steritest™ NEO Devices for Liquid

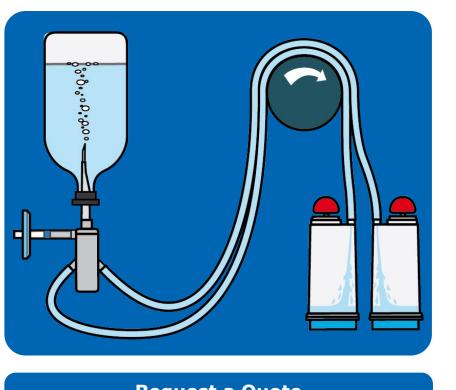
Steritest™ NEO Devices for Liquid

NEW Steritest[™] NEO Devices for

Steritest™ NEO Devices for Liquids in Large Vials (TZHALV210)









Benefits

New Features

Video - New Features

Video - New Devices

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Steritest™ NEO Devices for Solubl

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

NEW Steritest™ NEO Devices for

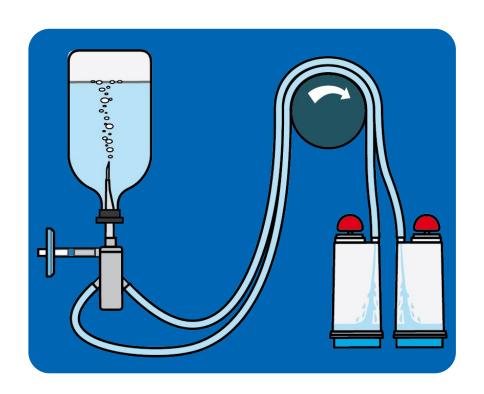
Steritest™ NEO Devices for Liquids in Large Vials - Double-Packed (TZHALV205)

Product #



• Double-packed for quick transfer into sterility testing environments

Maximum Temperature Maximum Operating Pressure	45 °C 3.15 bars at 25 °C (45 psi at 77 °F)
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Materials of Construction Outer bag: Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Multilayer 170 µm film (Polyamide + Polyethylene derivate) Shell made of PET, Cover made of Tyvek® paper Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6
Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm



More

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Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

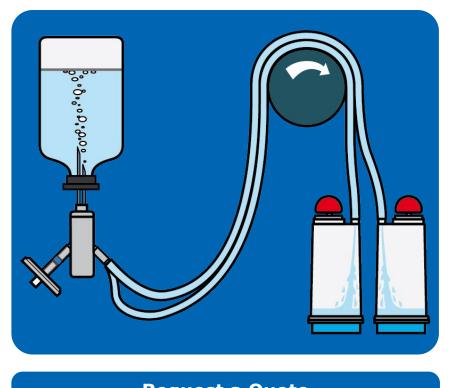
NEW Steritest[™] NEO Devices for

Steritest™ NEO Devices for Liquids in Small Vials (TZHASV210)



Mixed Esters of Cellulose (HA) membrane, Canister Base Membrane $0.45~\mu m$ Materials of Construction Primary blister: Shell made of PET, Cover made of Tyvek® paper Filtration Chamber (Canister): Styrene acrylonitrile (SAN) Double Lumen Tubing: PVC, 850 mm length Stainless steel and polyamide 6-6 Needle: 120 mL (graduation marks at 25, Sample Container Capacity 50, 75 and 100 mL) 300 mL/min at 690 mbar (10 psi) Minimum Flow Rate (for water) 45 °C Maximum Temperature Maximum Operating Pressure 3.15 bars at 25 °C (45 psi at 77 °F) Sterilization Gamma irradiation **Order Now**

Vented double needle for small vials with septa





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Steritest™ NEO Devices for Solubl

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

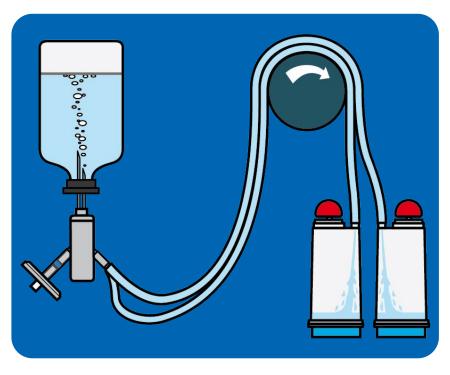
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Small Vials - Double-Packed (TZHASV205)



• Double-packed for quick transfer into sterility testing environments

Mixed Esters of Cellulose (HA) membrane, 0.45 µm
Multilayer 170 µm film (Polyamide + Polyethylene derivate) Shell made of PET, Cover made of Tyvek® paper Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6
120 mL (graduation marks at 25, 50, 75 and 100 mL)
300 mL/min at 690 mbar (10 psi)
45 °C
3.15 bars at 25 °C (45 psi at 77 °F)
Gamma irradiation



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Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

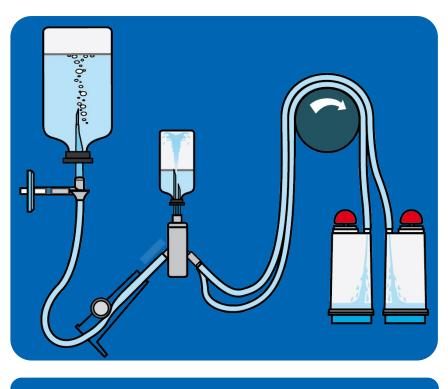
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Soluble Powders in Vials ③ (TZHADV210)



- 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

Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm	
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	
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Steritest™ NEO "Blue Base" Devices

for products WITHOUT antimicrobial agents and medical devices



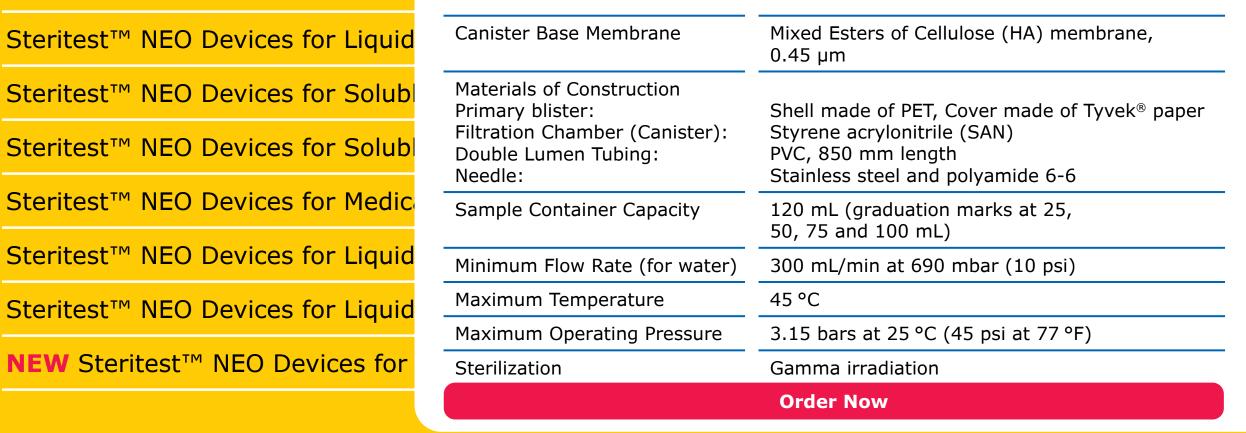


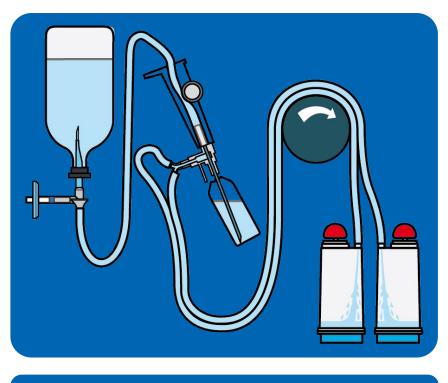
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Steritest™ NEO Devices for Liquid Steritest™ NEO Devices for Liquid Steritest™ NEO Devices for Liquid Steritest™ NEO Devices for Liquid

×

- 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







Benefits

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Video - New Devices

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Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

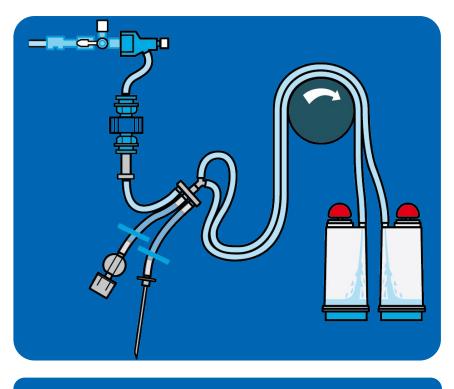
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Medical Devices and Collapsible Bags (TZHAMD210)



- Three adapters provided; male Luer, female Luer or single needle allow connection to a variety of test devices
- Separate vent needle

t	Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 μm
	Materials of Construction Primary blister:	Shell made of PET, Cover made of Tyvek® paper
	Filtration Chamber (Canister): Double Lumen Tubing: Needle:	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)
t	Maximum Temperature	45 °C
	Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
	Sterilization	Gamma irradiation
		Order Now





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Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

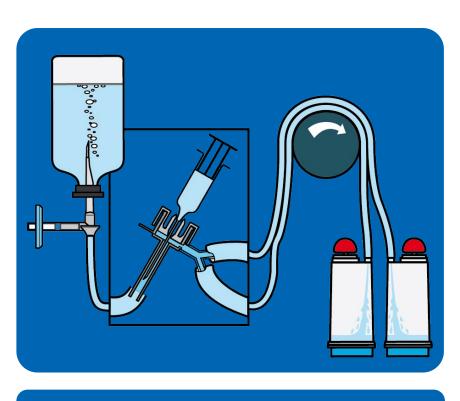
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Syringes (TZHASY210)



- Adapter allows for sequential testing of syringe contents and needle surfaces
- Vented double needle

Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm	
Materials of Construction Primary blister: Filtration Chamber (Canister):	Shell made of PET, Cover made of Tyvek® paper Styrene acrylonitrile (SAN)	
Double Lumen Tubing: Needle:	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	
Order Now		
	Materials of Construction Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle: Sample Container Capacity Minimum Flow Rate (for water) Maximum Temperature Maximum Operating Pressure	





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Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

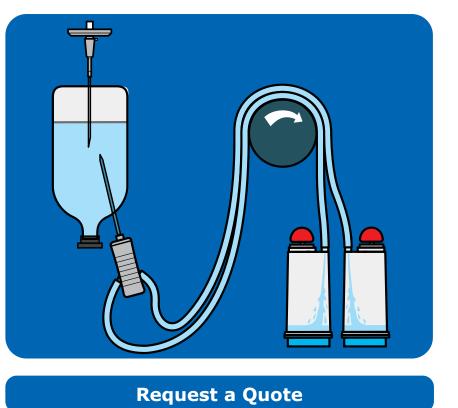
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Plastic Containers (TZHAPC210)



- Non-coring single needle minimizes blockage when piercing plastic containers
- Separate vent needle

Order Now	
Sterilization	Gamma irradiation
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
Maximum Temperature	45 °C
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
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
Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm





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Application

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

NEW Steritest[™] NEO Devices for

Steritest™ NEO Devices for Liquids in Cartridges and Small Soft Plastic Containers (TZHACA210)

Product #

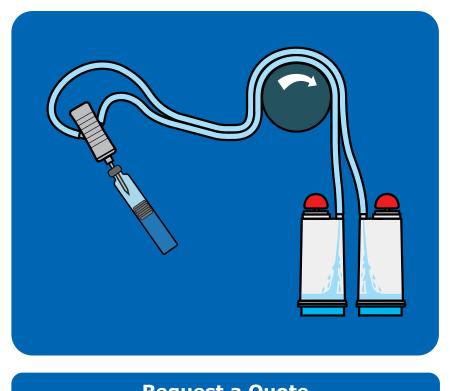


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• Single short (20 mm) needle for easy access to cartridges and small soft plastic containers

• Separate vent needle

Canister Base Membrane Mixed Esters of Cellulose (HA) membrane, $0.45 \, \mu m$ Materials of Construction Primary blister: Shell made of PET, Cover made of Tyvek® paper Filtration Chamber (Canister): Styrene acrylonitrile (SAN) Double Lumen Tubing: PVC, 850 mm length Stainless steel and polyamide 6-6 Needle: 120 mL (graduation marks at 25, Sample Container Capacity 50, 75 and 100 mL) Minimum Flow Rate (for water) 300 mL/min at 690 mbar (10 psi) 45 °C Maximum Temperature 3.15 bars at 25 °C (45 psi at 77 °F) Maximum Operating Pressure Sterilization Gamma irradiation **Order Now**



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for antibiotics, products WITH antimicrobial agents and medical devices









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Steritest™ NEO Devices for Liquid

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Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Powde

NEW Steritest™ NEO Devices for

Steritest™ NEO "Red Base" Devices

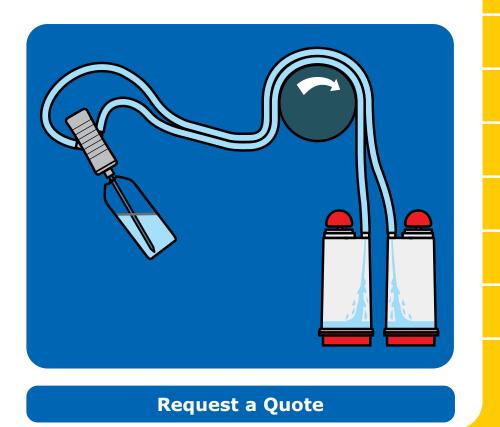
for antibiotics, products WITH antimicrobial agents and medical devices



Steritest™ NEO Devices for Liquids in Ampoules Steritest™ NEO Devices for Liquid (TZHVAB210) Steritest™ NEO Devices for Liquid

- Single needle for easy access to ampoules
- Separate vent needle

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	
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Steritest™ NEO Devices for Liquid

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Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Powde

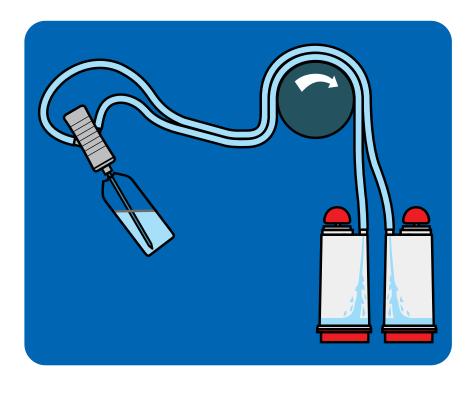
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Ampoules - Double-Packed (TZHVAB205)



- Separate vent needle
- Double-packed for quick transfer into sterility testing environments

Canister Base Membrane	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF
Materials of Construction Outer bag: Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Multilayer 170 µm film (Polyamide + Polyethylene derivate) 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
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NEW Steritest™ NEO Devices for

Steritest™ NEO "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices



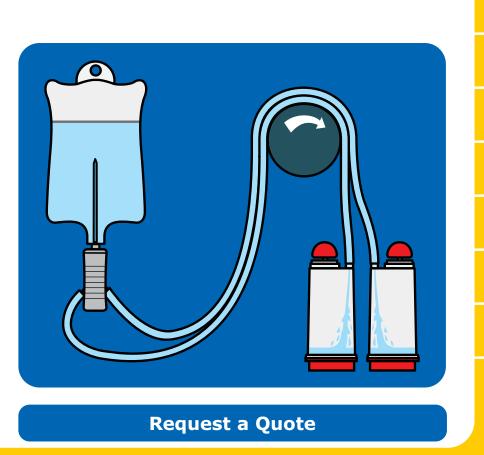
in Collapsible Bags (TZHVAB210)

Single needle for easy access to collapsible bags

Product #

Separate vent needle

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
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Steritest™ NEO Devices for Medic

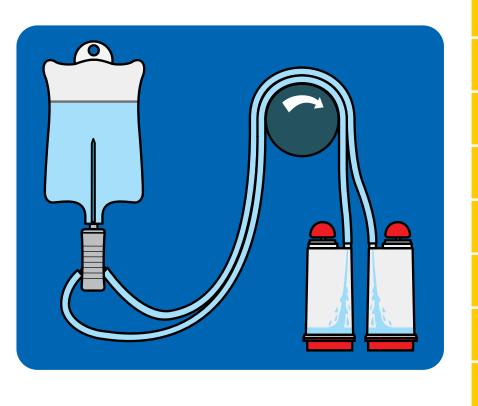
Steritest™ NEO Devices for Powde

NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Collapsible Bags - Double-Packed (TZHVAB205)

- Single needle for easy access to collapsible bags
- Separate vent needle
- Double-packed for quick transfer into sterility testing environments

Canister Base Membrane	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF	
Materials of Construction Outer bag: Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Multilayer 170 µm film (Polyamide + Polyethylene derivate) 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	
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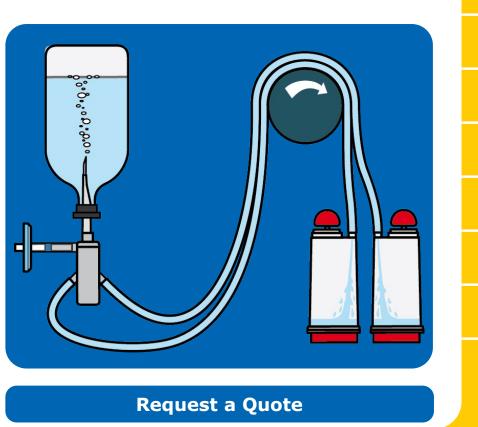
Steritest™ NEO Devices for Powde

NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Large Vials (TZHVLV210)

Vented double needle for large glass containers with septa





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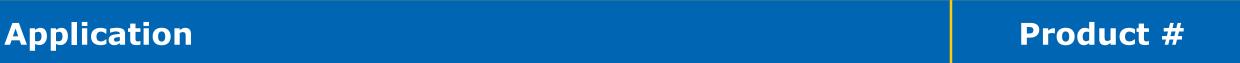
Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Powde

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Steritest™ NEO "Red Base" Devices

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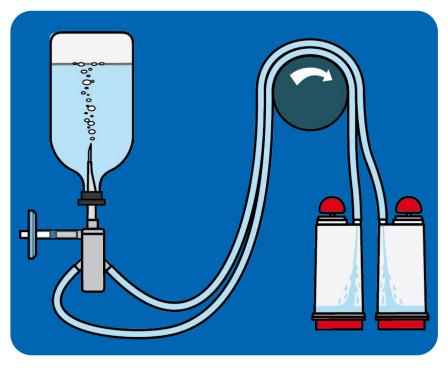


Steritest™ NEO Devices for Liquids in Large Vials - Double-Packed (TZHVLV205)



• Double-packed for quick transfer into sterility testing environments

Canister Base Membrane	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF
Materials of Construction Outer bag: Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Multilayer 170 µm film (Polyamide + Polyethylene derivate) 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
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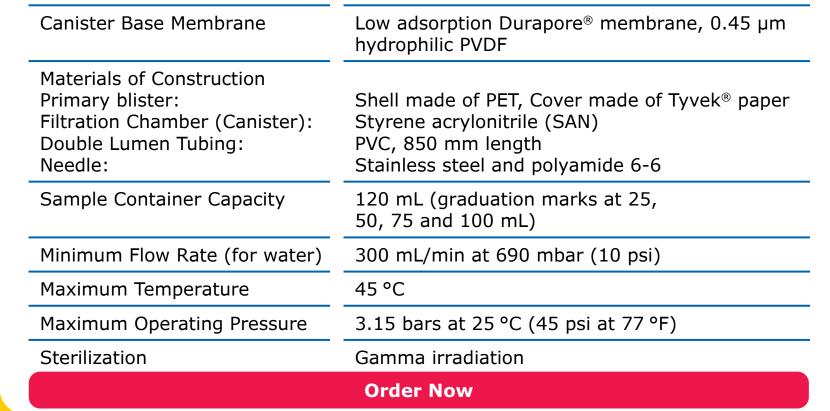
Steritest™ NEO Devices for Medic

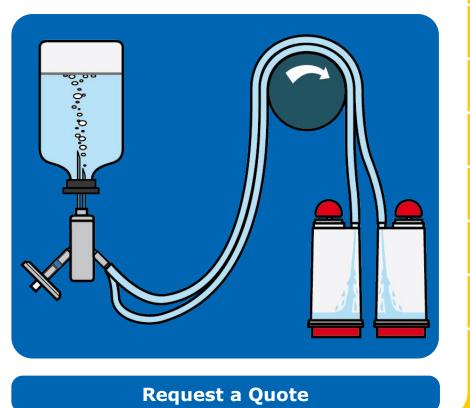
Steritest™ NEO Devices for Powde

NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Small Vials (TZHVSV210)

Vented double needle for small vials with septa





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Steritest™ NEO "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices



Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Solubl

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Powde

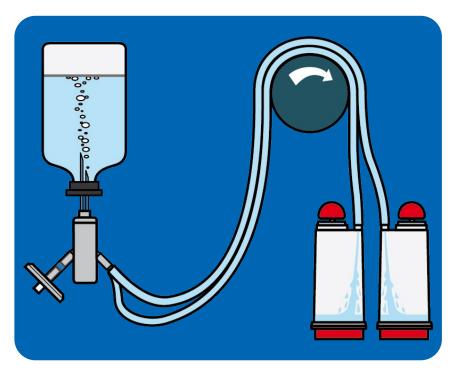
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Small Vials - Double-Packed (TZHVSV205)



• Double-packed for quick transfer into sterility testing environments

Canister Base Membrane	Low adsorption Durapore® membrane, 0.45 µm
campter base richibrane	hydrophilic PVDF
Materials of Construction Outer bag: Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Multilayer 170 µm film (Polyamide + Polyethylene derivate) 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
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Benefits

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Video - New Devices

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Steritest™ NEO "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices



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Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Powde

NEW Steritest™ NEO Devices for

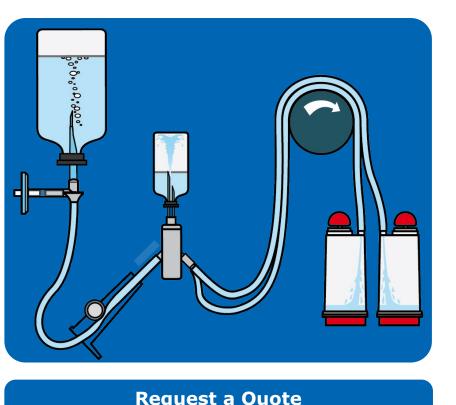
Steritest™ NEO Devices for Soluble Powders in Vials (TZHVDV210)



• Vented double needle

 Simultaneously dissolves/ dilutes the sample in sterile diluent and transfers the resulting solution to canisters

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				
Order Now					



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Steritest™ NEO "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices





Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Solubl

Steritest™ NEO Devices for Medic

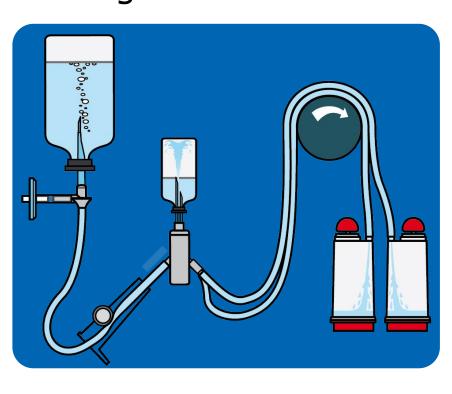
Steritest™ NEO Devices for Powde

NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Soluble Powders in Vials - Double-Packed (TZHVDV205)

- 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
- Double-packed for quick transfer into sterility testing environments

Canister Base Membrane	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF				
Materials of Construction Outer bag: Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Multilayer 170 µm film (Polyamide + Polyethylene derivate) 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				
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Steritest™ NEO "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices



Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

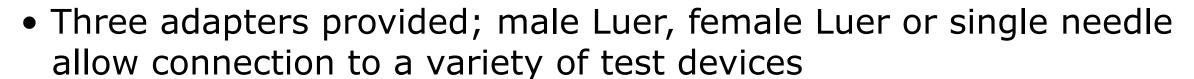
Steritest™ NEO Devices for Solubl

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Powde

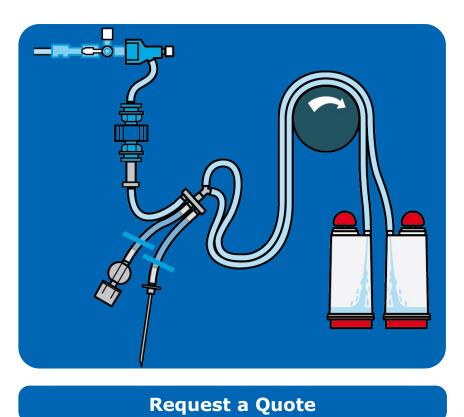
NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Medical Devices and Collapsible Bags (TZHVMD210)



Separate vent needle

3.15 bars at 25 °C (45 psi at 77 °F) Gamma irradiation
45 °C
300 mL/min at 690 mbar (10 psi)
120 mL (graduation marks at 25, 50, 75 and 100 mL)
Shell made of PET, Cover made of Tyvek® paper Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6
Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF



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Steritest™ NEO "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices



X

More Product # **Add to Cart Application Information**

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

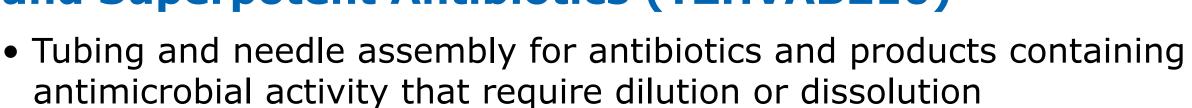
Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Powde

NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Powders and Superpotent Antibiotics (TZHVAB210)



- 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)

Steritest™ NEO Devices

Steridilutor® NEO devices for Sample Preparation and Dilution

Recommended Accessories: Sterile vent needles

TZHVAB210



TZVC00010 (1)



TEFG02525





Benefits

New Features

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Steritest™ NEO "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices



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Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Liquid

Application

Steritest™ NEO Devices for Liquid

Steritest™ NEO Devices for Solub

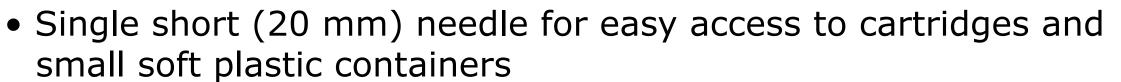
Steritest™ NEO Devices for Solub

Steritest™ NEO Devices for Medic

Steritest™ NEO Devices for Powde

NEW Steritest™ NEO Devices for

Steritest™ NEO Devices for Liquids in Cartridges and Small Soft Plastic Containers (TZHVCA210)



Separate vent needle

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
	Order Now
	Materials of Construction Primary blister: Filtration Chamber (Canister): Double Lumen Tubing: Needle: Sample Container Capacity Minimum Flow Rate (for water) Maximum Temperature Maximum Operating Pressure





Benefits

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Video - New Features

Video - New Devices

Specifications

Regulations

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Complete Sterility
Testing Offer

Ordering Information

Steritest™ NEO "Green Base" Devices + Sterile IPM

for products dissolved in solvents requiring increased chemical compatibility

Application	Product #	More Information	Add to Cart
Steritest™ NEO Devices for Solvents, Creams, Ointments, and Veterinary Injectables	TZHVSL210		
Sterile Irradiated Isopropyl Myristate	1466280006		







Benefits

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Video - New Devices

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Regulations

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Steritest™ NEO "Green Base" Devices + Sterile IPM

for products dissolved in solvents requiring increased chemical compatibility

Application

Steritest™ NEO Devices for Solver and Veterinary Injectables

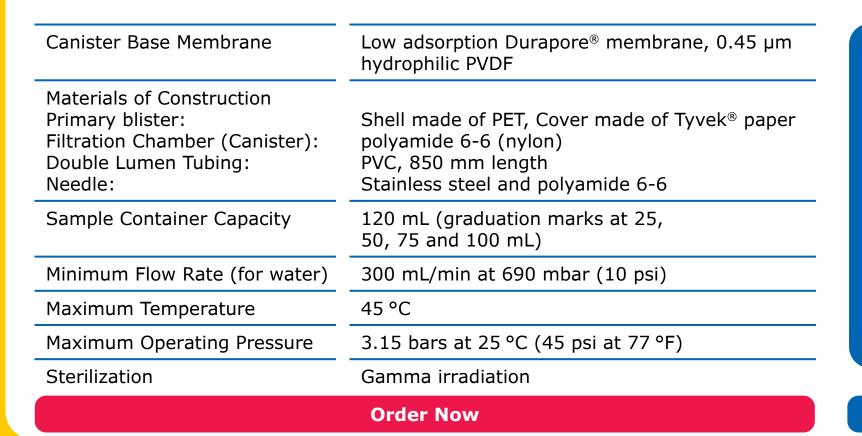
Sterile Irradiated Isopropyl Myrist

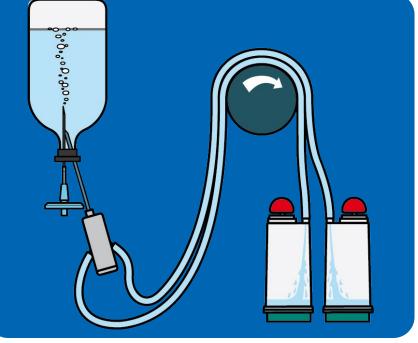
Steritest™ NEO Devices for Solvents, Creams, Ointments, and Veterinary Injectables (TZHVSL210)

Product #



• Canister designed for testing products dissolved in solvents such as isopropyl myristate / Better resistance to pressure, thanks to canister connections and reinforced base structure





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Steritest™ NEO "Green Base" Devices + Sterile IPM

for products dissolved in solvents requiring increased chemical compatibility



More Information

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Steritest™ NEO Devices for Solver and Veterinary Injectables

Application

Sterile Irradiated Isopropyl Myrist

Sterile Irradiated Isopropyl Myristate (1466280006)

- Sterile and ready-to-use
- 360 mL in 500 mL bottle with red flip cap and septum
- 6 bottles per box
- To be used with the Steritest™ NEO green base canister <u>TZHVSL210</u>



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Benefits

New Features

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Video - New Devices

Specifications

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Sterility Testing Accessories for Liquid Transfer and Dilution

Application	Product #	More Information	Add to Cart
Steridilutor® NEO Devices without Expansion Chamber for Sample Preparation and Dilution	TZV000010		
Steridilutor® NEO Devices with Expansion Chamber for Sample Preparation and Dilution	TZVC00010	(1)	
Steridilutor® NEO Devices for Liquid Transfer	TZA000010		
Steritest™ Vent Needles	TEFG02525		



Benefits

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Video - New Devices

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Sterility Testing Accessories for Liquid Transfer and Dilution

Application

Product #

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Steridilutor® NEO Devices without for Sample Preparation and Dilution

Steridilutor® NEO Devices with Ex for Sample Preparation and Dilution

Steridilutor® NEO Devices for Liqu

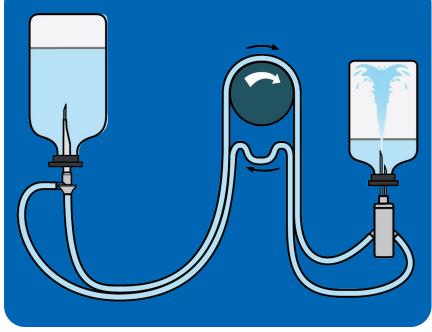
Steritest™ Vent Needles

Steridilutor® NEO Devices without Expansion Chamber for Sample Preparation and Dilution (TZV000010)



- 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)
- Small diameter double needle connects test product to diluent
- Diluted product subsequently filtered with suitable Steritest™ NEO canisters

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Benefits

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Video - New Devices

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Sterility Testing Accessories for Liquid Transfer and Dilution

Application

Steridilutor® NEO Devices without for Sample Preparation and Dilutio

Steridilutor® NEO Devices with Ex for Sample Preparation and Dilution

Steridilutor® NEO Devices for Liqu

Steritest™ Vent Needles

Product

More Information

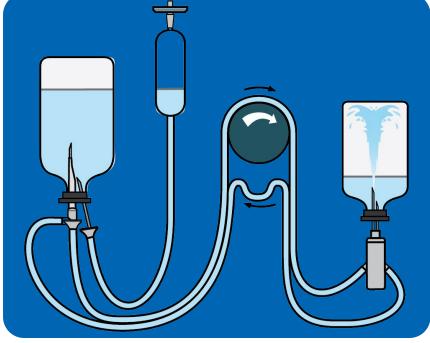
Add to Cart

Steridilutor® NEO Devices with Expansion Chamber for Sample Preparation and Dilution (TZVC00010)



- 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

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Sterility Testing Accessories for Liquid Transfer and Dilution

Application

Product #

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Steridilutor® NEO Devices without for Sample Preparation and Dilution

Steridilutor® NEO Devices with Exfor Sample Preparation and Dilution

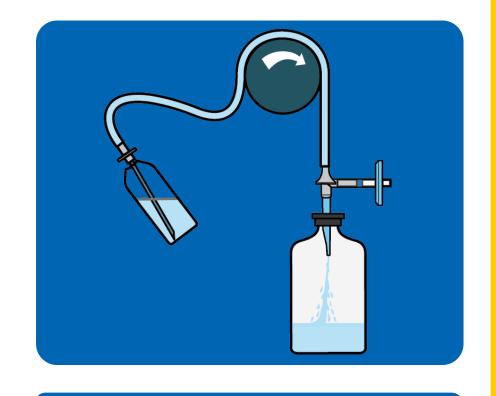
Steridilutor® NEO Devices for Liqu

Steritest™ Vent Needles

Steridilutor® NEO Devices for Liquid Transfer (TZA000010)



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



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Sterility Testing Accessories for Liquid Transfer and Dilution

Application

Steridilutor® NEO Devices without

for Sample Preparation and Dilution

Steridilutor® NEO Devices with Ex

for Sample Preparation and Dilution

Steridilutor® NEO Devices for Liqu

Steritest™ Vent Needles

Steritest™ Vent Needles

(TEFG02525)

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

Product #

For sterility and growth promotion qualification of media batches



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Benefits

Regulations

Culture Media

Rinsing Fluids

Double Packed

Customized Culture Media

Closure Caps

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Complete Sterility Testing Offer

Our sterility media and rinsing fluids are a critical component of your Steritest™ solution. They provide the highest level of quality and testing confidence. They have been formulated and tested to meet the requirements of the USP <71>, EU Pharmacopoeia < 2.6.1> and JP Pharmacopoeia <4.06>. Steritest™ sterility media and rinse solutions are manufactured in an ISO 9001, environmentally controlled production center.

Each lot undergoes a stringent quality control (QC) procedure, including pH, sterility and growth promotion testing according to USP, EP and JP methods. Our manufacturing approach ensures the highest level of clarity for our media and rinsing fluids, therefore improving accuracy and significantly reducing the risk of incorrect interpretation and false results.





Benefits

Regulations

Culture Media

Rinsing Fluids

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Customized Culture Media

Closure Caps

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Complete Sterility Testing Offer

Benefits

Compliant to pharmacopoeias
 EP / USP / JP

Culture media and rinsing fluids have been formulated and tested to meet the requirements of the USP <71>, EU Pharm. <2.6.1> and JP Pharm. <4.06>.

- Optimal cap design to reduce the risk of cross contamination and growth inhibition
- 1. Screw cap version, the rimless cap design minimizes the risks of cross contamination and optimizes the disinfection procedures.
- 2. Crimp cap version provides a tamperproof closure to ensure a high level of security.
- High standards manufacturing process

Manufactured in ISO® 9001 controlled environments where each lot is certified for pH, sterility, and growth promotion using ATCC® strains specified by the USP.

Multiple configuration and volumes

Whether the product is filterable or not, our sterility testing culture media and rinsing fluids come in multiple configurations and volumes.

• Improved traceability through barcodes on each bottle

Simply scan the 2D barcode to access the product-related data. Easy data processing in a broad range of systems.

• Easy to use with all Steritest™ devices

A non-coring, large diameter septum area is easy to pierce for operator safety and productivity.

 Validated to fulfill all your sterility and bioburden needs

Fluids A, D, and K can be used in combination with the Steritest™ sterility testing system or for bioburden testing to rinse membranes and dilute or dissolve samples.



Benefits

Regulations

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Complete Sterility Testing Offer

Regulations and Industry benchmark

Regulations

Consistent Performance

Certificates of Quality

Documented Qualification

Regulations

Our culture media and rinsing fluids are designed, manufactured and tested to meet with the recommendations of Pharmacopoeias for Sterility testing.

- European Pharmacopoeia, 2.6.1 Sterility, 2.6.12 & 2.6.13. Microbiological examination of non sterile products
- United States Pharmacopoeia, <71> Sterility tests, <61> & <62> Microbiological examination of non sterile products; <1227> Validation of microbial recovery from pharmacopoeial articles
- Japanese Pharmacopoeia, 4.06 Sterility test



Benefits

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Testing Offer

Regulations and Industry benchmark

Regulations

Consistent Performance

Certificates of Quality

Documented Qualification

Consistent Performance

We know that the performance of the culture media and rinse fluids is a critical parameter for sterility testing suitability.

That's why our media are formulated with selected raw materials to ensure optimal and consistent growth performance.

Our bottles are filled and sterilized an ISO 9001 accredited facility. Our strong quality program mimics the GMP guidelines in order to bring confidence and support to our Pharma customers.



Benefits

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Regulations and Industry benchmark

Regulations

Consistent Performance

Certificates of Quality

Documented Qualification

Certificate of Quality

Each batch follows a stringent quality controls, including batch records review and QC testing before release.

- A Certificate of Quality can be downloaded from our website
- A Certificate of Analysis is also available upon request



Benefits

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Regulations and Industry benchmark

Regulations

Consistent Performance

Certificates of Quality

Documented Qualification

Documented Qualification

Products and manufacturing processes are fully validated to meet with your reliability need for sterility testing.

Validation summaries can be provided upon request.

Full documentation, including validation protocols, reports, risk analysis and change controls can be consulted during an audit in our manufacturing facility.



Benefits

Regulations

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Rinsing Fluids

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Complete Sterility Testing Offer

Sterility Testing Culture Media

Soybean-Casein Digest Medium (Trypcase Soy Broth, TSB) is suitable for the culture of both fungi and aerobic bacteria. This medium is used for sterility testing by membrane filtration or by direct inoculation. It is also used as pre-enrichment broth for non sterile products. Compliant to the USP, EP and JP Pharmacopoeias.

Material Table



Fluid Thioglycollate Medium (FTM) is primarily intended for the detection of anaerobic bacteria. However, it also enables aerobic bacterial detection. This medium is used for sterility testing by membrane filtration or direct inoculation as described in the USP, EP and JP Pharmacopoeias.

Material Table

Clear Thioglycollate Medium has the same growth promotion properties as the standard FTM and is compliant to the USP, EP and JP Pharmacopoeias. This alternative formulation brings extra visual clarity versus the FTM which has a slight turbidity or haze due to presence of agar. A high visual clarity medium is preferred by many users, when compared with the slightly turbid appearance of FTM.

Material Table



Benefits

Regulations

Culture Media

Rinsing Fluids

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Customized Culture Media

Closure Caps

Ordering Information

Ordering Information



Sterility Testing Culture Media

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12	(1)	
(Trypcase Soy Broth, TSB)	Screw cap with septum – double packed	100 mL	12	STBMTSB12DP	(1)	
	Crimp cap with septum	100 mL	10	1.46317		
Fluid Thioglycollate Medium,	Screw cap with septum	100 mL	12	STBMFTM12		
FTM	Screw cap with septum – double packed	100 mL	12	STBMFTM12DP	()	
	Crimp cap with septum	100 mL	10	1.46406		
Clear Thioglycollate Medium,	Screw cap with septum	100 mL	12	STBMCTM12		
CTM	Screw cap with septum – double packed	100 mL	12	STBMCTM12DP	()	
	Crimp cap with septum	100 mL	10	1.46456		

Complete Sterility
Testing Offer



Benefits

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Rinsing Fluids

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Sterility Testing Culture Media

Sterility Testing Culture Media								
Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart		
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12				
(Trypcase Soy Broth, TSB)								
Fluid Thioglycollate Medium, FTM	for sterility testing i	 Intended for the detection of aerobic bacteria and fungi. This medium is used for sterility testing by membrane filtration or by direct inoculation. 						

Clear Thioglycollate Medium, CTM

Closure	Screw cap with septum
Volume (mL)	100 mL
Packaging	12 per pack
Sterilization	Autoclaving
Color	Light yellow clear
Shelf life	12 months
pH at 25 °C	pH 7.3 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>
QC organisms	B. subtilis (ATCC 6633), C. albicans (ATCC 10231), A. niger (ATCC 16404), S. aureus (ATCC 6538), P. aeruginosa (ATCC 9027)
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Sterility Testing Culture Media

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12		
(Trypcase Soy Broth, TSB)	Trypcase Soy B (STBMTSB12DE	•	SB - D	ouble-pac	ked	

Fluid Thioglycollate Medium, FTM

• Intended for the detection of aerobic bacteria and fungi. This medium is used for sterility testing by membrane filtration or by direct inoculation.



Closure	Screw cap with septum - double packed
	<u> </u>
Volume (mL)	100 mL
Packaging	12 per pack
Sterilization	Autoclaving + Ethylene oxide
Color	Light yellow clear
Shelf life	12 months
pH at 25 °C	pH 7.3 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>
QC organisms	B. subtilis (ATCC 6633), C. albicans (ATCC 10231), A. niger (ATCC 16404), S. aureus (ATCC 6538), P. aeruginosa (ATCC 9027)
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DP = Double Packeu

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Benefits

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Culture Media

Rinsing Fluids

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Customized Culture Media

Closure Caps

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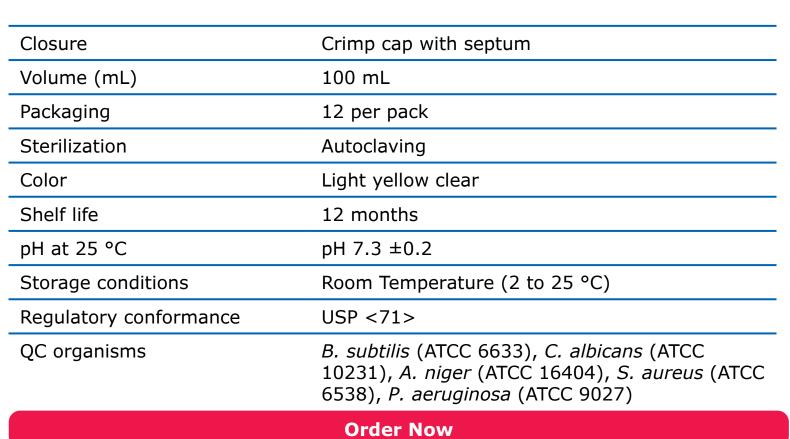
Complete Sterility
Testing Offer

Ordering Information

Clear Thioglycollate Medium,

CTM

Sterility Testing Culture Media						
Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12		
(Trypcase Soy Broth, TSB) Fluid Thioglycollate Medium, FTM	 Trypcase Soy B Intended for the detended for sterility testing b 	tection of a	aerobic ba	acteria and fu		m is used





DP = Double Packeu



Benefits

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Closure Caps

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Ordering Information

Sterility Testing Culture Media

Clear Thioglycollate Medium,

CTM

Sterility lesting Culture Media								
Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart		
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12				
(Trypcase Soy Broth, TSB)	Fluid Thioglyco	llate M	edium	, FTM (ST	BMFTM12)	8		
	Intended for the det				•			
Fluid Thioglycollate Medium,	aerobic bacterial detection. This medium is used for sterility testing by membrane filtration or direct inoculation.							
FTM								

Closure	Screw cap with septum
Volume (mL)	100 mL
Packaging	12 per pack
Sterilization	Autoclaving
Color	Light yellow, slightly opalescent and viscous liquid with a pink ring in suspension < 1 cm
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>
QC organisms	C. sporogenes (ATCC 11437), S. aureus (ATCC 6538), P. aeruginosa (ATCC 9027)
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Benefits

Regulations

Culture Media

Rinsing Fluids

Double Packed

Customized Culture Media

Closure Caps

Ordering Information

Complete Sterility
Testing Offer

Ordering Information

Sterility Testing Culture Media

occimicy resums cartains ricara								
Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart		
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12				
(Trypcase Soy Broth, TSB)	Fluid Thioglycollate Medium, FTM - Double-packed (STBMFTM12DP)							
Fluid Thioglycollate Medium, FTM	aerobic bacterial de	 Intended for the detection of anaerobic bacteria however, it also enables aerobic bacterial detection. This medium is used for sterility testing by membrane filtration or direct inoculation. 						

Clear Thioglycollate Medium, CTM

Closure	Screw cap with septum - double packed
Volume (mL)	100 mL
Packaging	12 per pack
Sterilization	Autoclaving + ethylene oxide
Color	Clear, with no precipitate and free of visible particles
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>
QC organisms	C. sporogenes (ATCC 11437), S. aureus (ATCC 6538), P. aeruginosa (ATCC 9027)
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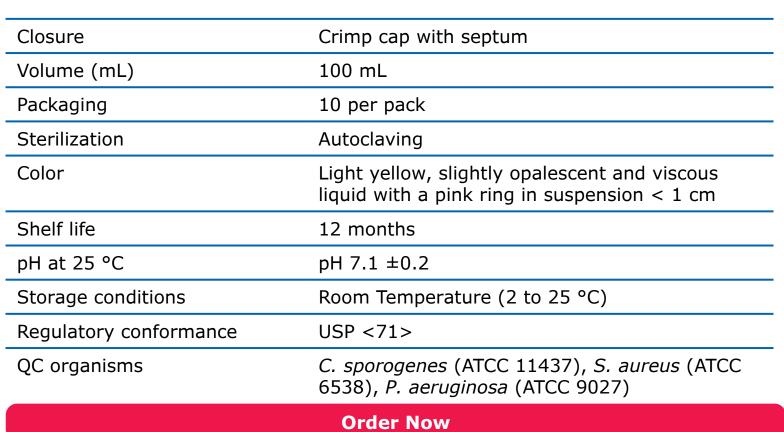
Complete Sterility
Testing Offer

Ordering Information

Clear Thioglycollate Medium,

CTM

Sterility Testing Culture Media								
Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart		
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12				
(Trypcase Soy Broth, TSB)	Fluid Thioglycollate Medium, FTM (1.46406)							
Fluid Thioglycollate Medium, FTM	 Intended for the detection of anaerobic bacteria however, it also enables aerobic bacterial detection. This medium is used for sterility testing by membrane filtration or direct inoculation. 							





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Benefits

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Sterility Testing Culture Media

Clear Thioglycollate Medium,

CTM

Sterility lesting Culture Media								
Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart		
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12				
(Trypcase Soy Broth, TSB)	Clear Thioglyco			_	_			
	 Intended for the detection of anaerobic bacteria however, it also enables aerobic bacterial detection. This medium is used for sterility testing by membrane filtration or direct inoculation. 							
Fluid Thioglycollate Medium,								
FTM								

Closure	Screw cap with septum
Volume (mL)	100 mL
Packaging	12 per pack
Sterilization	Autoclaving
Color	Light yellow, slightly opalescent and viscous liquid with a pink ring in suspension < 1 cm
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>
QC organisms	C. sporogenes (ATCC 11437), S. aureus (ATCC 6538), P. aeruginosa (ATCC 9027)

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Sterility Testing Culture Media

FTM

CTM

Clear Thioglycollate Medium,

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12		
(Trypcase Soy Broth, TSB)	Clear Thioglycollate Medium, CTM - Double-packed (STBMCTM12DP)					
Fluid Thioglycollate Medium,	Intended for the det			•		

bacterial detection. This medium is used for sterility testing by membrane filtration or direct inoculation.

	6538), <i>P. aeruginosa</i> (ATCC 9027)
QC organisms	C. sporogenes (ATCC 11437), S. aureus (ATCC
Regulatory conformance	USP <71>
Storage conditions	Room Temperature (2 to 25 °C)
pH at 25 °C	pH 7.1 ±0.2
Shelf life	12 months
Color	Light yellow, slightly opalescent and viscous liquid with a pink ring in suspension < 1 cm
Sterilization	Autoclaving + ethylene oxide
Packaging	12 per pack
Volume (mL)	100 mL
Closure	Screw cap with septum – double packed
	Volume (mL) Packaging Sterilization Color Shelf life pH at 25 °C Storage conditions Regulatory conformance



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Benefits

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Closure Caps

Ordering Information

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Clear Thioglycollate Medium,

CTM

Sterility Testing Culture Media								
Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart		
Soybean-Casein Digest Medium	Screw cap with septum	100 mL	12	STBMTSB12				
(Trypcase Soy Broth, TSB)	Clear Thioglyco	ollate M	edium	, CTM (1.4	46456)	×		
	• Intended for the detection of anaerobic bacteria, however also enables aerobic bacterial detection. This medium is used for sterility testing by membrane filtration or direct inoculation.							
Fluid Thioglycollate Medium,								
FTM								

Closure	Crimp cap with septum
Volume (mL)	100 mL
Packaging	10 per pack
Sterilization	Autoclaving
Color	Light yellow, slightly opalescent and viscous liquid with a pink ring in suspension < 1 cm
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>
00	C (ATCC 11427) C (ATCC





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Sterility Testing Rinsing Fluids

Fluid A is a rinsing fluid recommended by the European (EP), United States (USP) and Japanese (JP) Pharmacopeia for the rinsing of aqueous solutions during sterility testing by membrane filtration. It is also used for diluting soluble solids for the same application. In addition, fluid A is recommended as a rinsing fluid for membrane filtration of non sterile products.

Material Table

Fluid K is suitable for testing specimens that contain petrolatum, oils, or oily solutions. Excellent for rinsing pathways of medical devices, and for samples that are "difficult" to filter or dissolve.

Fluid D is recommended by the United States Pharmacopeia (USP) for the rinsing of solutions containing oil or lecithin during sterility testing by membrane filtration. Fluid D can also be used for the removal of antimicrobial activity by membrane filtration for non sterile products.

Material Table

Sterile Isopropyl myristate (IPM) is sterilized using gamma-irradiation, and ready-to-use. The use of IPM is recommended in EP <2.6.1>, JP <4.06> and <USP 71> as diluent for oils and oily solutions, as well as for ointments and creams because its solvent properties improve the filterability of these samples.

Material Table

Material Table



Benefits

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Customized Culture Media

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Sterility Testing Rinsing Fluids

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A	USP Rinse Fluid A		4	STBMRFA94	(1)	
	Corow can with contum	600 mL	4	STBMRFA64	(1)	
	Screw cap with septum	300 mL	4	STBMRFA34	(1)	
	100 mL	12	STBMRFA12	(1)		
	Screw cap with septum – double packed	P 100 mL	12	STBMRFA12DP	(j)	
	Crimp cap with septum	300 mL	6	1.46415	(1)	
		100 mL	10	1.46470	(1)	
USP Rinse Fluid D	Screw cap with septum	300 mL	4	STBMRFD34	(1)	
	Crimp cap with septum	300 mL	6	1.46483	(1)	
USP Rinse Fluid K	Screw cap with septum	300 mL	4	STBMRFK34	(1)	

Solvent

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
Sterile Isopropyl Myristate (IPM)	Crimp cap with septum	360 mL	6	1.46628		

DP = Double Packed



Benefits

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Complete Sterility Testing Offer

Ordering Information

Sterility Testing Rinsing Fluids

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid A (STBMRFA94)

• Suitable as a general rinse buffer, and compatible with most samples. Excellent for dissolving or diluting samples, reconstituting commercial microorganisms, or as a transport medium for microorganisms.

Closure	Screw cap with septum			
Volume (mL)	900 mL			
Packaging	4 per pack			
Sterilization	Autoclaving			
Color	Clear, with no precipitate and free of visible particles			
Shelf life	12 months			
pH at 25 °C	pH 7.1 ±0.2			
Storage conditions	Room Temperature (2 to 25 °C)			
Regulatory conformance	USP <71>, EP <2.6.1>, JP <4.06>			
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)			
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USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)



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Complete Sterility Testing Offer

Ordering Information

Sterility Testing Rinsing Fluids

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

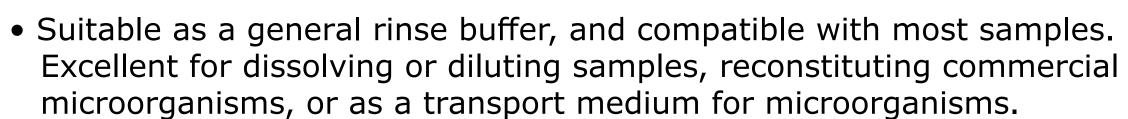
Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid A (STBMRFA64)



Closure	Screw cap with septum
Volume (mL)	600 mL
Packaging	4 per pack
Sterilization	Autoclaving
Color	Clear, with no precipitate and free of visible particles
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>, EP <2.6.1>, JP <4.06>
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)
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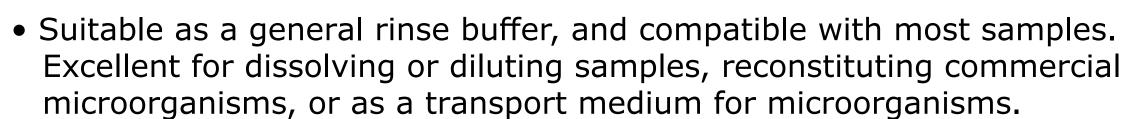
Complete Sterility Testing Offer

Ordering Information

Sterility Testing Rinsing Fluids

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid A (STBMRFA34)



Closure	Screw cap with septum			
Volume (mL)	300 mL			
Packaging	4 per pack			
Sterilization	Autoclaving			
Color	Clear, with no precipitate and free of visible particles			
Shelf life	12 months			
pH at 25 °C	pH 7.1 ±0.2			
Storage conditions	Room Temperature (2 to 25 °C)			
Regulatory conformance	USP <71>, EP <2.6.1>, JP <4.06>			
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)			
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USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)



Benefits

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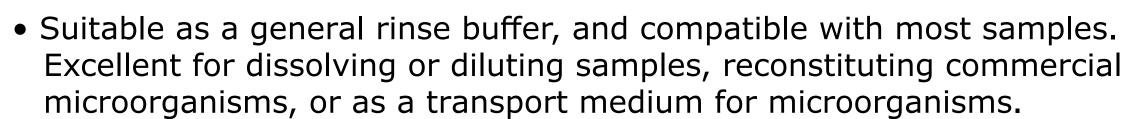
Complete Sterility Testing Offer

Ordering Information

Sterility Testing Rinsing Fluids

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid A (STBMRFA12)



Closure	Screw cap with septum			
Volume (mL)	100 mL			
Packaging	12 per pack			
Sterilization	Autoclaving			
Color	Clear, with no precipitate and free of visible particles			
Shelf life	12 months			
pH at 25 °C	pH 7.1 ±0.2			
Storage conditions	Room Temperature (2 to 25 °C)			
Regulatory conformance	USP <71>, EP <2.6.1>, JP <4.06>			
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)			
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USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)



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Sterility Testing Rinsing Fluids

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94		

Rinsing Fluid USP Rinse Fluid A - Double-Packed (STBMRFA12DP)

• Suitable as a general rinse buffer, and compatible with most samples. Excellent for dissolving or diluting samples, reconstituting commercial microorganisms, or as a transport medium for microorganisms.

Closure	Screw cap with septum – double packed
Volume (mL)	100 mL
Packaging	12 per pack
Sterilization	Autoclaving + Ethylene oxide
Color	Clear, with no precipitate and free of visible particles
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>, EP <2.6.1>, JP <4.06>
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)
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USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)



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Sterility Testing Rinsing Fluids

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

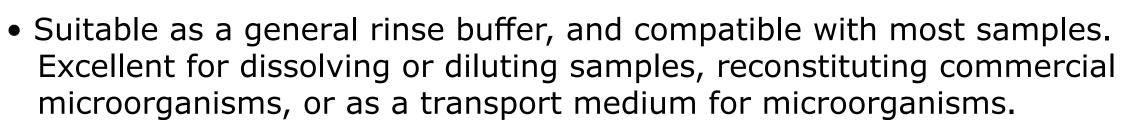
Rinse fluid

solution bottle

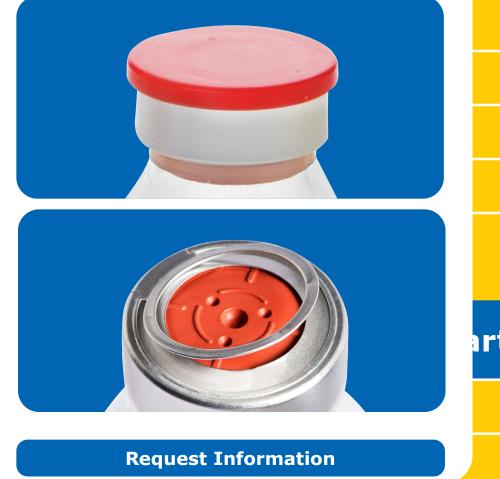
Sterile Isopropyl Myristate (IPM)

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid A (1.46415)



Closure	Crimp cap with septum
Volume (mL)	300 mL
Packaging	6 per pack
Sterilization	Autoclaving
Color	Clear, with no precipitate and free of visible particles
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>, EP <2.6.1>, JP <4.06>
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)
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Sterility Testing Rinsing Fluids

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

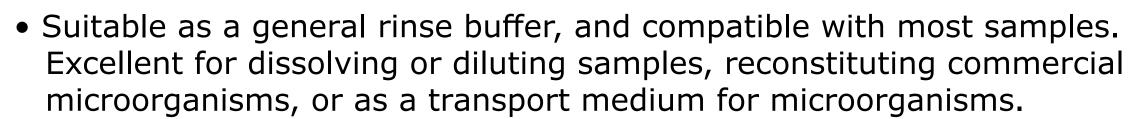
Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid A (1.46470)



Closure	Crimp cap with septum
Volume (mL)	100 mL
Packaging	10 per pack
Sterilization	Autoclaving
Color	Clear, with no precipitate and free of visible particles
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>, EP <2.6.1>, JP <4.06>
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)
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Sterility Testing Rinsing Fluids

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

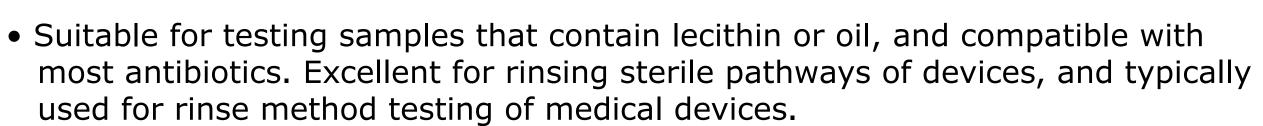
Rinse fluid

solution bottle

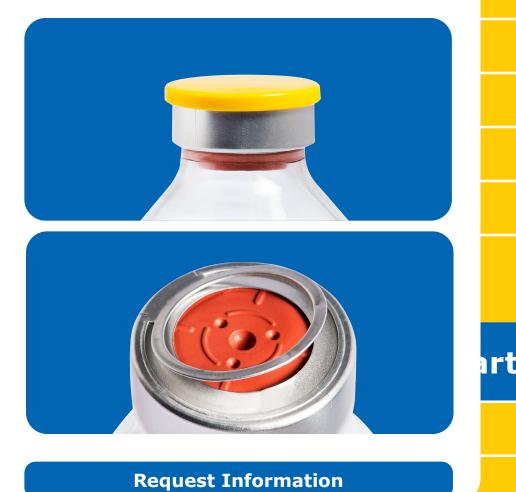
Sterile Isopropyl Myristate (IPM)

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid D (1.46483)



Closure	Crimp cap with septum			
Volume (mL)	300 mL			
Packaging	6 per pack			
Sterilization	Autoclaving			
Color	Clear, with no precipitate and free of visible particles			
Shelf life	12 months			
pH at 25 °C	pH 7.1 ±0.2			
Storage conditions	Room Temperature (2 to 25 °C)			
Regulatory conformance	USP <71>			
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)			
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Sterility Testing Rinsing Fluids

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

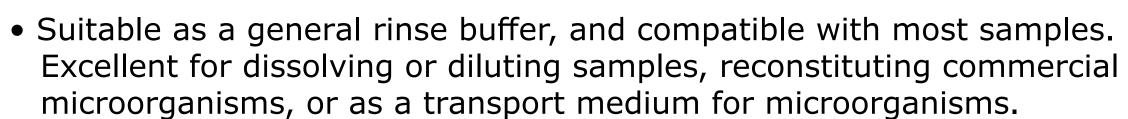
Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid D (STBMRFD34)



Closure	Screw cap with septum
Volume (mL)	300 mL
Packaging	4 per pack
Sterilization	Autoclaving
Color	Clear, with no precipitate and free of visible particles
Shelf life	12 months
pH at 25 °C	pH 7.1 ±0.2
Storage conditions	Room Temperature (2 to 25 °C)
Regulatory conformance	USP <71>
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)
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Rinsing Fluids

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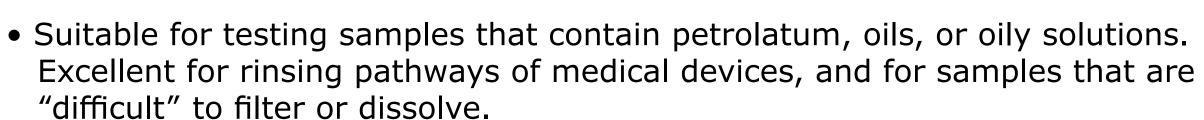
Complete Sterility Testing Offer

Ordering Information

Sterility Testing Rinsing Fluids

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94	fi	

Rinsing Fluid USP Rinse Fluid K (STBMRFK34)



Closure	Screw cap with septum			
Volume (mL)	300 mL			
Packaging	4 per pack			
Sterilization	Autoclaving			
Color	Light yellow			
Shelf life	12 months			
pH at 25 °C	pH 6.9 ±0.2			
Storage conditions	Room Temperature (2 to 25 °C)			
Regulatory conformance	USP <71>, EP <2.6.1>, JP <4.06>			
QC organisms	S. aureus (ATCC 6538), B. subtilis (ATCC 6633), P. aeruginosa (ATCC 9027), C. albicans (ATCC 10231), A. niger (ATCC 16404), C. sporogenes (ATCC 11437)			
Order Now				



Request Information

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)



Benefits

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Closure Caps

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Complete Sterility Testing Offer

Ordering Information

Sterility Testing Rinsing Fluids

Rinse fluid solution bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
USP Rinse Fluid A		900 mL	4	STBMRFA94		
	Sterile Isopropyl myristate (IPM) (146628)					×
	·	Improve dissolution of viscous products, ointments and creams prior to membrane				

- filtration
- Sterilized and ready-to-use
- To be use in combination of the Steritest™ NEO Green base (TZHVSL210)

Closure	Crimp cap with septum		
Volume (mL)	300 mL		
Packaging	6 per pack		
Maximum Temperature	45 °C		
Sterilization	Gamma irradiation		
Color	Clear, with no precipitate and free of visible particles		
Shelf life	12 months		
Storage conditions	15 to 25 °C		
Order Now			







Request Information

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid

solution bottle

Sterile Isopropyl Myristate (IPM)



Benefits

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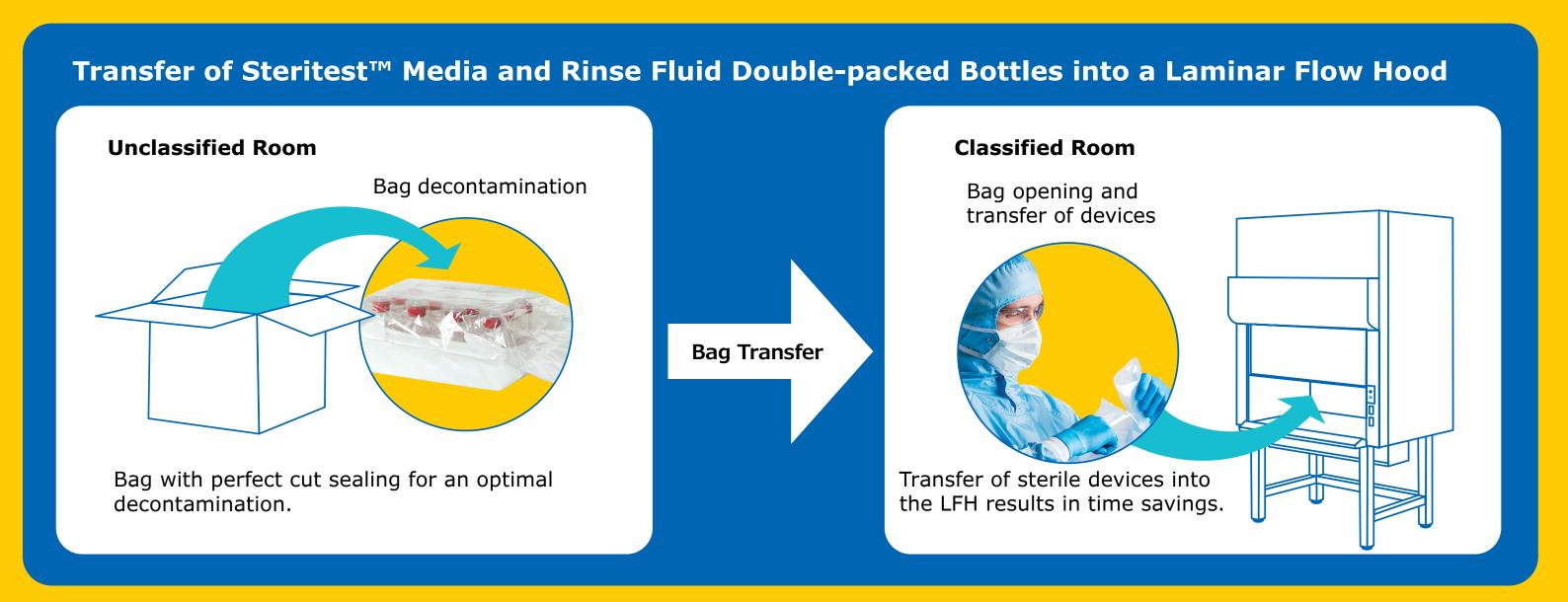
Complete Sterility Testing Offer

Double-Packed Sterility Testing Media & Rinse FluidsGamma Sterilized

Sterility testing culture media and rinsing fluids are also available in a double-packed format. The sterilized double Tyvek® packaging helps to minimize the risk of cross-contamination in laminar flow hoods and to secure an efficient decontamination of isolator chambers. These products are supplied as 100 mL screw cap bottles.

The sterilization efficiency of the packaging, including the space between the protective cap and the septum, is verified on each batch with biological indicators.

This simplified decontamination procedure saves operator time by reducing cleaning steps.





Benefits

Regulations

Culture Media

Rinsing Fluids

Double Packed

Customized Culture Media

Closure Caps

Ordering Information

Complete Sterility Testing Offer

Customized Culture Media

If for your application, our standard offer is not appropriate, we also offer tailor-made products.

With our multipurpose filling lines, we are able to produce a wide range of customized products and volume sizes, as well as a large choice of bottle closures.

We can create a new taylor-made items for your needs:

- Filling volume
- Bottling size
- Specific formulation
- pH
- QC testing strains
- Cap type and color
- ...

Please contact us to discuss the best solution for your culture media needs.





Benefits

Regulations

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Double Packed

Customized Culture Media

Closure Caps

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Complete Sterility Testing Offer

Closure caps

Screw Cap with Septum

The rimless cap design minimizes the risks of cross contamination and optimizes the disinfection procedures, avoiding the risk of inhibition from disinfectant residuals.

The stopper softness allows easy piercing with needles for operator safety.



Crimp Cap with Septum

The crimp cap version provides a tamperproof closure to ensure a high level of security.





Benefits

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Complete Sterility
Testing Offer

Culture Media and Diluting/Rinsing Fluids

Culture Media



Material Table

Solvent



Material Table



Material Table



Benefits

Perfect Fit for Your Testing Environment

Video

Pump Specifications

Onscreen Guidance

Software

Smart Accessories

Ordering Information

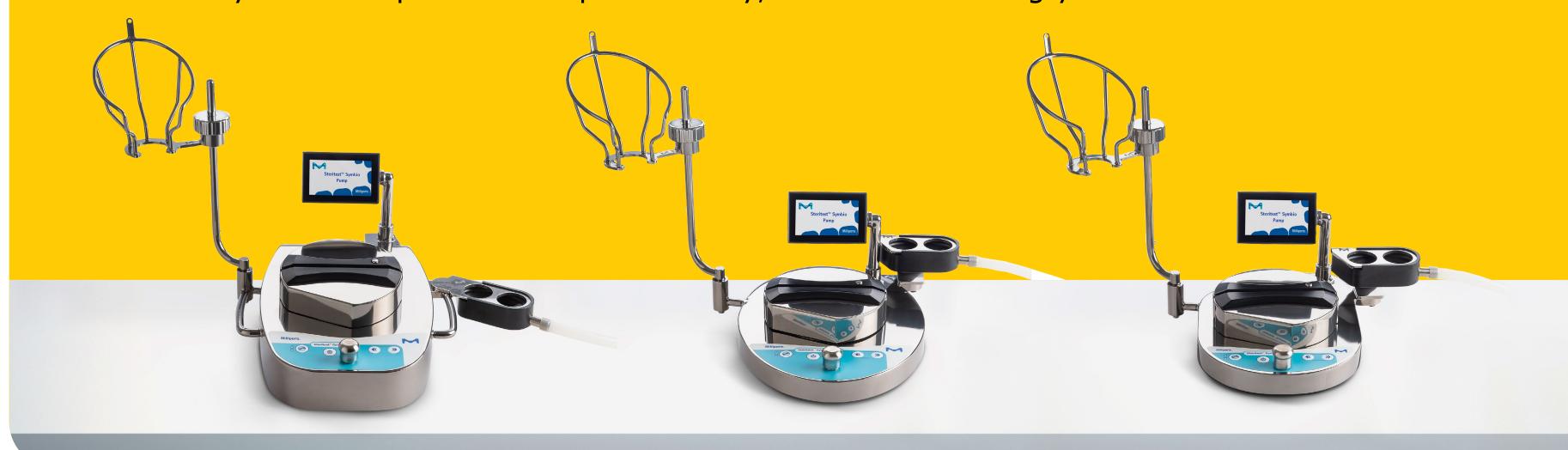
Complete Sterility Testing Offer

Our sterility testing Steritest™ Symbio pumps accompanied by our smart accessories are designed for ideal integration into any testing environment.

When used in combination with our closed membrane filtration devices and high quality culture media and rinsing fluids, this equipment offers an optimized and fully regulatory compliant testing process (USP <71>, EU Pharmacopoeia < 2.6.1> and JP Pharmacopoeia <4.06>).

DESIGNED TO FIT YOUR TESTING ENVIRONMENT

Whether you carry out your sterility testing in a cleanroom, isolator, or laminar flow hood, our Steritest™ Symbio Pumps ensure reproducibility, while streamlining your workflow.





Benefits

Perfect Fit for Your Testing Environment

Video

Pump Specifications

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Complete Sterility
Testing Offer

Benefits

Easy-to-Use Reliable Safe Ergonomic User-Friendly

Easy-to-Use

- Reduced pump height for easy access in laminar flow hoods
- Compact pump frees working space and loading capacity in isolators
- Compatible with vertical and horizontal air flows



Benefits

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Complete Sterility Testing Offer

Benefits

Easy-to-Use Reliable Safe Ergonomic User-Friendly

Reliable

- The automatic pump head closure ensures quick and easy tube placement, as well as reliable splitting of the liquid sample
- Highly precise timer function: small volumes are sampled with high precision



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Complete Sterility Testing Offer

Benefits

Easy-to-Use Reliable Safe Ergonomic User-Friendly

Safe

- Cleanroom-friendly hardware: air-tight housing and passive cooling prevent particle emission
- Two pressure modes including automatic pumping speed reduction alert the operator, reducing the risk of test interruption and minimizing the stress on any microorganisms that may be present
- Easy to clean and resistant to gas decontamination in isolators



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Benefits

Easy-to-Use Reliable Safe Ergonomic User-Friendly

Ergonomic

- The housing's ergonomic shape allows easy tube loading; no risk of pinching gloves and consequent test interruption
- Adjustable bottle holder height and tiltable display for perfect screen visibility
- Buttons designed to be operated with isolator gloves
- Easy to clean and resistant to gas decontamination in isolators



Benefits

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Benefits

Easy-to-Use Reliable Safe Ergonomic User-Friendly

User-Friendly

- Clear user interface displayed on a 11 cm (4.3 in.) color LCD screen
- Choice of operating language (Simplified Chinese, English, French, German, Italian, Japanese, Portuguese, Spanish, Russian or Turkish)
- Test methods library: store up to 250 filtration protocols and follow them step-by-step on the screen
- Easy to clean and resistant to gas decontamination in isolators



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Complete Sterility Testing Offer

The Perfect Fit for Your Testing Environment

We understand the challenges and requirements of testing environments. That's why we have developed a complete set of pumps to suit the way you work.

Steritest™ Symbio LFH Pump



With its compact design, the Steritest™
Symbio LFH Pump can be used comfortably in the smallest testing environments, including in the laminar flow hood, biosafety cabinet, cleanroom or even inside an isolator.

Steritest™ Symbio ISL Pump



The Steritest™ Symbio ISL Pump is optimized for extremely convenient sterility testing inside isolators. Its table-integrated design offers more working space and loading volume in isolators. What's more, its ergonomic buttons and length can be easily experted while wearing.

What's more, its ergonomic buttons and knob can be easily operated while wearing isolator gloves. The pump is compatible with all standard round-table cutouts and is a perfect replacement for Steritest™ Integral and Steritest™ Equinox Isolator pumps (without table rework).

Steritest™ Symbio FLEX Pump



This Steritest™ Symbio FLEX Pump is very versatile, and can be installed in multiple ways – in either an isolator or a laminar flow hood. The pump is compatible with all standard round cutouts, and is also the perfect replacement for the Steritest™ Equinox Isofit, as it will also match its oval cutout without the need for table rework.

Ordering information

Ordering information

Ordering information



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Specifications - Steritest™ Symbio Pumps

	Isolator	Laminar flow hood	Multiple ways (isolator or a laminar flow hood)		
	Steritest™ Symbio ISL	Steritest™ Symbio LFH	Steritest™ Symbio FLEX		
			On feet in a laminar flow hood in an isolator		
Width	588 mm (23.1 in.)	633 mm (24.9 in.)	645 mm (25.4 in.) 645 mm (25.4 in.) 611 mm (24.1 in.) 645 mm (25.4 in.)		
Depth	313 mm (12.3 in.)	372 mm (14.6 in.)	355 mm (14.0 in.) 355 mm (14.0 in.) 361 mm (14.2 in.) 361 mm (14.2 in.)		
Height	354 mm (13.9 in.)	410 mm (16.1 in.)	464 mm (18.3 in.) 472 mm (18.6 in.) 356 mm (14.0 in.) 459 mm (18.1 in.)		
Weight	17.6 kg (38.8 lb)	15.8 kg (34.8 lb) 19.6 kg (43.2 lb)			
Pump head height	81 mm (3.2 in.)	158 mm (6.2 in.)	189 mm (7.4 in.) 197 mm (7.8 in.) 82 mm (3.2 in.) 185 mm (7.3 in.)		
Pump housing & 316L Stainless steel Pump head					
Rotation speed	up to 240 rpm				
Power supply voltage	100 to 240 Volt AC, 50/60 Hz				
Request more information or a quote					
Request a demo					



Benefits

Perfect Fit for Your Testing Environment

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Complete Sterility Testing Offer

Step-by-Step Onscreen Guidance

Easy and Reliable Test Reproducibility

Whatever your reasons, Steritest™ Symbio Pumps safeguard your testing procedure, ensure test method reproducibility and help you save time.

The Test Method Mode displays your sterility test protocols in an easy step-by-step way, including customized handling information.

Simply choose the desired test protocol in the Steritest™ Symbio Pump's test methods library. The test method revision number is displayed for conformity check, and the method also shows the right Steritest™ NEO filtration device(s) to use.

You will save time thanks to preset speed and timer values, automatic activation of the syringe dilution accesory or pressure regulation mode.





Benefits

Perfect Fit for Your Testing Environment

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Complete Sterility
Testing Offer

Software - Enhance Your Steritest™ Symbio Pumps Capabilities in 5 Steps

The dedicated Steritest™ Symbio Software allows easy creation and management of test methods and simplified synchronization.

Step 1: Download the Steritest™ Symbio Software from our website SigmaAldrich.com/ steritest-software and install it on your laboratory computer

Step 2: Create your test methods library; a preview screen displays the future appearance on the pump screen

Step 3: Select the test method to be transferred to one or more Steritest™ Symbio Pumps

Step 4: Update the pump memory (USB flash drive or network cable)

Step 5: Print and sign the test methods details after cross checking with your quality system



Download the software



Benefits

Perfect Fit for Your Testing Environment

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Complete Sterility Testing Offer

Smart accessories for streamlining your workflow and increasing safety

Procedure Step

Testing Environment Setup

Sample Handling

Filtration

Waste Management Transport and Incubation

Steritest™
Communication
Hub Holder for
Hoods



- Easily attach the communication hub to one of the legs of the laminar flow hood
- Allows easy access to the pump's main switch, accessories connectors and keeps the floor free of cables

Order Now

Request Information

Steritest™
Connection
Cable Extension
with Tri-Clover® Clamp



 Use the optional connection cable extension with Tri-Clover® clamp for the connection of the Steritest™ Symbio LFH or FLEX pump to the communication hub when used in an isolator without pump integration hole

Order Now



Benefits

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Testing Offer

Smart accessories for streamlining your workflow and increasing safety

Procedure Step

Testing
Environment
Setup

Sample Handling

Filtration

Waste Management Transport and Incubation

Steritest™ Glass Ampoule Breaker





- Glass parts are collected inside the container (up to 60 ampoules)
- Easy to clean and empty
- Stable feet allow flexible placement in your testing environment

Order Now

Request Information

Steritest™ Holder for Steridilutor® NEO Vent Chamber



 Prevent vials from leaking when reconstituting powders by using the holder to keep the Steridilutor® NEO vent chamber above the liquid level

Order Now



Benefits

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Complete Sterility Testing Offer

Smart accessories for streamlining your workflow and increasing safety

Procedure Step

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Environment
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Sample Handling

Filtration

Waste Management Transport and Incubation

Steritest™ Holder for Sterile Bags

 Free your work bench by hanging sterile bags on the holder hooks



Steritest™ Syringe Support

 Safe handling of syringes with needles

 Automatic dispensing of sterile fluid to dilute the content of the syringes, eliminating the need to turn the dilution bottle between syringes during testing

Order Now

Request Information

Order Now



Benefits

Perfect Fit for Your Testing Environment

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Complete Sterility Testing Offer

Smart accessories for streamlining your workflow and increasing safety

Procedure Step

Testing Environment Setup

Sample Handling

Filtration

Waste Management Transport and Incubation

Steritest™ Waste Overfilling Sensor for Solid Containers

- User is warned via both an audible signal and visual alert on the Steritest™ Symbio pump screen when the waste container is almost full
- Test in progress can be finished before the waste container is emptied or replaced



Order Now



Benefits

Perfect Fit for Your Testing Environment

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Smart Accessories

Ordering Information

Complete Sterility Testing Offer

Smart accessories for streamlining your workflow and increasing safety

Procedure Step

Testing
Environment
Setup

Sample Handling

Filtration

Waste Management Transport and Incubation

Steritest™ Canisters Carrying Tray and Rack

- Enable safe transport and incubation of up to 20 canisters filled with media
- No risk of canisters falling out of the tray
- Easy visual inspection of up to 5 canisters at once



Order Now



Benefits

Perfect Fit for Your Testing Environment

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Software

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Complete Sterility
Testing Offer

Ordering Information

Steritest™ Symbio Pumps

Product name	Product #	Request a Demo	Add to Cart
Steritest™ Symbio LFH Pump	SYMBLFH01WW	()	
Steritest™ Symbio ISL Pump	SYMBISL01WW		
Steritest™ Symbio FLEX Pump	SYMBFLE01WW		

Steritest™ Symbio Accessories

Product name	Product #	Request a Demo	Add to Cart
Steritest™ Glass Ampoule Breaker	SYMBABR01		
Steritest™ Holder for Steridilutor® Vent Chamber	SYMBSVB01		
Steritest™ Holder for Sterile Bags	SYMBSVB01		
Steritest™ Syringe Support	SYMBSYS01		
Steritest™ Waste Overfilling Sensor for Containers	SYMBWFS01		
Steritest™ Canisters Carrying Tray	SYMBCAN08		
Steritest™ Canisters Carrying Rack	SYMBRACK2	(j)	
Steritest™ Communication Hub Holder for Hoods	SYMBCHH01	(1)	
Steritest™ Communication Hub Holder for Isolators	SYMBCHI01	(j)	
Steritest™ Connection Cable Extension with Tri-Clover® Clamp	SYMBXTC01	(f)	



Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

Request a Quote

Complete Sterility Testing Offer

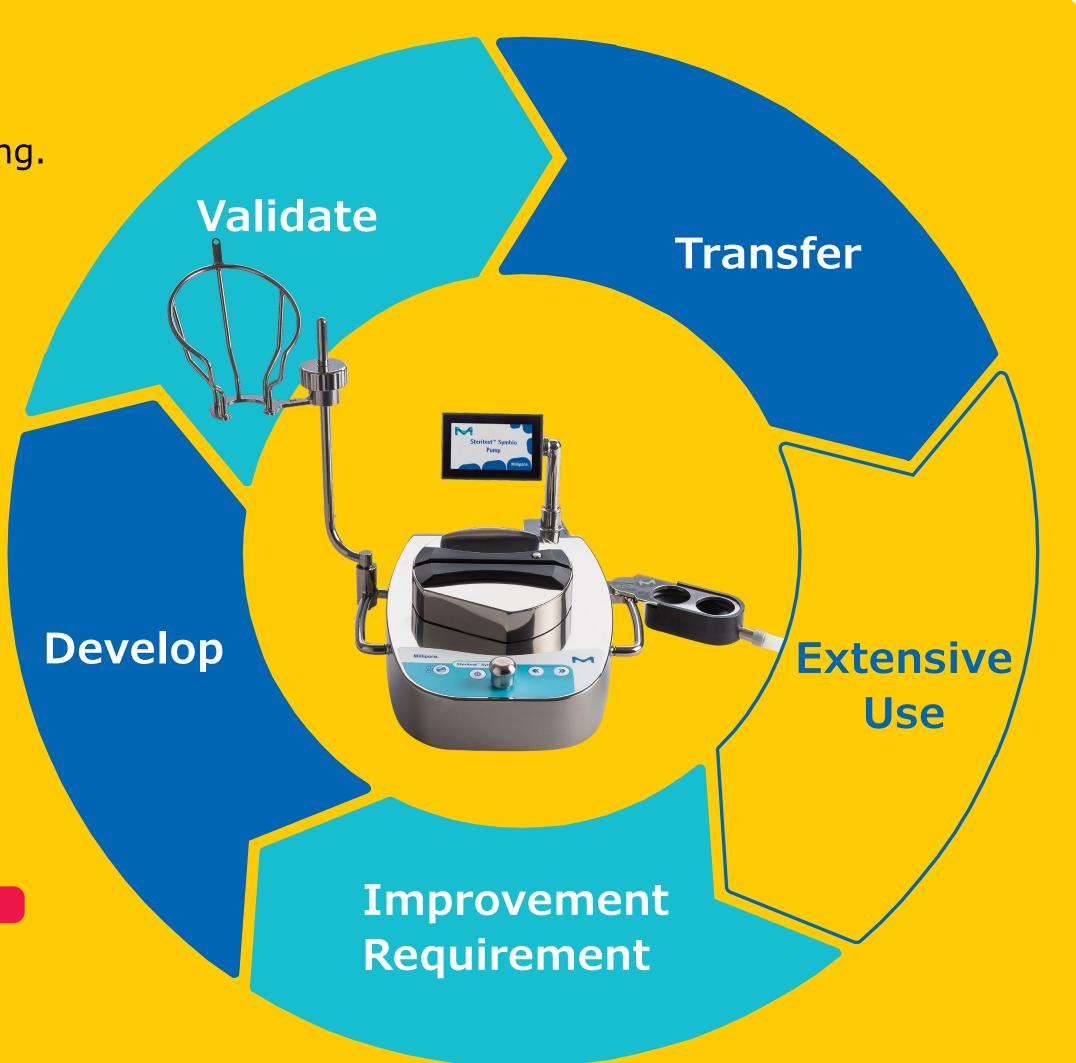
A team of experts

Our services portfolio supporting the Steritest™ family for sterility testing.

Reduce your sterility testing workload and focus on critical activities.

To request a quote for a method development, IQ/OQ service, PQ consultancy, preventive maintenance, service plan or training, please contact your local sales representative.

Contact us





Method Development

Validation Protocols

Validation Services

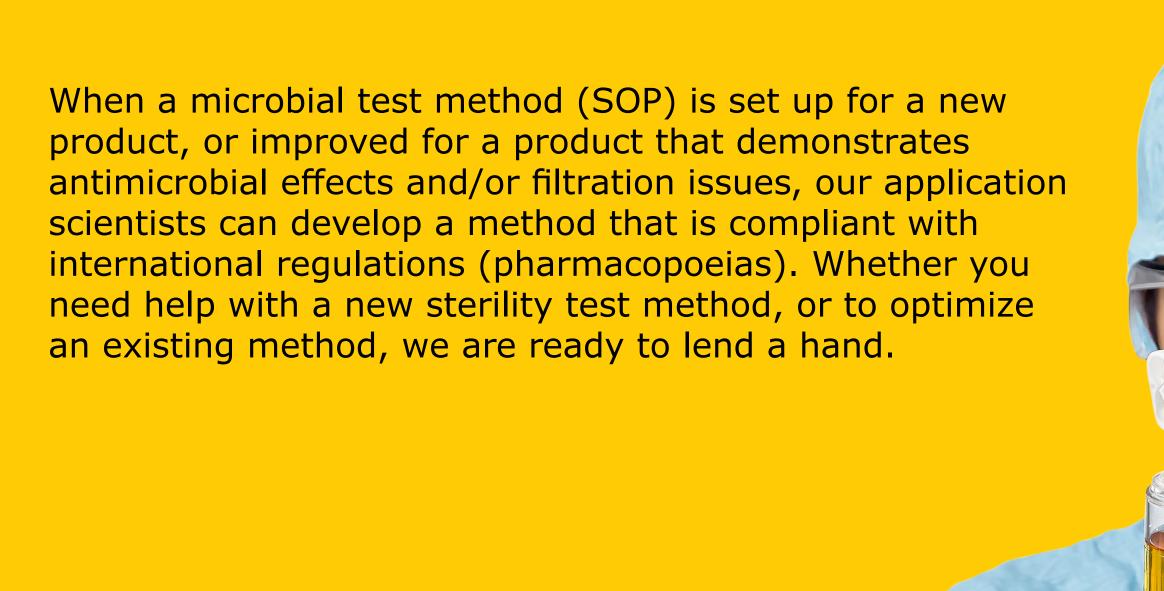
Maintenance & Service Plans

Training

Request a Quote

Complete Sterility Testing Offer

Consider it done





Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

Request a Quote

Complete Sterility Testing Offer

Validation protocols

Ready-to-use validation protocols

Validation workflow

Validation protocols

Steritest™ Symbio pumps validation protocol

European A4: SYMBA4VP1 US Letter: SYMBLTVP1

Leave it to us

cGMPs and cGLPs require equipment and test methods to be validated before routine use. Our ready-to-use validation protocols for sterility testing are based on our internal product qualification test methods. These extensive protocols will enable the QC/QA lab to quickly initiate your Validation Master Plan and perform IQ, OQ and PQ (suitability of the test methodology) with ease.



Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

Request a Quote

Complete Sterility Testing Offer

Validation protocols

Ready-to-use validation protocols

Validation workflow



1. Validation Master Plan

• Defined structure, responsibilities for qualification



2. Installation Qualification (IQ)

- Verification and identification of the equipment
- Verification of the product's utilities and operating environment requirements
- Equipment and personnel preparation



3. Operational Qualification (OQ)

 Verification of the product's functionality (hardware, software, devices)



4. Performance Qualification (PQ)

 Test Method suitability verification (microbiology validation procedures)



5. Final Report

 Summarizes all testing performed for final approval of validation



Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

Request a Quote

Dedicated experts

We have experienced and trained validation engineers who are skilled to assist in validation protocol implementation within the QC microbiology laboratory, so the QC/QA departments do not have to allocate resources. A basic technical training on your installed equipment is also provided during the validation engineer's visit. Rely on our expertise in various situations such as:

- New lab equipment
- New product or reformulated product testing
- Compliance with updated regulations: EP, USP, JP, etc.

After the IQ/OQ has been completed we can support with PQ consultancy

Complete Sterility Testing Offer



Method Development

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Maintenance & Service Plans

Training

Request a Quote

Complete Sterility Testing Offer

Services

Annual preventive maintenance

Breakdown and spare parts

Service plans

Efficient operation

Preventive maintenance and system verification enable efficient operation of critical testing equipment. Every Steritest™ pump should be serviced regularly to ensure its performance remains compliant with the specifications, as per GLP and GMP. We recommend checking and calibrating the pump on an annual basis. Upon completion of the service, we will provide you with a report defining the service performed on your pump as well as our recommendations.





Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

Request a Quote

Complete Sterility Testing Offer

Services

Annual preventive maintenance

Breakdown and spare parts

Service plans

Reduce the risk

Annual preventive maintenance will reduce the risk of breakdown and ensure that your Steritest™ pump works within system specifications. However, in case a breakdown does occur on your pump, our service team will repair it as diligently as possible at your site or in our local service center. Depending on your service plan level, spare parts and labor are covered during the service plan validity period (Total plans only).





Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

Request a Quote

Complete Sterility
Testing Offer

Services

Annual preventive maintenance

Breakdown and spare parts

Service plans

You have the choice between 3 coverage levels

	Service Essential™	Service Advanced™	Service Total™	
Preventive maintenance	Yes (1/year)	Covered by Essential plan	Covered by Essential plan	
Maintenance kit (quoted separately)	Yes	No	No	
Number floating repair (labor and shipment/travel)	No	Yes (1/year)	Yes (unlimited)	
Spare parts	No	No	Yes	
Return shipment	Yes	Yes	Yes	
Travel fees	No, quoted separately No, quoted separately		No, quoted separately	
Options	To be ordered separately			
Second preventive maintenance contact	Yes	Yes	Yes	
Request a quote				



Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

Request a Quote

Complete Sterility Testing Offer

Training offer

Steritest™ School

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)

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

Why take chances?

Be confident of your results with our comprehensive sterility testing solutions. To discuss a specific sterility testing application, please contact your local sales representative.

For availability of Steritest™ school, AOT and services, contact us



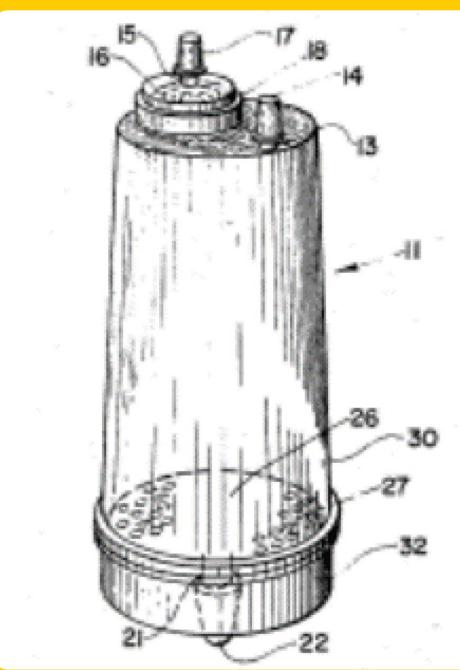


You all know the Steritest™ system, but DO YOU KNOW THE STORY OF ITS INVENTION?

×

Fernand Burghard, Millipore's European Manufacturing Director until 2000, was part of the Steritest™ adventure from the beginning.

In an interview, he tells us about how this breakthrough sterility testing system came into being.





Next >





When and why was there an idea to develop something like the Steritest™ system?



In the early 70s, large pharmaceutical companies In 1972, Jack Buch, Millipore founder and were struggling with the sterility testing needed to release a pharmaceutical to the market.

Sterility tests were performed openly under a laminar flow hood. Many false positives, often more than 30%, were observed, leading to additional tests and controls, discarded production lots, and manufacturing delays.

The financial consequences were huge and drug access for patients impaired. Millipore found out about these sterility testing and end-user issues from customers in the United States.

Chairman, settled in Molsheim (France) and had some clear user requirement specifications for a new product in mind. His way to go was:

- a 125 mL volume container
- a closed system
- a 47 mm membrane
- 2 canisters
- a needle and a Y-piece to connect tubing to the 2 canisters.

This was the start of the Steritest™ adventure!







Next >





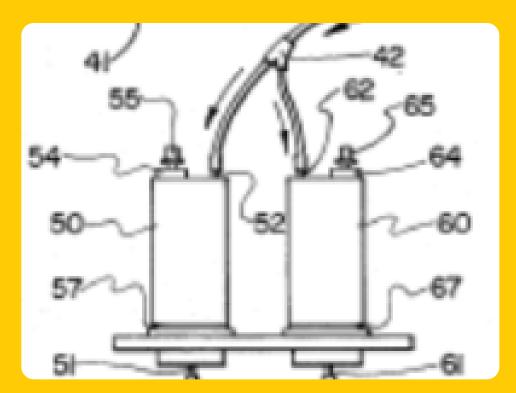
Is the Steritest™ system the result of in-depth market research or of a gut feeling?

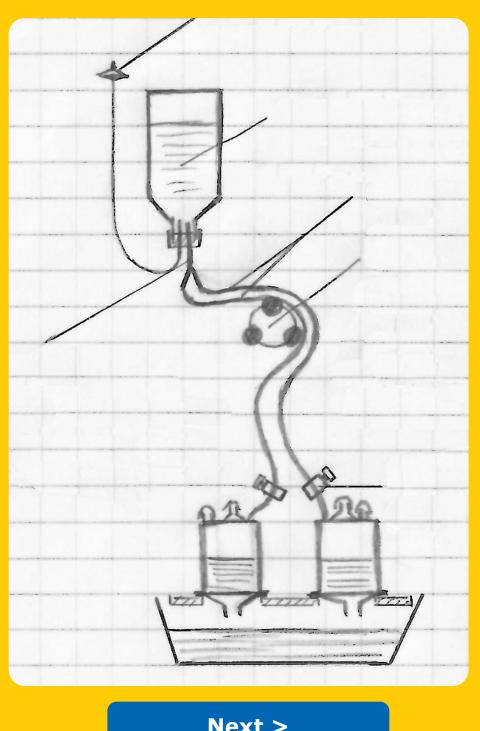


The Steritest™ system was developed to address a need clearly expressed by customers in the pharmaceutical industry, at a global level, to improve the reliability and robustness of the test for sterility.

How much time was required to develop the Steritest™ system and introduce it to the market?

More than 2 years were needed to develop a solution, because there were several issues to deal with. The concept was unique and innovative, a revolution in the sterility testing world, which required hard work from a multidisciplinary, audaciously bold, and creative team.







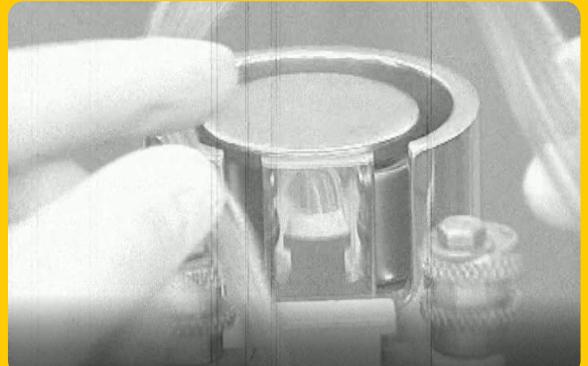


What was the biggest challenge during development, and how did you solve it?

×

Equal splitting into the 2 canisters needed quite some effort. We had to work on the plastic tubing and eventually we came to the conclusion that we had to replace the classical vacuum pump by a peristaltic one.

The marketable product resulted from a close collaboration with a local partner, specialized in industrial engineering, and the courage and conviction of a curiosity-driven and motivated team.

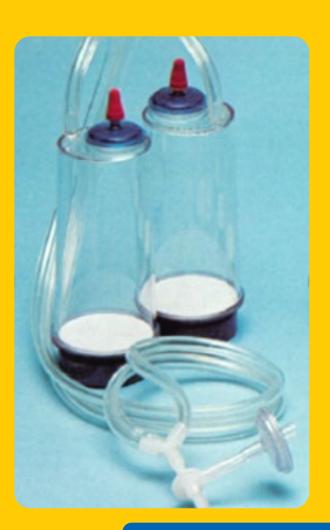


Which three words would best characterize the Steritest™ system?

Only one: extraordinary. Our pharma customers' need was clear: they had a high level of false positive test results, leading to significant drug quarantine costs and time wasted on follow-up tests.

All this had to stop.

We felt the mission to find a radical solution, a solution to this worldwide issue in the industry.



Next >





Did you imagine back in 1974 that the Steritest™ system would become the standard for sterility testing in the pharmaceutical industry, something they all use, like a Petri dish or a pipette?

×

We had high hopes, justified by the enormous market size. The issue was a global one, and we strongly believed in our solution.



45 years after market introduction, the Steritest™ system remains the reference for sterility testing. How do you feel about that?

I am personally very proud to have contributed to the creation of Steritest™ system, a reliable solution that helps customers and patients all over the world.



Next >





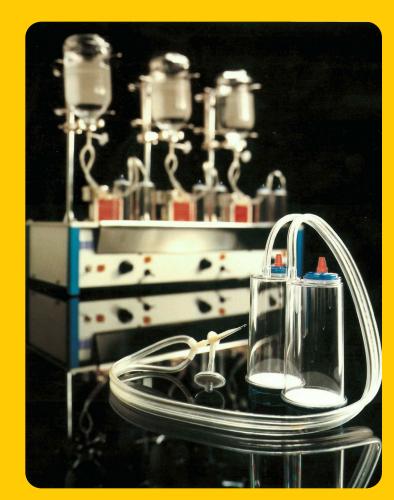
Concluding remarks from Estelle Zelter, Global Product Manager Sterility Testing



In 2020, the Steritest™ system celebrated its 45th anniversary as a commercial product. Curiosity and innovation still motivate our teams.

Like Fernand Burghard and his colleagues did, we listen carefully to our customers in order to continuously improve our existing products while respecting regulatory requirements.

At the same time, we look to the future, developing breakthrough technologies and innovative products.



Over the 45 years, the Steritest™ system has been refined. There's a fully compliant portfolio for sterility testing that includes membrane filtration devices, pumps and accessories, culture media and fluids, and related services.

The many years of experience have yielded comprehensive method development & consultancy expertise, validation protocols (IQ/OQ/PQ & requalification), service plans and trainings (Sterility Testing remote school, advanced operator training, ...), of which we today are proud.







For further information about our Steritest™ products please contact our local sales representative or visit our website

SigmaAldrich.com/sterility-testing

To discuss with our Experts:

SigmaAldrich.com/info-sterility-testing

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