



MERCK

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

Story of the Steritest® system invention

Steritest® NEO Filtration Device

NEW M-Trace™ Software for Trusted & Efficient Data Recording

NEW Velax® cutting clamp

Culture Media & Rinsing Fluids

Peristaltic Steritest® Symbio Pump

Services & Training

Smart Accessories



Workflow

EASY WORKFLOW

In a 6-step procedure



Test Preparation

Filter Pre-wetting

Sample Filtration

Device Rinsing

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

Request information



Workflow

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.

[Request information](#)



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.

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Workflow

EASY WORKFLOW

In a 6-step procedure



Test
Preparation

Filter
Pre-wetting

Sample
Filtration

Device
Rinsing

Media
Transfer

Reading



Rinse product from both
canisters.

[Request information](#)



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.

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Workflow

EASY WORKFLOW

In a 6-step procedure



Test
Preparation

Filter
Pre-wetting

Sample
Filtration

Device
Rinsing

Media
Transfer

Reading



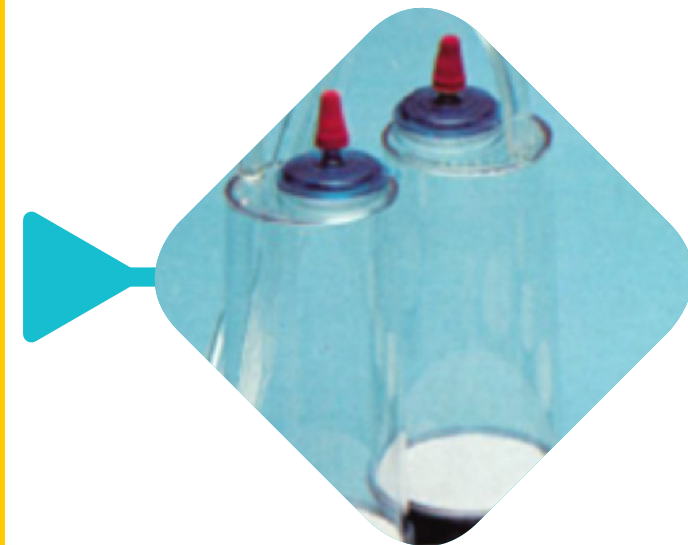
Incubate and examine the Steritest[®] NEO canisters for growth in accordance with the appropriate pharmacopoeias.

[Request information](#)



History

Sterility Testing OUR PIONEERING HISTORY



1975
First Steritest®
unit



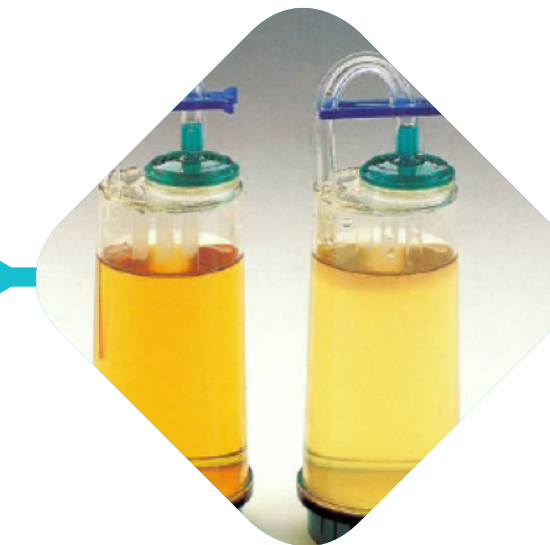
1985
New sealing
technique
& MCE
membrane



1986
PVDF
Membrane



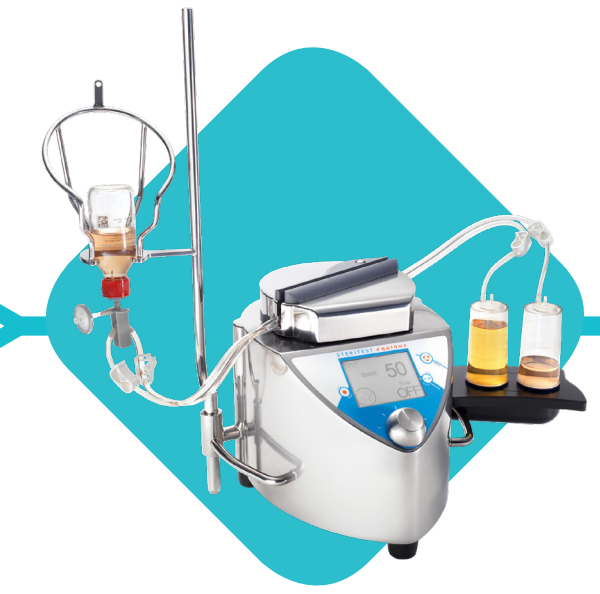
1988
Steritest®
Compact Pump



1994
Steritest®
device for oily
samples



1994
Steritest®
Integral Pump



2004
Steritest®
Equinox
Pumps



**2018
to 2022**
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

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1975



The first Steritest[®] device is launched by Millipore Corporation



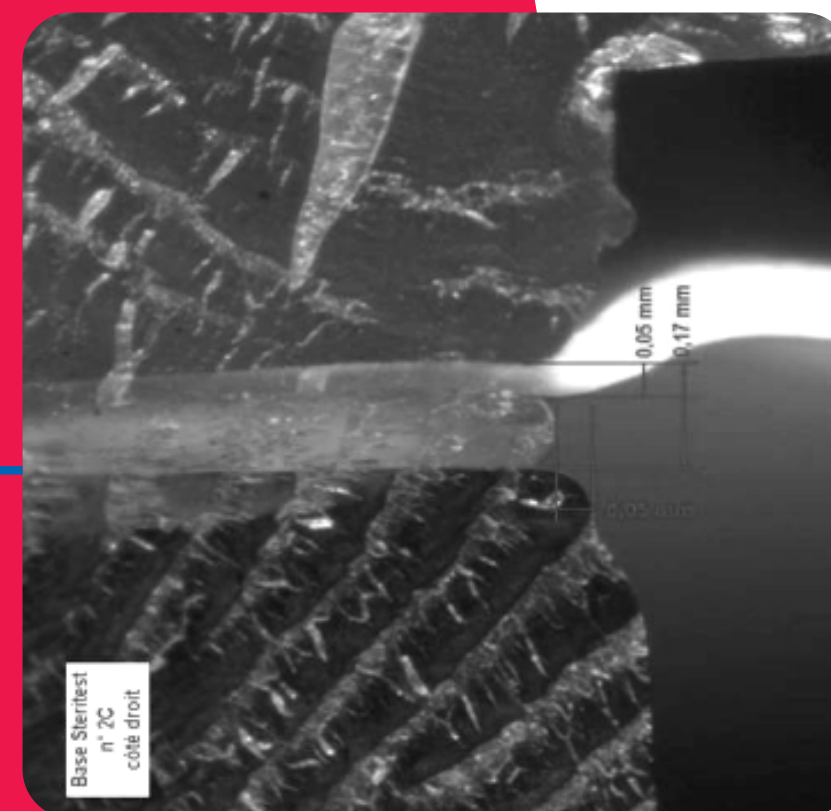
- A closed filtration device prevents external contamination (false positive results).
- The cellulose filter membrane with hydrophobic edge is pinched between canister top and base.
- The needle allows to sample the product out of the sterile vial the same way as the nurse or doctor would take the product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



1985



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



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.



[Request information](#)



1994



The Steritest® Integral pump

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





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.





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

[Request information](#)



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.



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.



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





2014



The Steritest® Symbio pumps

- Sterility testing becomes easier than ever.





Complete range of Steritest® accessories

Streamline your workflow and increase safety with smart accessories.

Sample Handling

Filtration

Waste Management

Transport and Incubation



SYMBSVB01

Steritest® Holder for Steridilutor® NEO Vent Chamber

SYMBABR01

Steritest® Glass Ampoule Breaker

SYMBSVB01

Steritest® Holder for Sterile Bags

SYMBSYS01

Steritest® Syringe Support

SYMBWFS01

Steritest® Waste Overfilling Sensor for Solid Containers

SYMBCAN08

Steritest® Canister carrying trays and **SYMBRACK2** Steritest® Rack



History



2018 TO 2022

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

[Request information](#)



Steritest® NEO

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 PIONEERS

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.



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Steritest® NEO

Benefits

New Features

Video - New Features

Video - New Devices

Specifications

Regulations

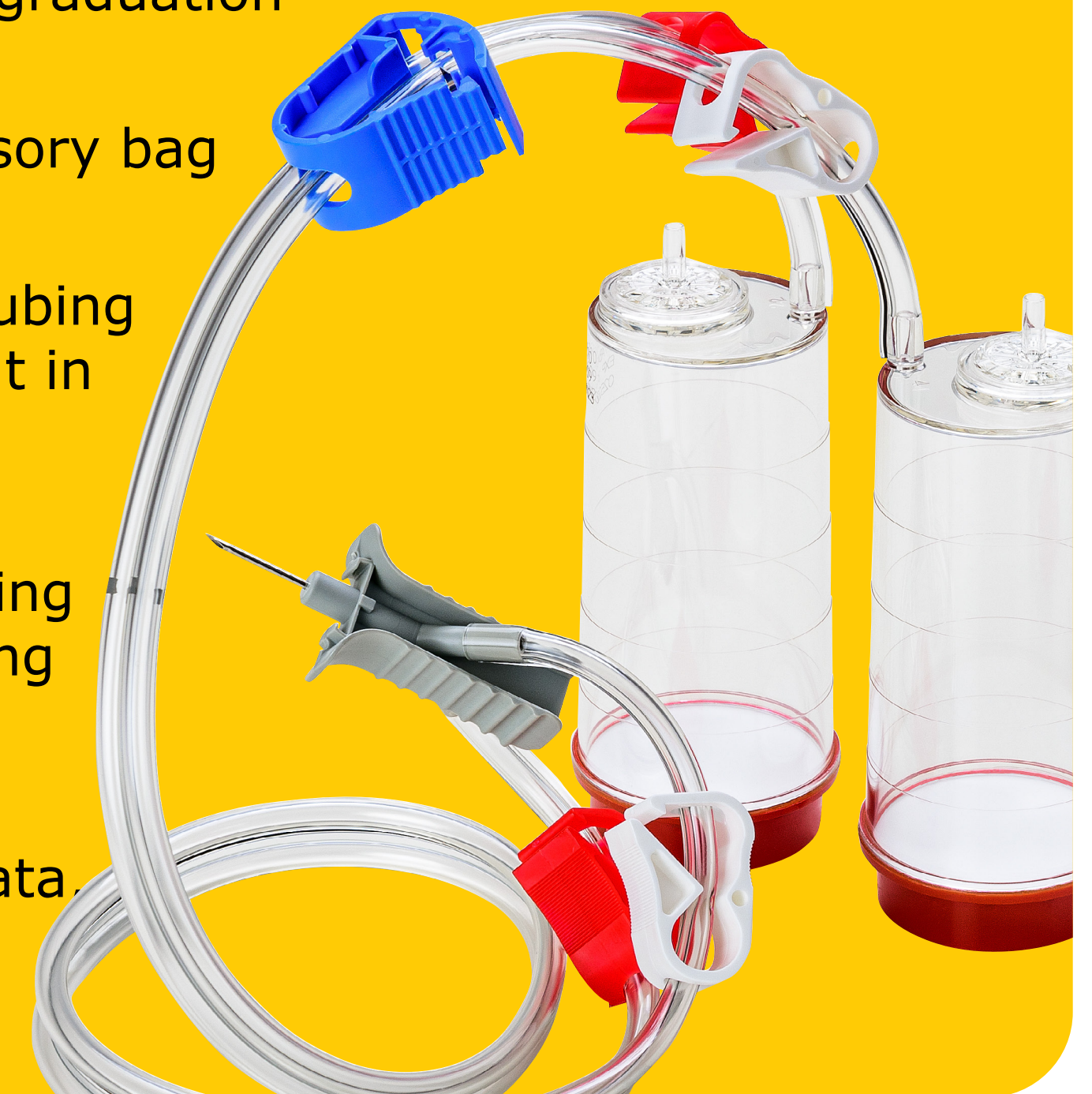
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Ordering Information

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
- No scissors needed. Press the Velax® cutting clamp to cut the tubing
- Smart Label with 2D data matrix barcode to retrieve product data.



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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



CLICK TO ENLARGE

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.



CLICK TO ENLARGE

Feel comfortable: new placement mark

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

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



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Feel free: easy to open accessory bag



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



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CLICK TO ENLARGE

Feel confident: colored clamps

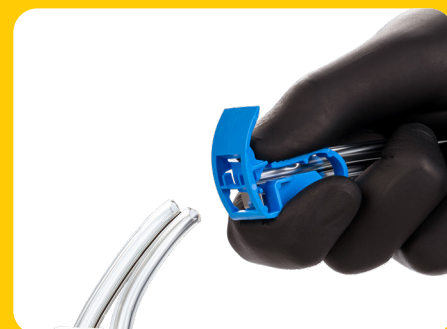
Prevent any filling errors and improve your workflow clarity, thanks to the pre-installed colored clamps and the existing blackline for accurate media filling.



CLICK TO ENLARGE

Feel safer: new designed needle guard and needle protector

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



CLICK TO ENLARGE

Feel safe: tubing disconnection tool

No scissors needed. Press the Velax® cutting clamp to cut the tubing.

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Feel confident: colored clamps



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EVOLUTION OF CONVENIENCE

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Feel safer: newly designed needle guard and needle protector



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EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY

Feel safe: No scissors needed. Cut the tubing using the Velax® cutting clamp mounted on every Steritest® NEO device.



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EVOLUTION OF CONVENIENCE

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CLICK TO ENLARGE

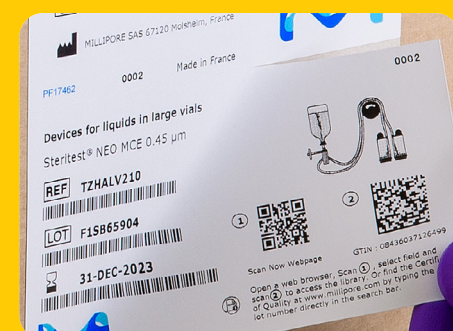
Feel secure: optimized identification and traceability

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

Peel-and-stick label with critical information to place in a lab notebook for accurate tracking.



CLICK TO ENLARGE

Smart Label with 2D data matrix barcode to retrieve product data, including the item code, batch number, shelf life, and global trade item number (GTIN). It allows an easy data processing in a broad range of systems (EPR, LIMS, etc...)

Learn more on: SigmaAldrich.com/smart-label



CLICK TO ENLARGE

Feel confident: 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.

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Steritest® NEO

Benefits

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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 secure: optimized identification and traceability



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Steritest® NEO

Benefits

New Features

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Complete Sterility Testing Offer

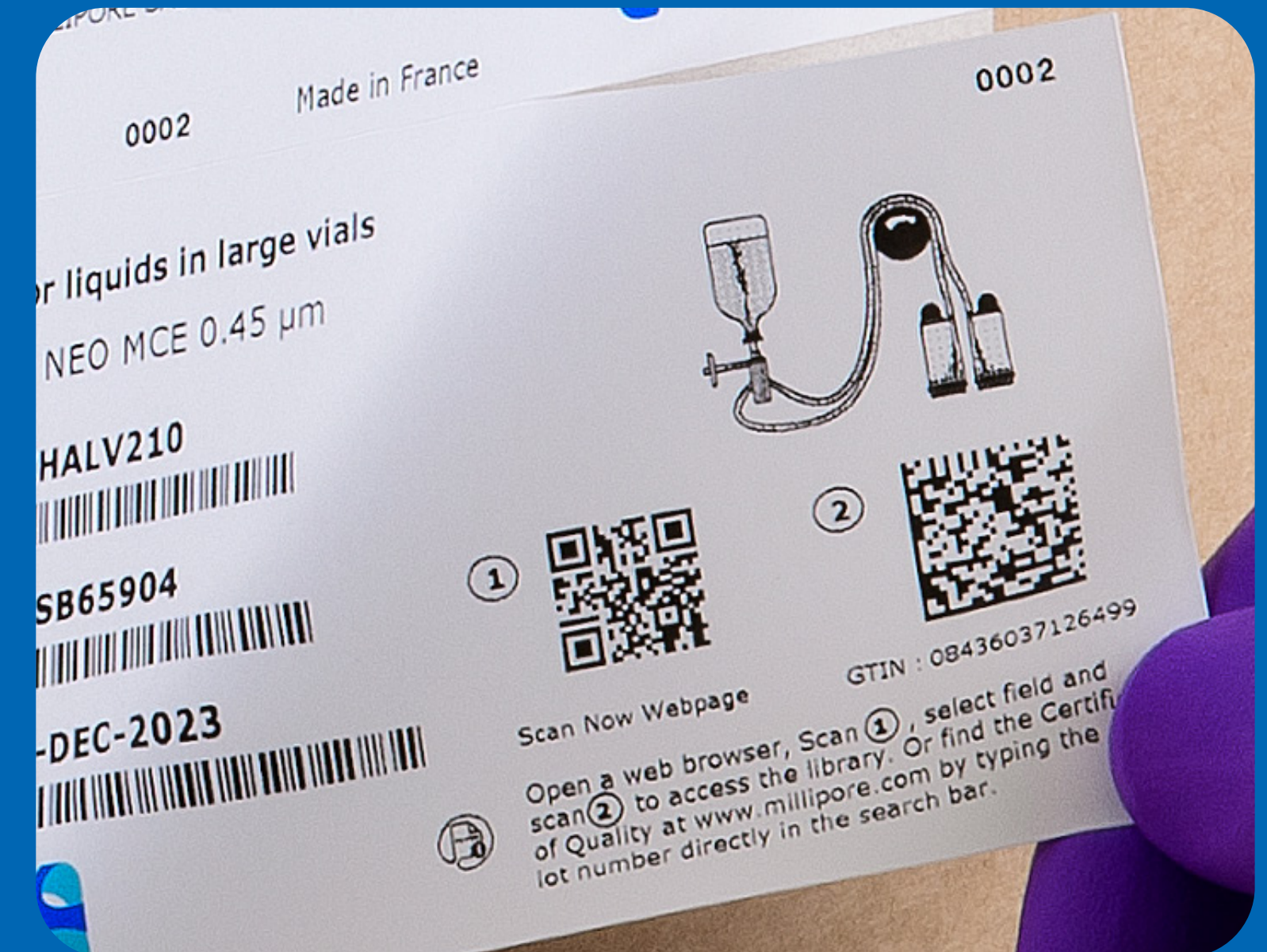
New features of the 4th generation of Steritest® devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY

Feel secure: optimized identification and traceability



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Steritest® NEO

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Testing Offer

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EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY

Feel confident: volume graduation on the canisters



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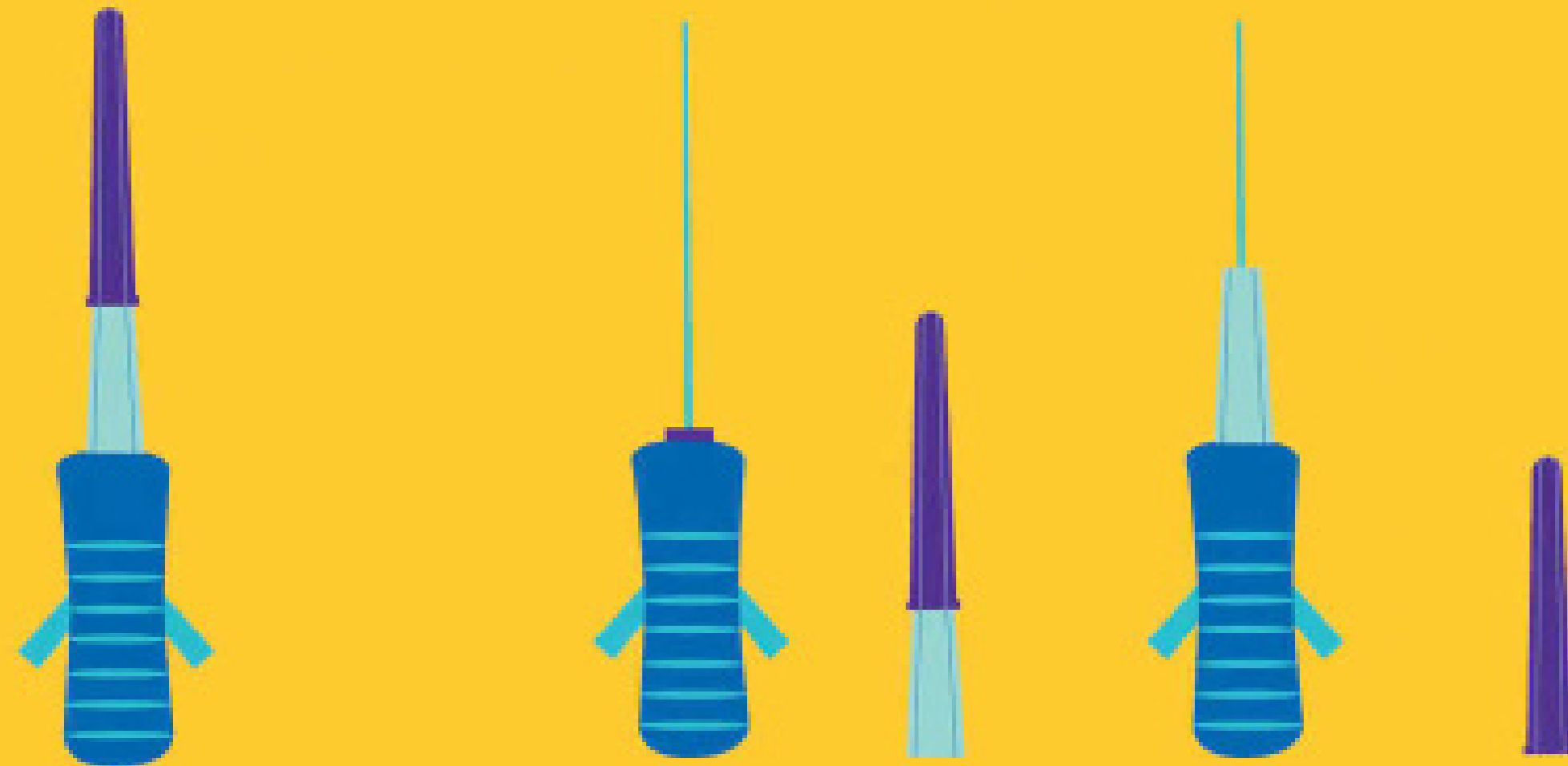
Ordering Information

**Complete Sterility
Testing Offer**

Video

Steritest® NEO devices: new features

Select your needle length
protective cap in 2 parts



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Steritest® NEO

Benefits

New Features

Video - New Features

Video - New Devices

Specifications

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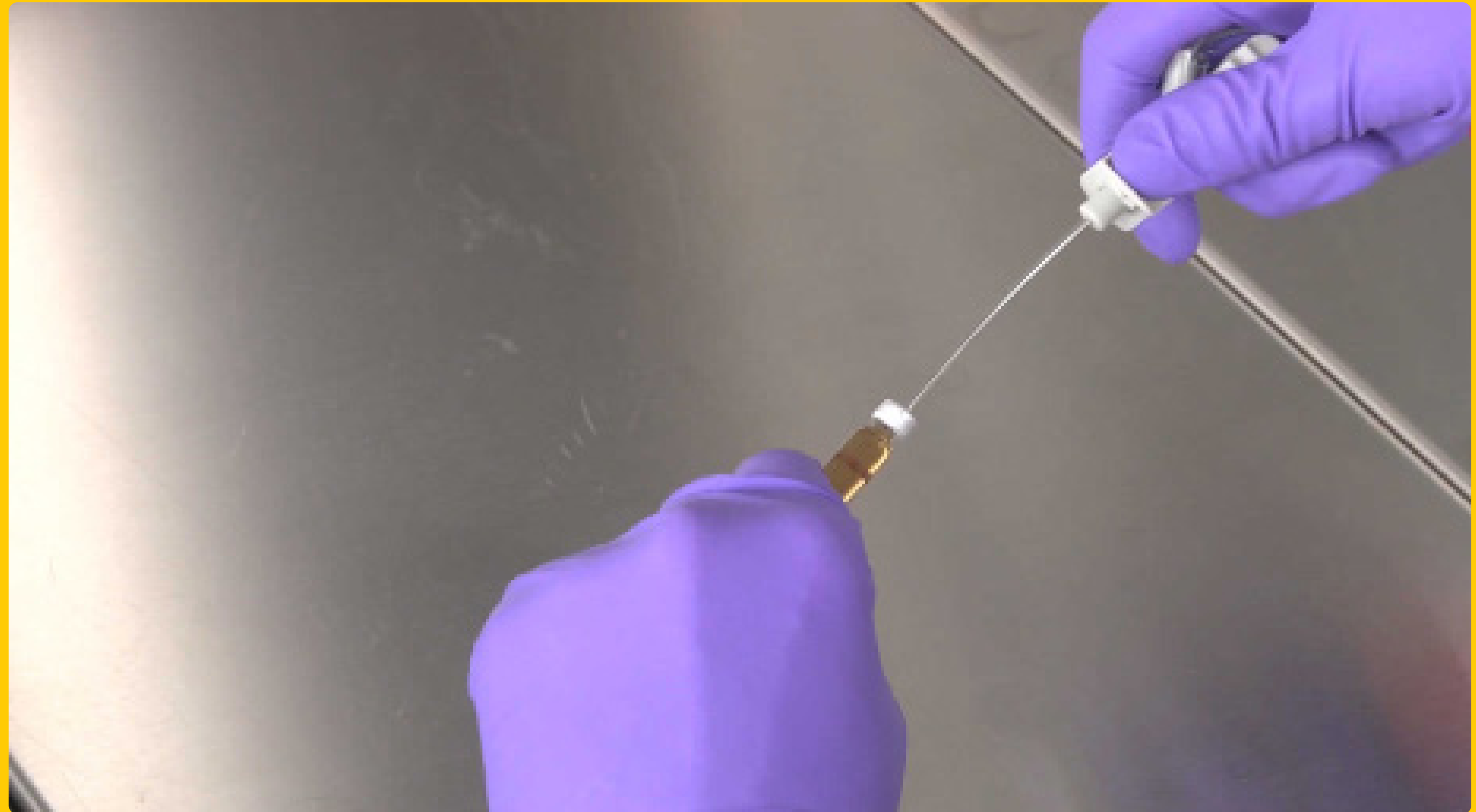
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Ordering Information

**Complete Sterility
Testing Offer**

Video

Steritest® NEO devices for cartridges and small soft plastic containers



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Steritest® NEO

Benefits

New Features

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Ordering Information

Complete Sterility Testing Offer

Specifications

Steritest® NEO "Blue Base" devices

for products WITHOUT antimicrobial agents and medical devices



Steritest® NEO "Red Base" devices

for antibiotics, products WITH antimicrobial agents and medical devices



Steritest® NEO "Green Base" devices

for products dissolved in solvents requiring increased chemical compatibility



Canister Base Color	Blue	Red	Green
Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm	Low adsorption Durapore® membrane (HV), 0.45 µm hydrophilic PVDF	Low adsorption Durapore® membrane (HV), 0.45 µm hydrophilic PVDF
Materials of Construction Filtration Chamber (Canister): Double Lumen Tubing: Needle:	Styrene acrylonitrile PVC, 850 mm length Stainless steel and polyamide 6-6	Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6	polyamide 6-6 (nylon) PVC, 850 mm length Stainless steel and polyamide 6-6
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)	120 mL (graduation marks at 25, 50, 75 and 100 mL)	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)	300 mL/min at 690 mbar (10 psi)	300 mL/min at 690 mbar (10 psi)
Maximum Temperature	45 °C	45 °C	45 °C
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)	3.15 bars at 25 °C (45 psi at 77 °F)	3.15 bars at 25 °C (45 psi at 77 °F)
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Ordering Information	Click here	Click here	Click here

Request information



Steritest® NEO

Benefits

New Features

Video - New Features

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**Complete Sterility
Testing Offer**

Regulations and Industry benchmark

Regulations

**Closed
Environment**

**Consistent
Performance**

**Certificates
of Quality**

**Documented
Qualification**



Request information



Steritest® NEO

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Regulations and Industry benchmark



Regulations

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>.

Request information



Steritest® NEO

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Regulations and Industry benchmark



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.

Request information



Steritest® NEO

Benefits

New Features

Video - New Features

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Complete Sterility
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Regulations and Industry benchmark



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

Request information



Steritest® NEO

Benefits

New Features

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Testing Offer**

Regulations and Industry benchmark



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.

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Testing Offer**

Regulations and Industry benchmark



Documented Qualification

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

Request information



Steritest® NEO

Benefits

New Features

Video - New Features

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Specifications

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Double Packed

Ordering Information

**Complete Sterility
Testing Offer**

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



Request information



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Double Packed

Ordering Information

Complete Sterility Testing Offer

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

DOUBLE PACKAGING 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.

Transfer of Steritest® NEO Double-packed Devices into a Laminar Flow Hood

Unclassified Room

Bag decontamination



Bag with perfect cut sealing for an optimal decontamination.

Bag Transfer

Classified Room

Bag opening and transfer of devices



Transfer of sterile devices into the LFH results in time savings.

Request information



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New Features

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Specifications

Regulations

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

Perfect for the majority of pharmaceutical drugs that do not have antimicrobial activity, our HA mixed cellulose esters membrane allows fast flow rates for optimum throughput performance.

Ordering Table

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.

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

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

Request information



Steritest® NEO

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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

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- Steritest® NEO Devices for Soluble
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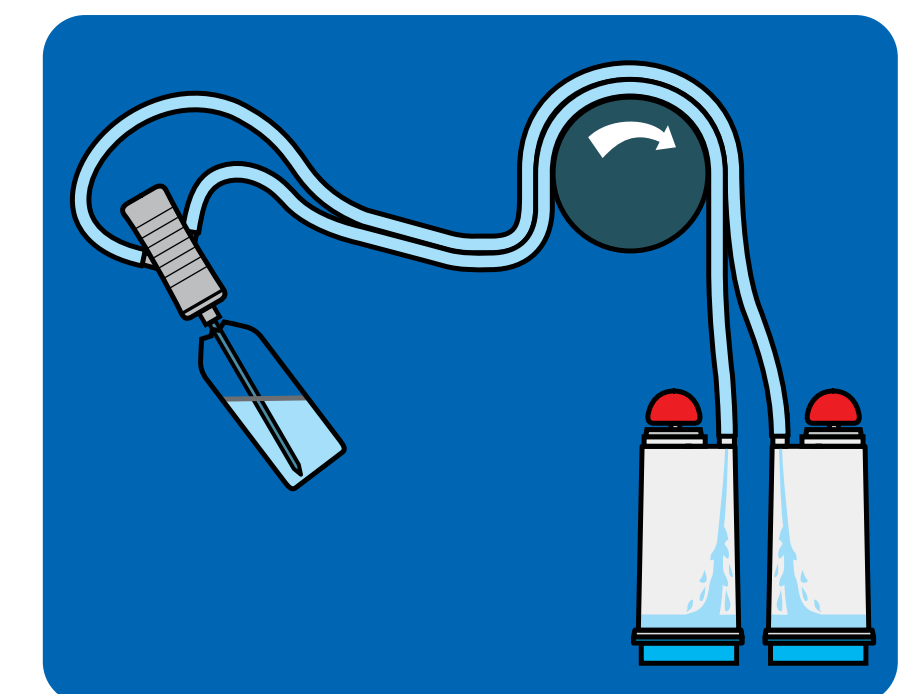
Steritest® NEO Devices for Liquids in Ampoules (TZHALA210)



- Single needle for easy access to ampoules
- 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

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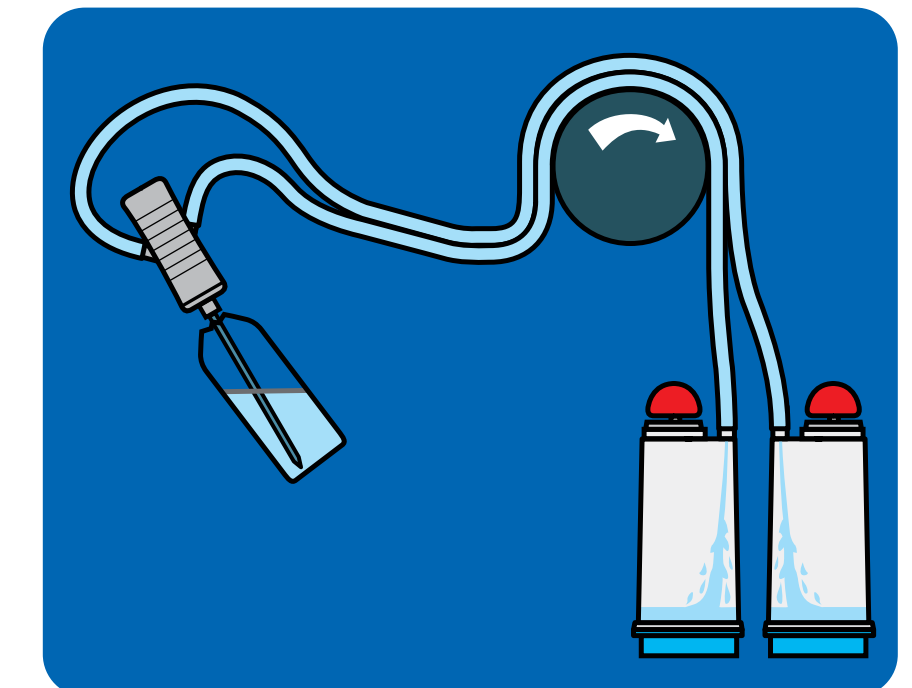
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Steritest® NEO Devices for Liquids in Ampoules - Double-Packed (TZHALA205)

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

Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm
Materials of Construction	
Outer bag:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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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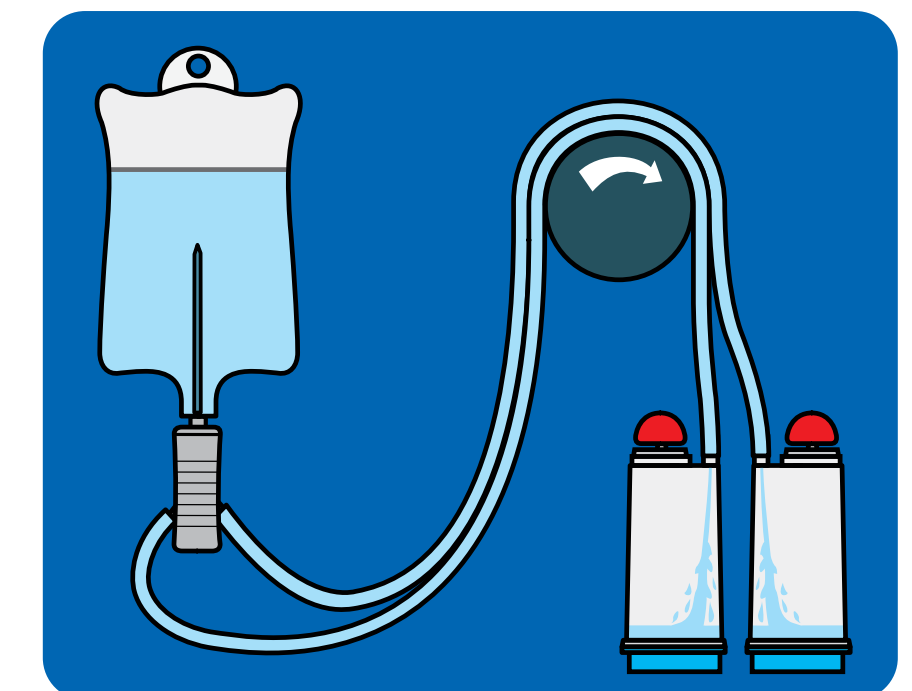
Steritest® NEO Devices for Liquids in Collapsible Bags (TZHALA210)



- Single needle for easy access to collapsible bags
- 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

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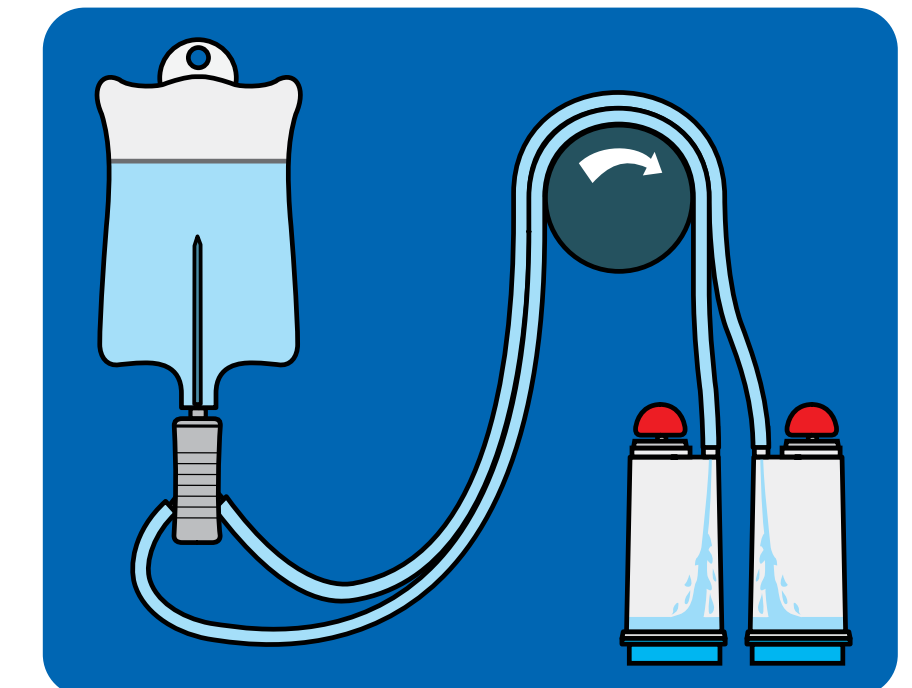
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Steritest® NEO Devices for Liquids in Collapsible Bags - Double-Packed (TZHALA205)

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

Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm
Materials of Construction	
Outer bag:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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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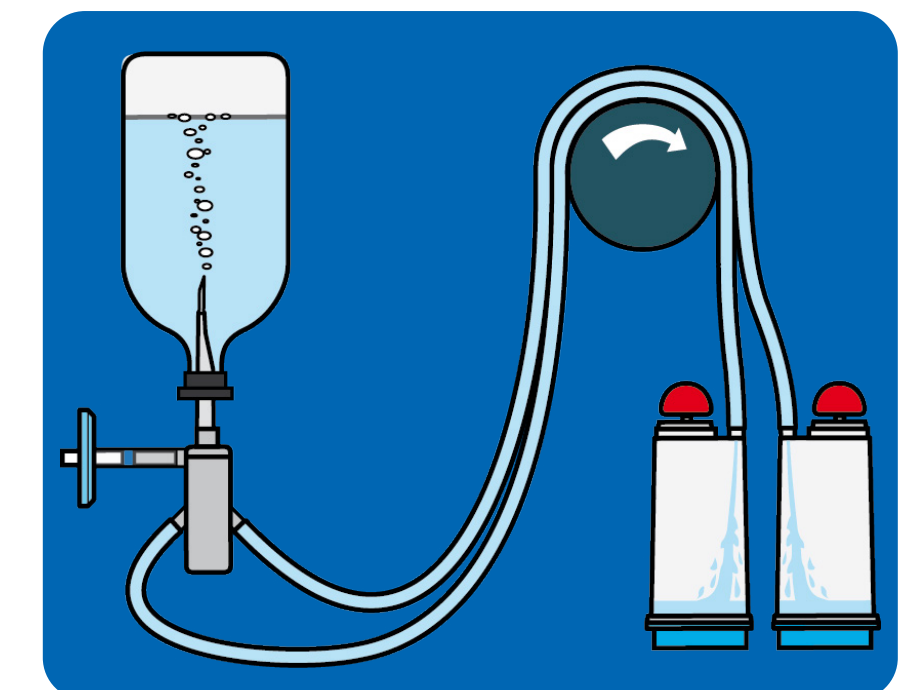
Steritest® NEO Devices for Liquids in Large Vials (TZHALV210)



- Vented double needle for large glass containers with septa

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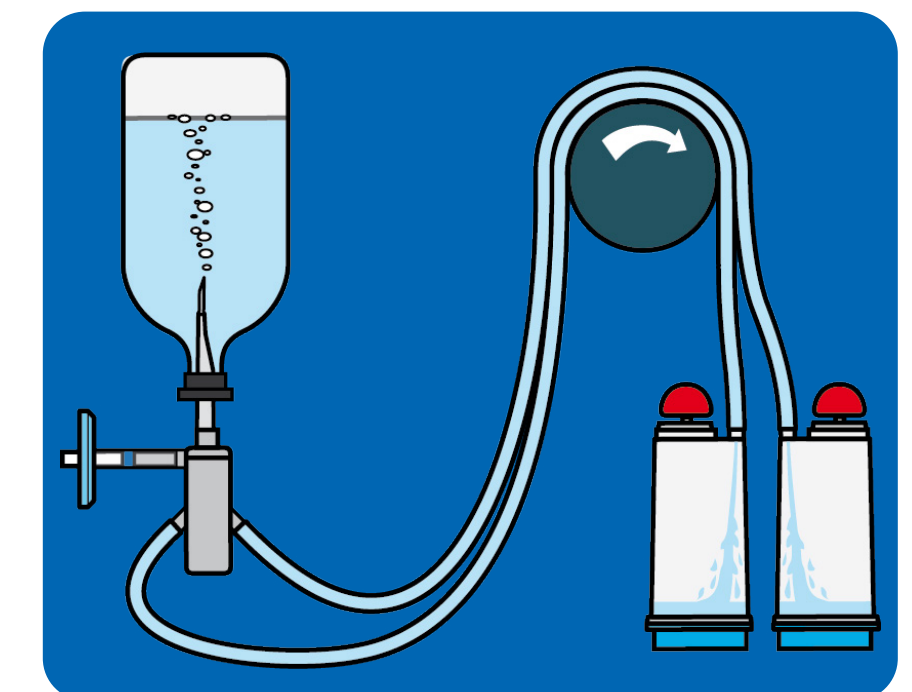
Steritest® NEO Devices for Liquids in Large Vials - Double-Packed (TZHALV205)



- Vented double needle for large glass containers with septa
- Double-packed for quick transfer into sterility testing environments

Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm
Materials of Construction	
Outer bag:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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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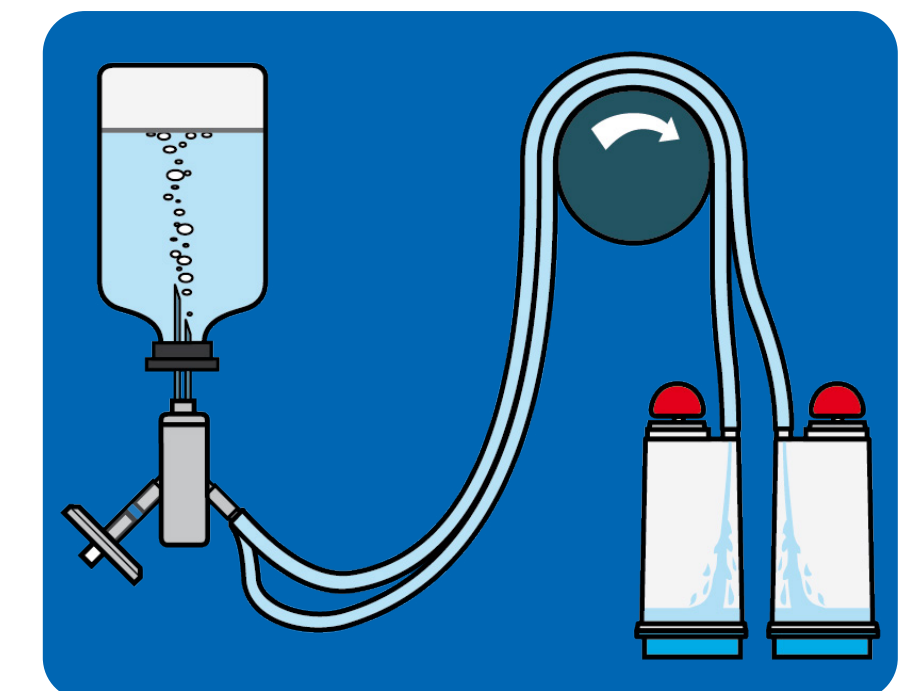
Steritest® NEO Devices for Liquids in Small Vials (TZHASV210)



- Vented double needle for small vials with septa

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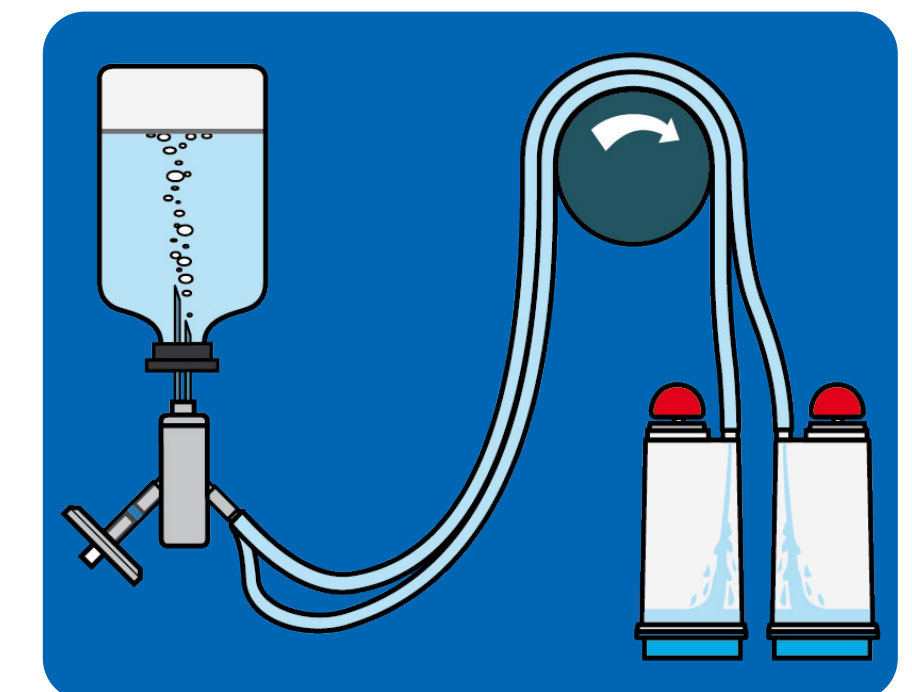
Steritest® NEO Devices for Liquids in Small Vials - Double-Packed (TZHASV205)



- Vented double needle for small vials with septa
- Double-packed for quick transfer into sterility testing environments

Canister Base Membrane	Mixed Esters of Cellulose (HA) membrane, 0.45 µm
Materials of Construction	
Outer bag:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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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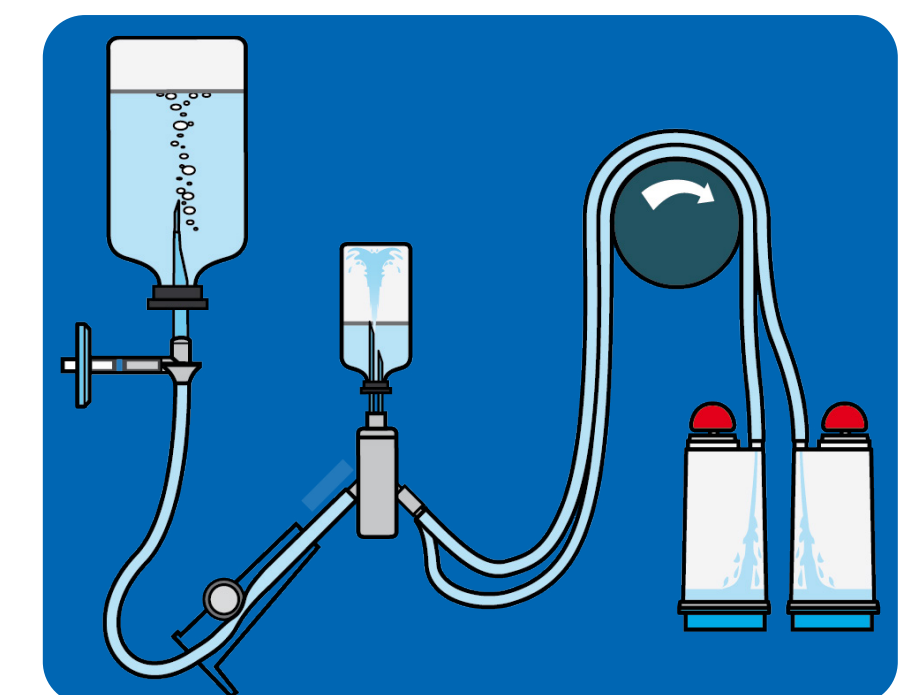
Steritest® NEO Devices for Soluble Powders in Vials (TZHADV210)



- 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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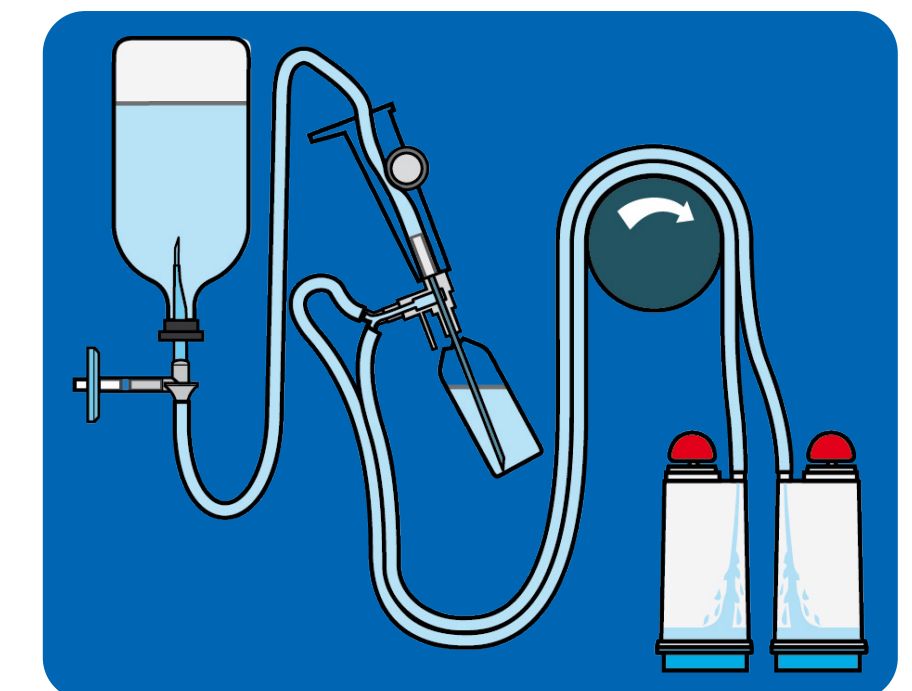
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Steritest® NEO Devices for Soluble Powders in Ampoules (TZHADA210)

- 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

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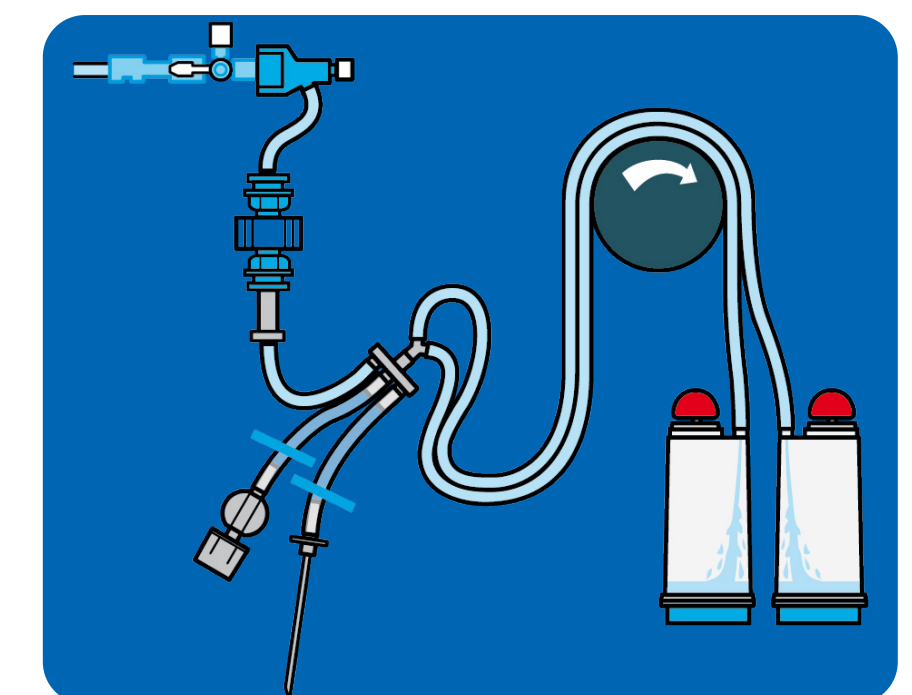
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Steritest® NEO Devices for Medical Devices and Collapsible Bags (TZHAMD210)

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

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)
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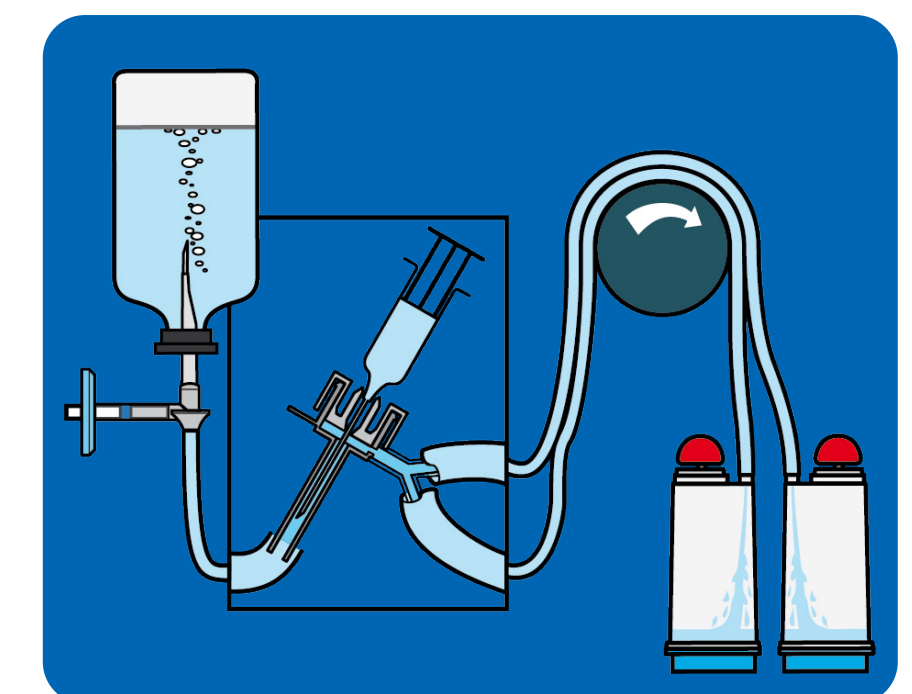
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Steritest® NEO Devices for Liquids in Syringes (TZHASY210)

- 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): 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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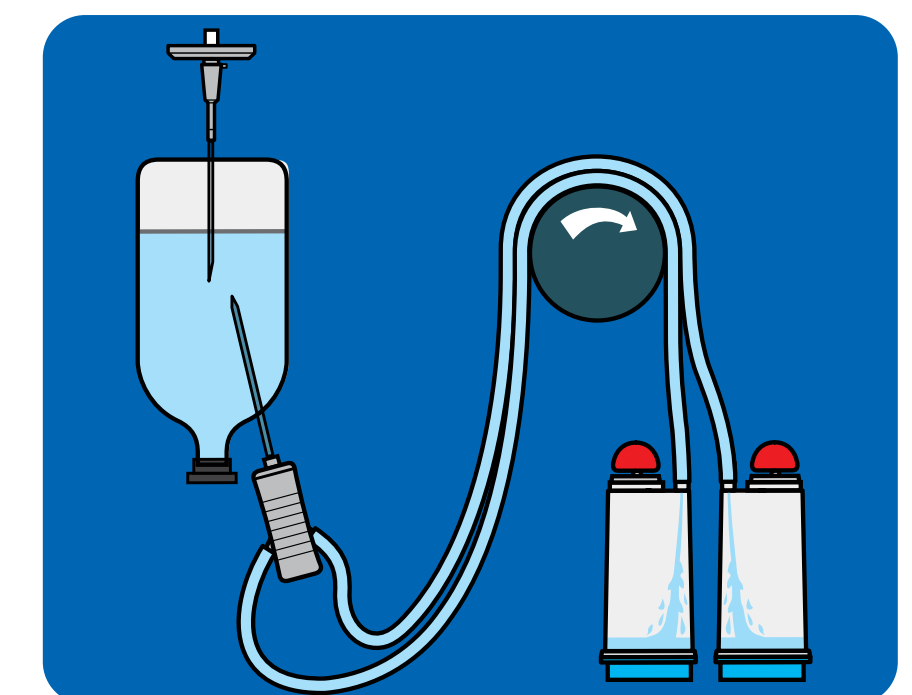
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Steritest® NEO Devices for Liquids in Plastic Containers (TZHAPC210)

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

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Steritest® NEO "Blue Base" Devices

for products WITHOUT antimicrobial agents and medical devices



Application

- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Medical
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids

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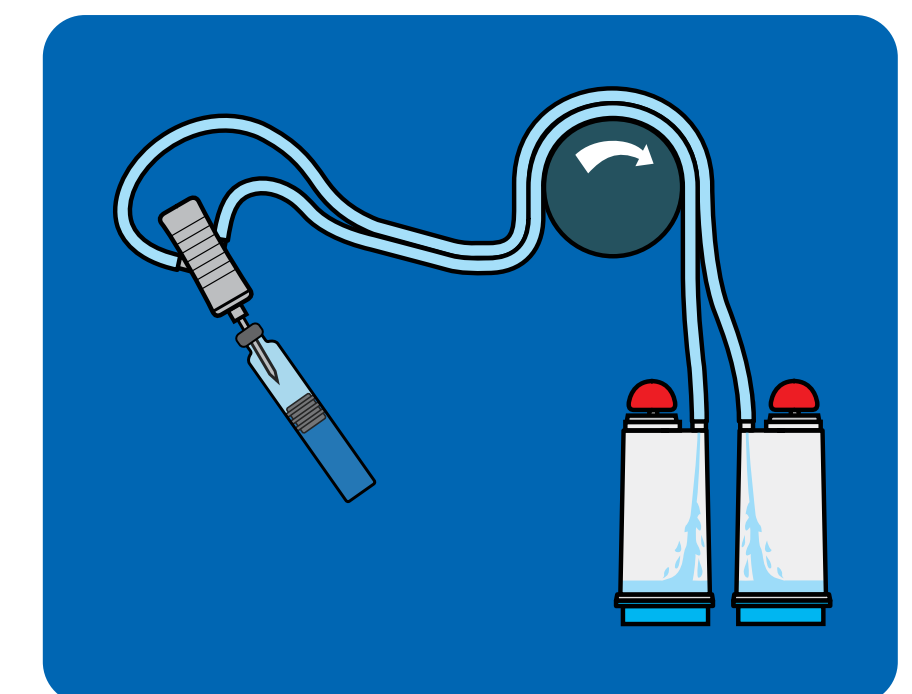
Steritest® NEO Devices for Liquids in Cartridges and Small Soft Plastic Containers (TZHACA210)



- 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 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 "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices



Application	Product #	More Information	Add to Cart
Steritest® NEO Devices for Liquids in Ampoules	TZHVAB210		
Steritest® NEO Devices for Liquids in Ampoules DP	TZHVAB205		
Steritest® NEO Devices for Liquids in Collapsible Bags	TZHVAB210		
Steritest® NEO Devices for Liquids in Collapsible Bags DP	TZHVAB205		
Steritest® NEO Devices for Liquids in Large Vials	TZHVLV210		
Steritest® NEO Devices for Liquids in Large Vials DP	TZHVLV205		
Steritest® NEO Devices for Liquids in Small Vials	TZHVSV210		
Steritest® NEO Devices for Liquids in Small Vials DP	TZHVSV205		
Steritest® NEO Devices for Soluble Powders in Vials	TZHVDV210		
Steritest® NEO Devices for Soluble Powders in Vials DP	TZHVDV205		
Steritest® NEO Devices for Medical Devices and Collapsible Bags	TZHVMD210		
Steritest® NEO Devices for Powders and Superpotent Antibiotics	TZHVAB210		
NEW Steritest® NEO Devices for Liquids in Cartridges	TZHVCA210		

DP = Double Packed

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Application

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- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Medical
- Steritest® NEO Devices for Powde

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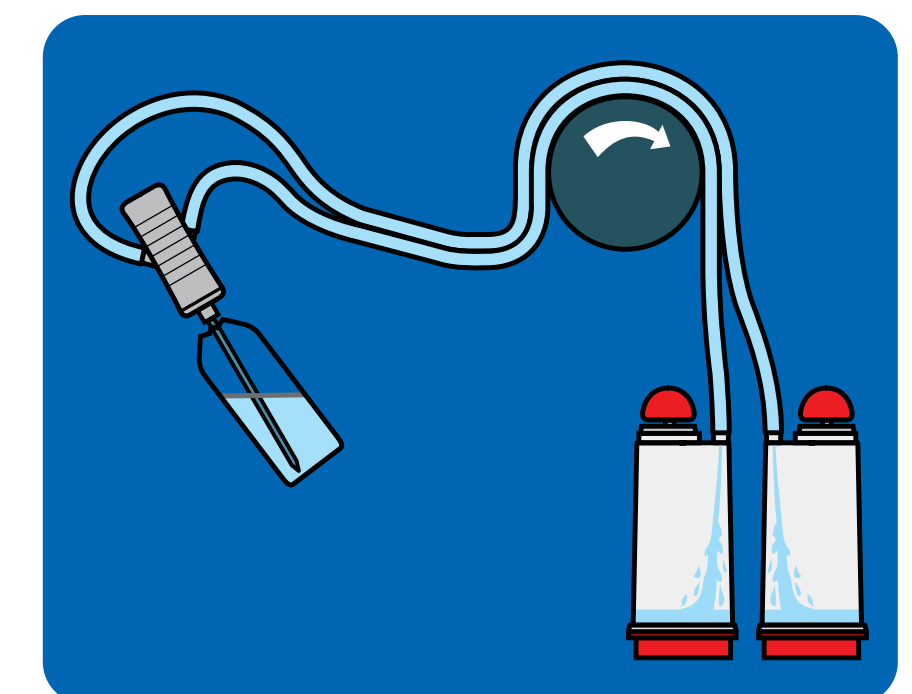
Add to Cart

Steritest® NEO Devices for Liquids in Ampoules (TZHVAB210)

- 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 Soluble
- Steritest® NEO Devices for Medical
- Steritest® NEO Devices for Powde

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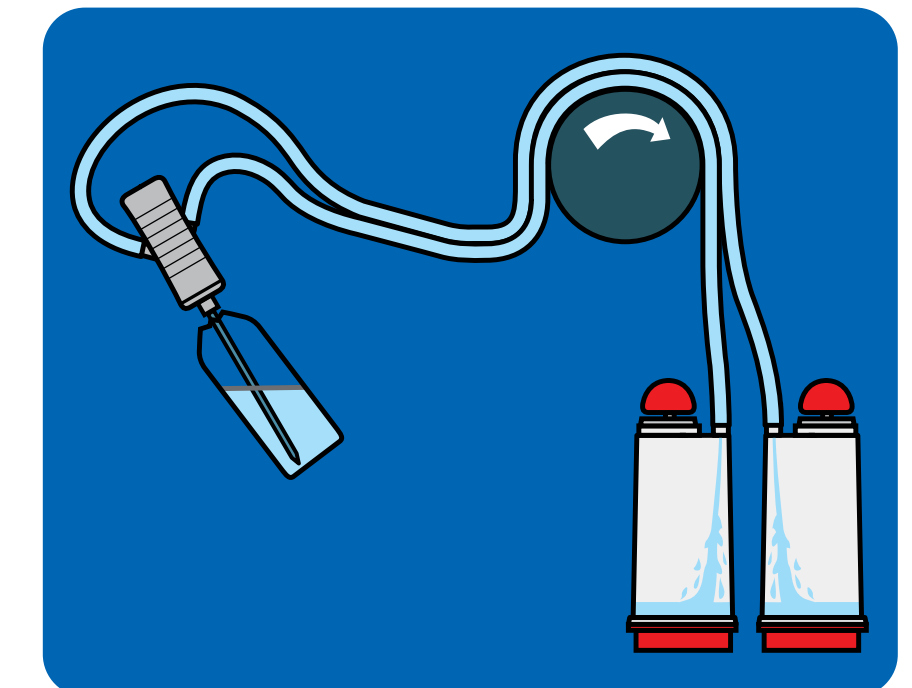
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Steritest® NEO Devices for Liquids in Ampoules - Double-Packed (TZHVAB205)

- Single needle for easy access to ampoules
- 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:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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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Application	Product #	More Information	Add to Cart
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- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
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- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Medical
- Steritest® NEO Devices for Powde

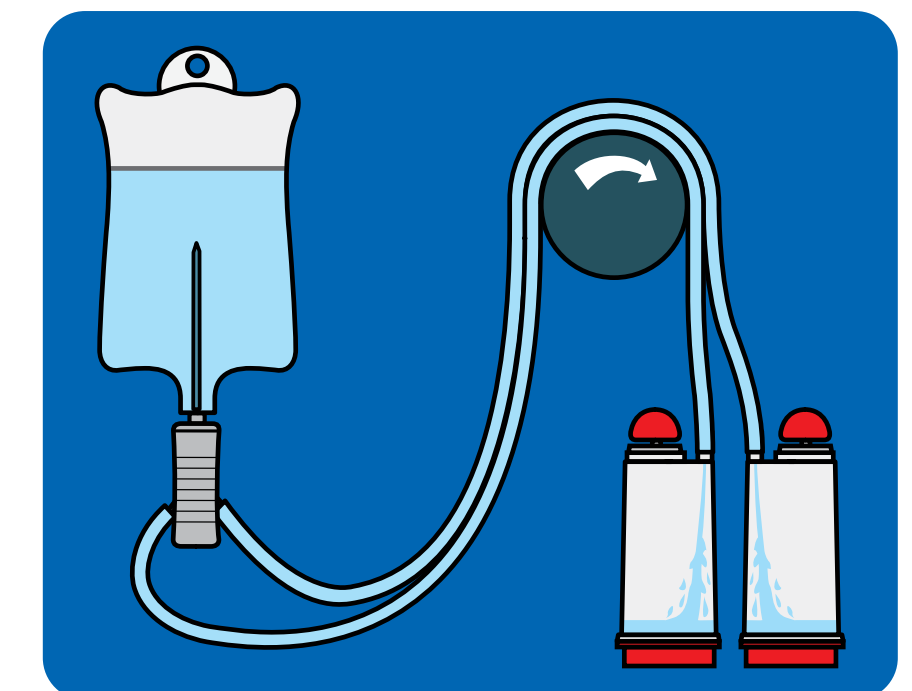
NEW Steritest® NEO Devices for L

Steritest® NEO Devices for Liquids in Collapsible Bags (TZHVB210)

- Single needle for easy access to collapsible bags
- 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 Soluble
- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Medical
- Steritest® NEO Devices for Powde

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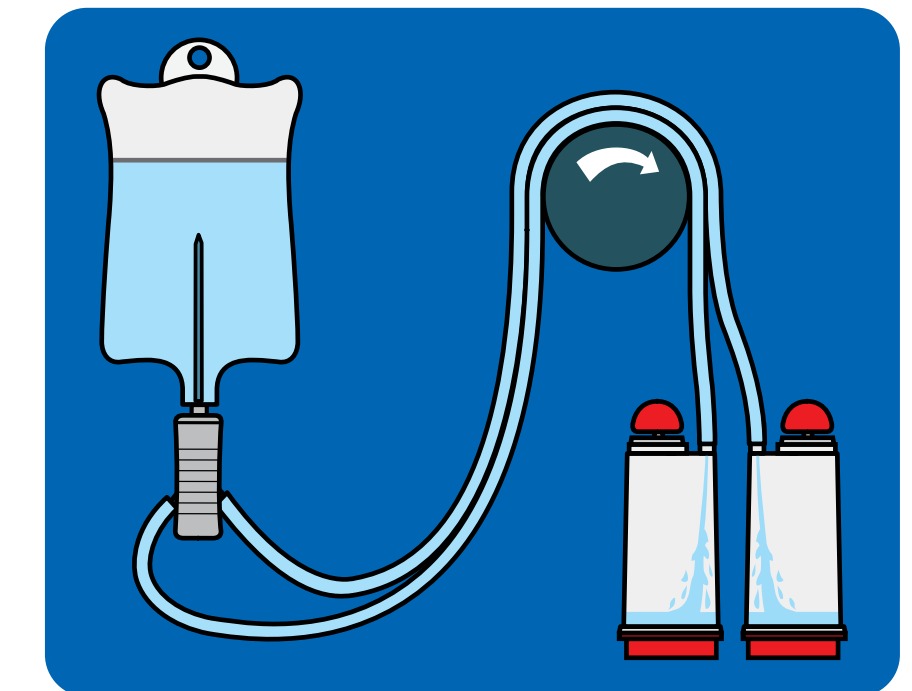
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Steritest® NEO Devices for Liquids in Collapsible Bags - Double-Packed (TZHVAB205)

- 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:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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

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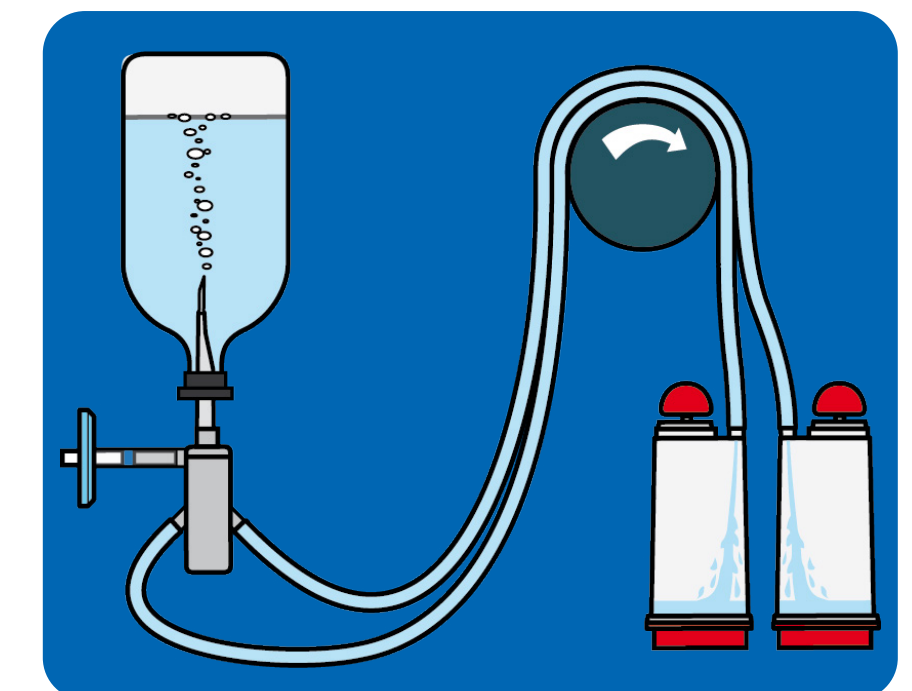
Steritest® NEO Devices for Liquids in Large Vials (TZHVLV210)



- Vented double needle for large glass containers with septa

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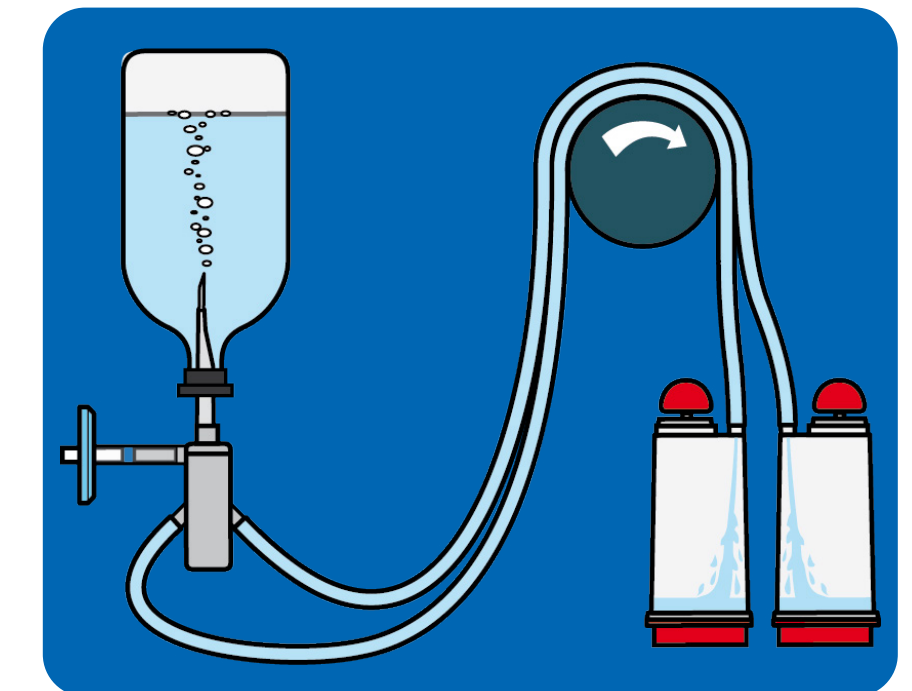
Steritest® NEO Devices for Liquids in Large Vials - Double-Packed (TZHVLV205)



- Vented double needle for large glass containers with septa
- 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:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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 Soluble
- Steritest® NEO Devices for Soluble
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- Steritest® NEO Devices for Powde

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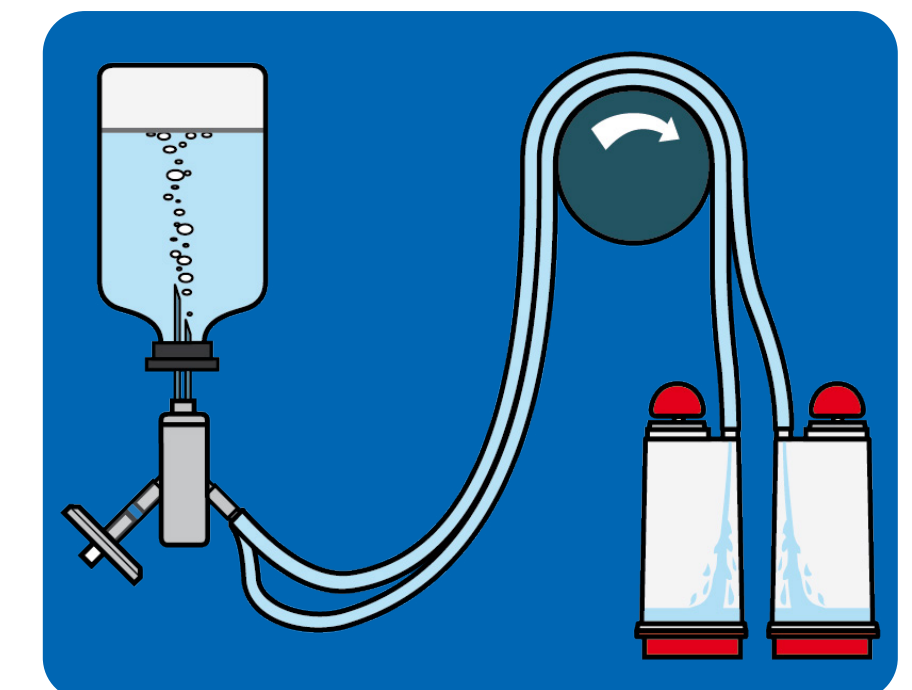
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Steritest® NEO Devices for Liquids in Small Vials (TZHVS210)

- Vented double needle for small vials with septa

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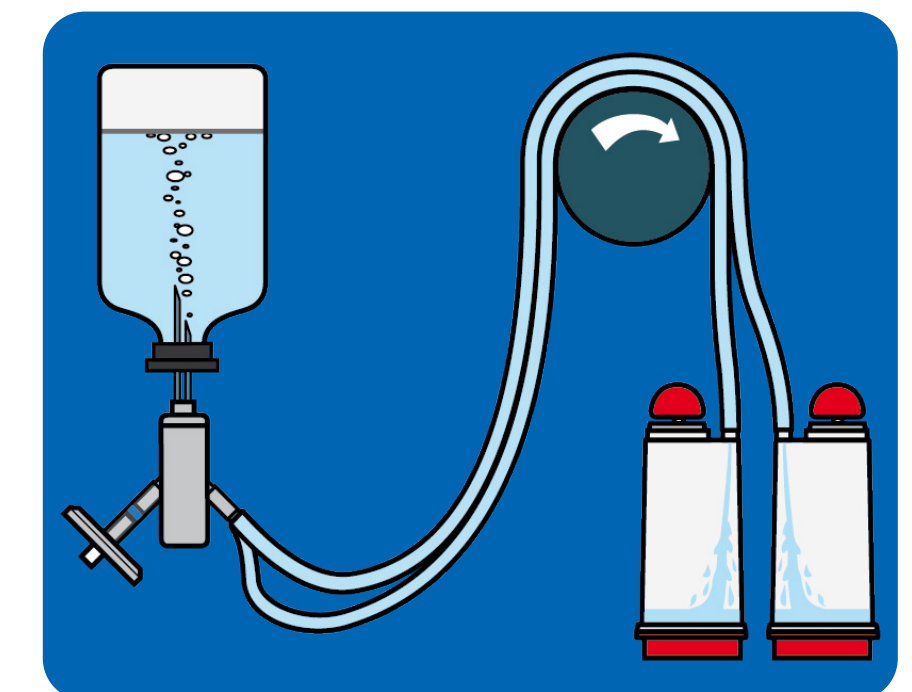
Steritest® NEO Devices for Liquids in Small Vials - Double-Packed (TZHVSV205)



- Vented double needle for small vials with septa
- 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:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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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Application

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- Steritest® NEO Devices for Soluble
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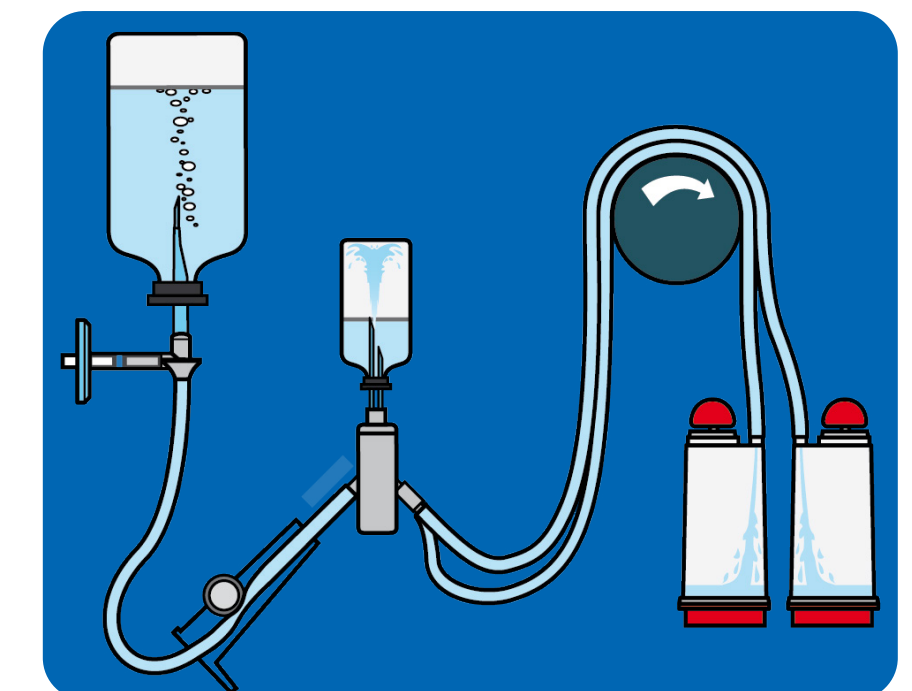
Steritest® NEO Devices for Soluble Powders in Vials (TZHV DV210)



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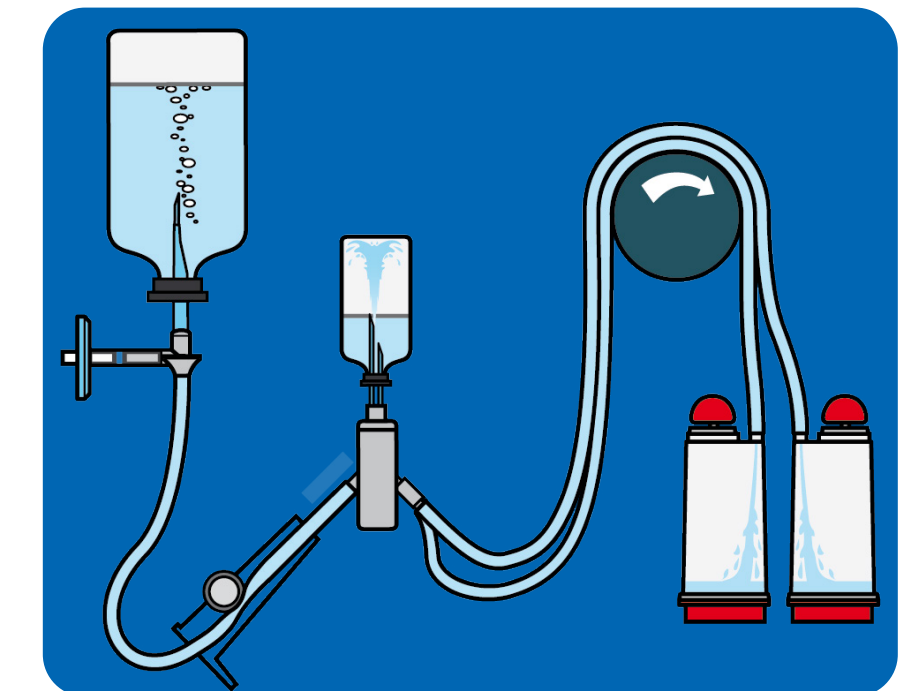
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Steritest® NEO Devices for Soluble Powders in Vials - Double-Packed (TZHVDV205)

- 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:	Multilayer 170 µm film (Polyamide + Polyethylene derivate)
Primary blister:	Shell made of PET, Cover made of Tyvek® paper
Filtration Chamber (Canister):	Styrene acrylonitrile (SAN)
Double Lumen Tubing:	PVC, 850 mm length
Needle:	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

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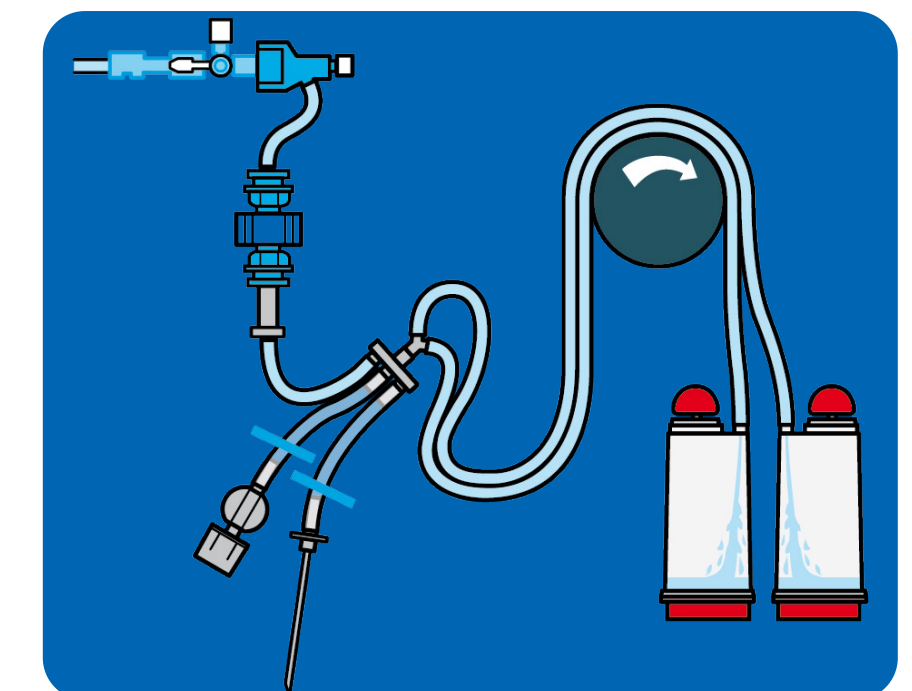
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Steritest® NEO Devices for Medical Devices and Collapsible Bags (TZHVM210)

- Three adapters provided; male Luer, female Luer or single needle allow connection to a variety of test devices
- 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 "Red Base" Devices

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Steritest® NEO Devices for Liquids			
Steritest® NEO Devices for Liquids			
Steritest® NEO Devices for Soluble			
Steritest® NEO Devices for Soluble			
Steritest® NEO Devices for Medical			
Steritest® NEO Devices for Powde			
NEW Steritest® NEO Devices for L			

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

- Tubing and needle assembly for antibiotics and products containing antimicrobial activity that require dilution or dissolution
- Aseptically connects the diluent or dissolution fluid to the product container for dilution
- Used for pooling superpotent antibiotics to reduce product membrane contact time when product is then filtered
- Contains vent with expansion chamber for optimized venting
- Diluted product subsequently filtered with Steritest® NEO device (TZHVAB210)

Steritest® NEO Devices	Steridilutor® NEO devices for Sample Preparation and Dilution	Recommended Accessories: Sterile vent needles
TZHVAB210	TZVC00010	TEFG02525

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Steritest® NEO

Benefits

New Features

Video - New Features

Video - New Devices

Specifications

Regulations

Double Packed

Ordering Information

Complete Sterility Testing Offer

Ordering Information

Steritest® NEO "Red Base" Devices

for antibiotics, products WITH antimicrobial agents and medical devices



Application

- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Liquids
- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Soluble
- Steritest® NEO Devices for Medical
- Steritest® NEO Devices for Powde

NEW Steritest® NEO Devices for L

Product

More Information

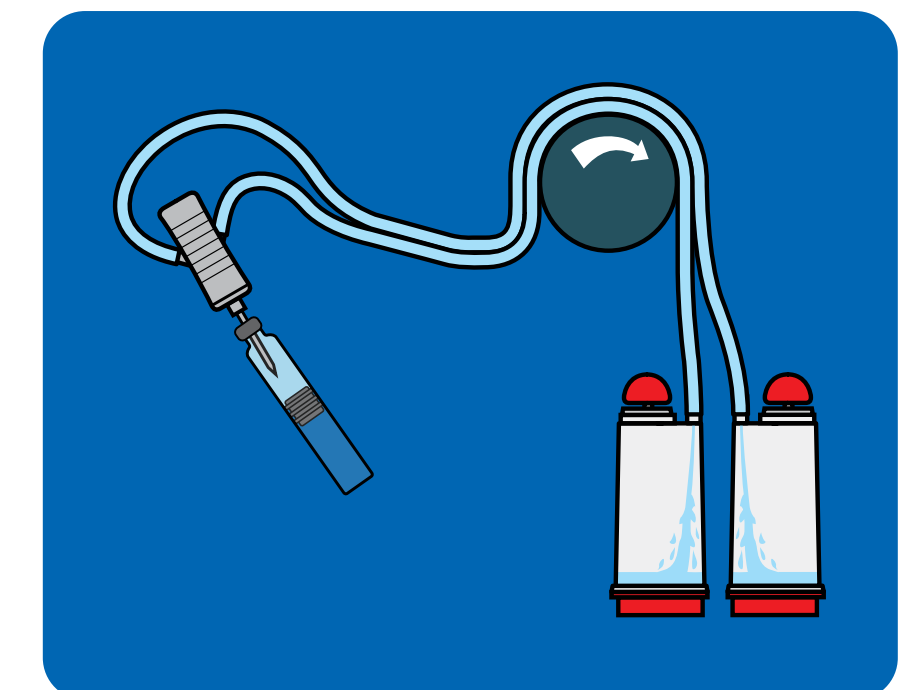
Add to Cart

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

- Single short (20 mm) needle for easy access to cartridges and small soft plastic containers
- 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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Video - New Devices

Specifications

Regulations

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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		

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Video - New Features

Video - New Devices

Specifications

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 Solvent and Veterinary Injectables

Sterile Irradiated Isopropyl Myristate

Product

More Information

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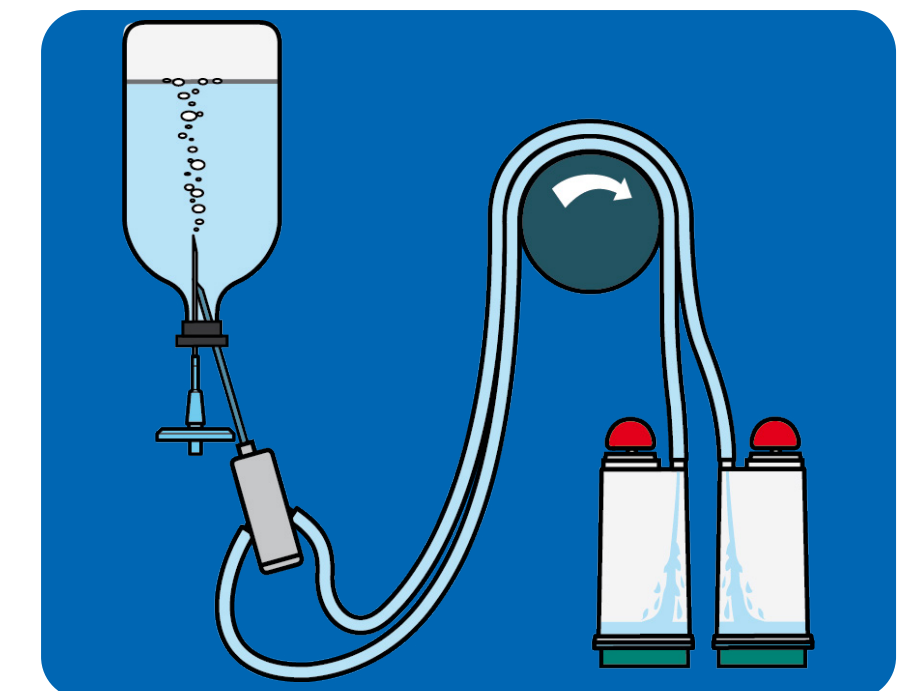
Steritest® NEO Devices for Solvents, Creams, Ointments, and Veterinary Injectables (TZHVSL210)



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

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 polyamide 6-6 (nylon) 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 "Green Base" Devices + Sterile IPM
for products dissolved in solvents requiring increased chemical compatibility



Application

Product #

More Information

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Steritest® NEO Devices for Solvent and Veterinary Injectables

Sterile Irradiated Isopropyl Myristate

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 [TZHVSL210](#)



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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		
Steridilutor® NEO Devices for Liquid Transfer	TZA000010		
Steritest® Vent Needles	TEFG02525		

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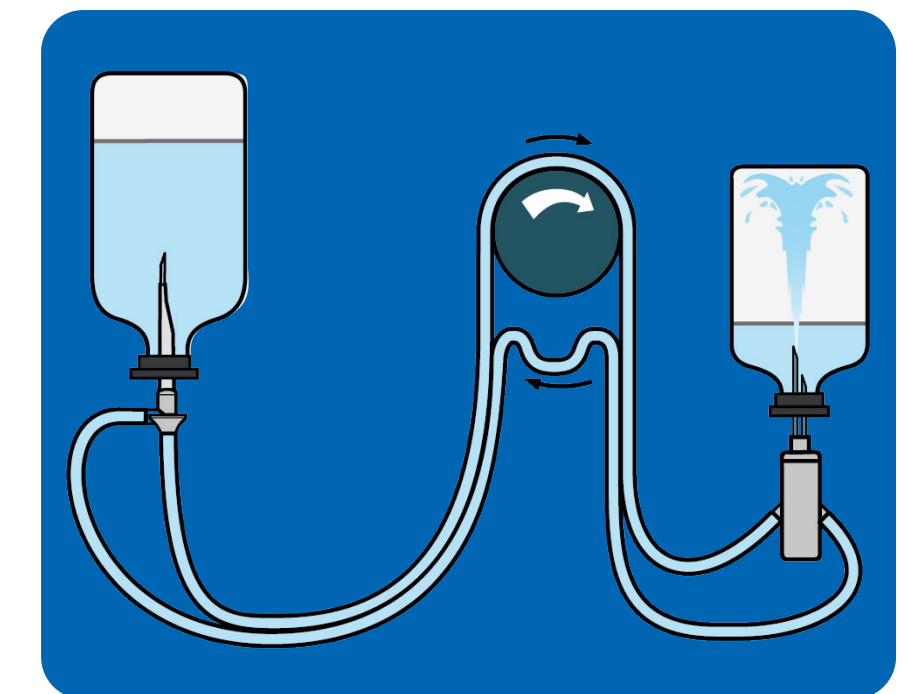
Ordering Information

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			
Steridilutor® NEO Devices with Expansion Chamber for Sample Preparation and Dilution			
Steridilutor® NEO Devices for Liquid Transfer			
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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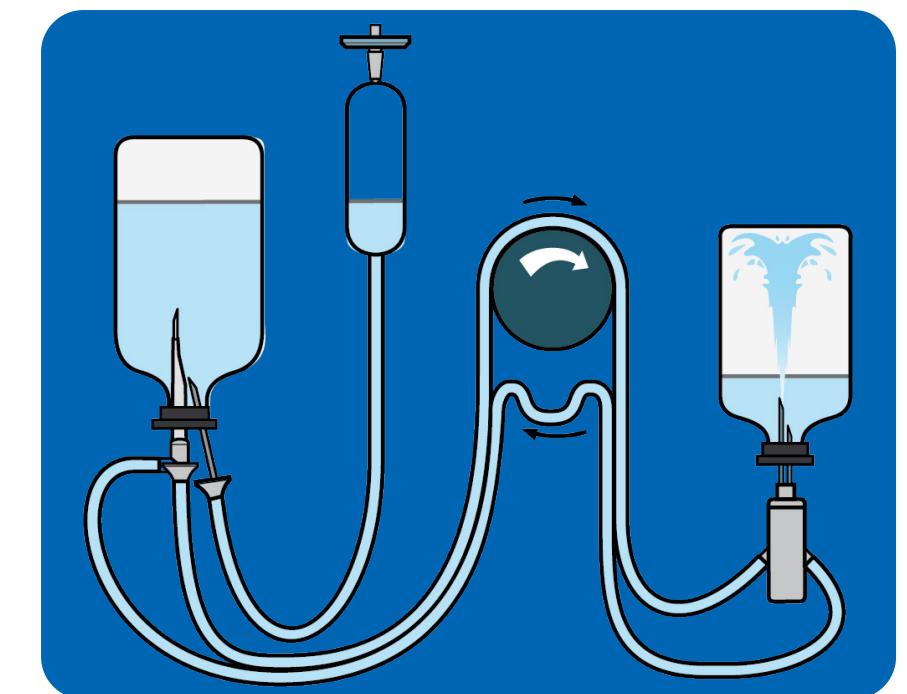
Ordering Information

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			
Steridilutor® NEO Devices with Expansion Chamber for Sample Preparation and Dilution			
Steridilutor® NEO Devices for Liquid Transfer			
Steritest® Vent Needles			

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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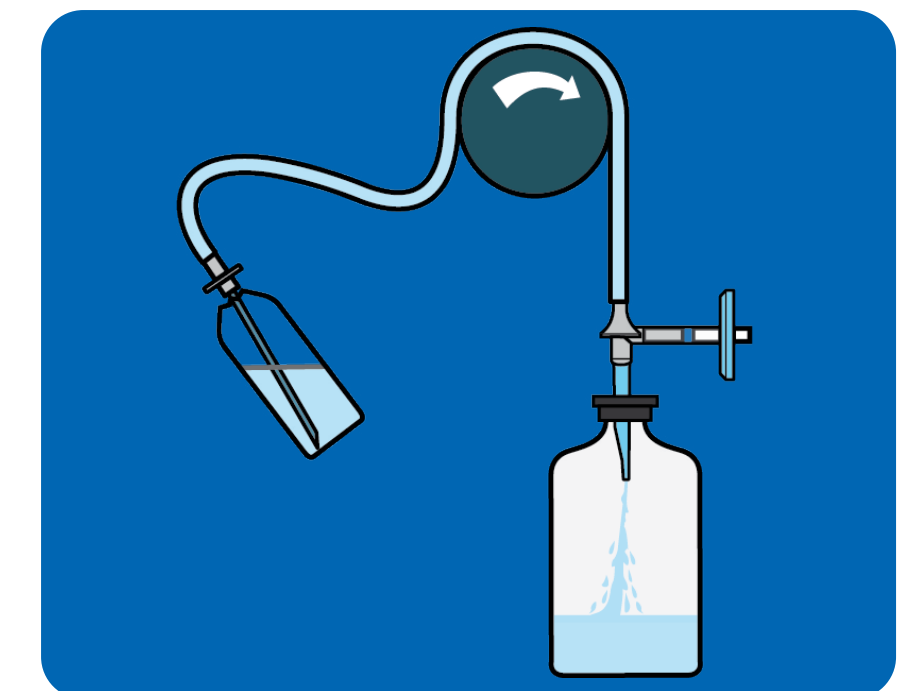
Sterility Testing Accessories for Liquid Transfer and Dilution

Application	Product #	More Information	Add to Cart
Steridilutor® NEO Devices without Exposed Needle for Sample Preparation and Dilution			
Steridilutor® NEO Devices with Exposed Needle for Sample Preparation and Dilution			
Steridilutor® NEO Devices for Liquid Transfer			
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	Product #	More Information	Add to Cart
Steridilutor® NEO Devices without Exposed Needle for Sample Preparation and Dilution			
Steridilutor® NEO Devices with Exposed Needle for Sample Preparation and Dilution			
Steridilutor® NEO Devices for Liquid Transfer			
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
- For sterility and growth promotion qualification of media batches



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Culture Media & Rinsing Fluids

Benefits

Regulations

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Rinsing Fluids

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Closure Caps

Ordering Information

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.



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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.

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Complete Sterility Testing Offer

Regulations and Industry benchmark



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

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Regulations and Industry benchmark



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

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Regulations and Industry benchmark



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

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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.

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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



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Culture Media & Rinsing Fluids

Benefits

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Culture Media

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Customized Culture Media

Closure Caps

Ordering Information

Complete Sterility Testing Offer

Ordering Information



Sterility Testing Culture Media

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

DP = Double Packed

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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 (Trypcase Soy Broth, TSB)	Screw cap with septum	100 mL	12	STBMTSB12		

Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Trypcase Soy Broth, TSB (STBMTSB12)

- 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
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	<i>B. subtilis</i> (ATCC 6633), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (ATCC 9027)

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Sterility Testing Culture Media

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
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Soybean-Casein Digest Medium (Trypcase Soy Broth, TSB)

Screw cap with septum

100 mL

12

STBMTSB12



Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Trypcase Soy Broth, TSB - Double-packed (STBMTSB12DP)



- 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
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	<i>B. subtilis</i> (ATCC 6633), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (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 (Trypcase Soy Broth, TSB)	Screw cap with septum	100 mL	12	STBMTSB12		

Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Trypcase Soy Broth, TSB (1.46317)

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

Closure	Crimp 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	<i>B. subtilis</i> (ATCC 6633), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (ATCC 9027)

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Ordering Information

Sterility Testing Culture Media

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
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Soybean-Casein Digest Medium (Trypcase Soy Broth, TSB)

Screw cap with septum

100 mL

12

STBMTSB12



Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Fluid Thioglycollate Medium, FTM (STBMFTM12)



- 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.

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	<i>C. sporogenes</i> (ATCC 11437), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (ATCC 9027)

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Sterility Testing Culture Media

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
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Soybean-Casein Digest Medium (Trypcase Soy Broth, TSB)

Screw cap with septum

100 mL

12

STBMTSB12



Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Fluid Thioglycollate Medium, FTM - Double-packed (STBMFTM12DP)



- 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.

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	<i>C. sporogenes</i> (ATCC 11437), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (ATCC 9027)

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Sterility Testing Culture Media

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
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Soybean-Casein Digest Medium (Trypcase Soy Broth, TSB)

Screw cap with septum

100 mL

12

STBMTSB12



Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Fluid Thioglycollate Medium, FTM (1.46406)



- 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.

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>
QC organisms	<i>C. sporogenes</i> (ATCC 11437), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (ATCC 9027)



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Sterility Testing Culture Media

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
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Soybean-Casein Digest Medium (Trypcase Soy Broth, TSB)

Screw cap with septum

100 mL

12

STBMTSB12



Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Clear Thioglycollate Medium, CTM (STBMCTM12)



- 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.

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	<i>C. sporogenes</i> (ATCC 11437), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (ATCC 9027)

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Sterility Testing Culture Media

Culture Media bottle	Closure	Volume (mL)	Qty/pk	Product #	More Information	Add to Cart
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Soybean-Casein Digest Medium (Trypcase Soy Broth, TSB)

Screw cap with septum

100 mL

12

STBMTSB12



Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Clear Thioglycollate Medium, CTM - Double-packed (STBMCTM12DP)



- 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.

Closure	Screw cap with septum – double packed
Volume (mL)	100 mL
Packaging	12 per pack
Sterilization	Autoclaving + ethylene oxide
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	<i>C. sporogenes</i> (ATCC 11437), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (ATCC 9027)

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DP = Double Packed

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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 (Trypcase Soy Broth, TSB)	Screw cap with septum	100 mL	12	STBMTSB12		

Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

Clear Thioglycollate Medium, CTM (1.46456)

- 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.

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>
QC organisms	<i>C. sporogenes</i> (ATCC 11437), <i>S. aureus</i> (ATCC 6538), <i>P. aeruginosa</i> (ATCC 9027)

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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.

Material Table

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

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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	Screw cap with septum	900 mL	4	STBMRFA94		
		600 mL	4	STBMRFA64		
		300 mL	4	STBMRFA34		
		100 mL	12	STBMRFA12		
	Screw cap with septum - double packed	DP 100 mL	12	STBMRFA12DP		
	Crimp cap with septum	300 mL	6	1.46415		
		100 mL	10	1.46470		
USP Rinse Fluid D	Screw cap with septum	300 mL	4	STBMRFD34		
	Crimp cap with septum	300 mL	6	1.46483		
USP Rinse Fluid K	Screw cap with septum	300 mL	4	STBMRFK34		

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		

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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 (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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)



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USP Rinse Fluid D

USP Rinse Fluid K

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Sterile Isopropyl Myristate (IPM)

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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 (STBMRFA64)

- 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)	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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)



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

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid solution bottle

Sterile Isopropyl Myristate (IPM)

DP = Double Packed

Rinsing Fluid USP Rinse Fluid A (STBMRFA34)

- 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)	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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)

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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 (STBMRFA12)

- 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)	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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid solution bottle

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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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)



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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 (1.46415)

- 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	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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)



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

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid solution bottle

Sterile Isopropyl Myristate (IPM)

DP = Double Packed

Rinsing Fluid USP Rinse Fluid A (1.46470)

- 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	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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)

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

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid solution bottle

Sterile Isopropyl Myristate (IPM)

DP = Double Packed

Rinsing Fluid USP Rinse Fluid D (1.46483)

- Suitable for testing samples that contain lecithin or oil, and compatible with most antibiotics. Excellent for rinsing sterile pathways of devices, and typically used for rinse method testing of medical devices.

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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)

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

USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid solution bottle

Sterile Isopropyl Myristate (IPM)

DP = Double Packed

Rinsing Fluid USP Rinse Fluid D (STBMRFD34)

- 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)	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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)

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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 K (STBMRFK34)

- Suitable for testing samples that contain petrolatum, oils, or oily solutions. Excellent for rinsing pathways of medical devices, and for samples that are "difficult" to filter or dissolve.

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	<i>S. aureus</i> (ATCC 6538), <i>B. subtilis</i> (ATCC 6633), <i>P. aeruginosa</i> (ATCC 9027), <i>C. albicans</i> (ATCC 10231), <i>A. niger</i> (ATCC 16404), <i>C. sporogenes</i> (ATCC 11437)

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		

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

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USP Rinse Fluid D

USP Rinse Fluid K

Solvent

Rinse fluid solution bottle

Sterile Isopropyl Myristate (IPM)

DP = Double Packed



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Double-Packed Sterility Testing Media & Rinse Fluids Gamma Sterilized

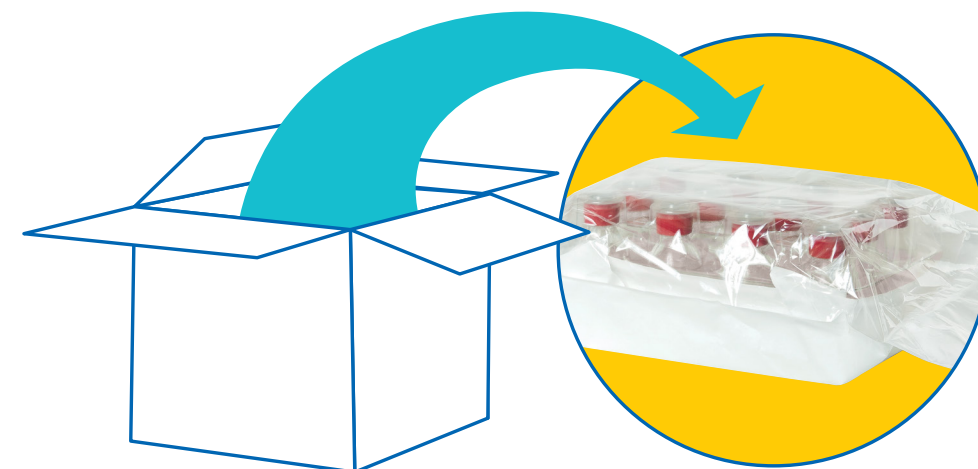
Sterility testing culture media and rinsing fluids are also available in a double-packed format. The sterilized double Tyvek® packaging helps to minimize the risk of cross-contamination in laminar flow hoods and to secure an efficient decontamination of isolator chambers. These products are supplied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

Transfer of Steritest® Media and Rinse Fluid Double-packed Bottles into a Laminar Flow Hood

Unclassified Room

Bag decontamination

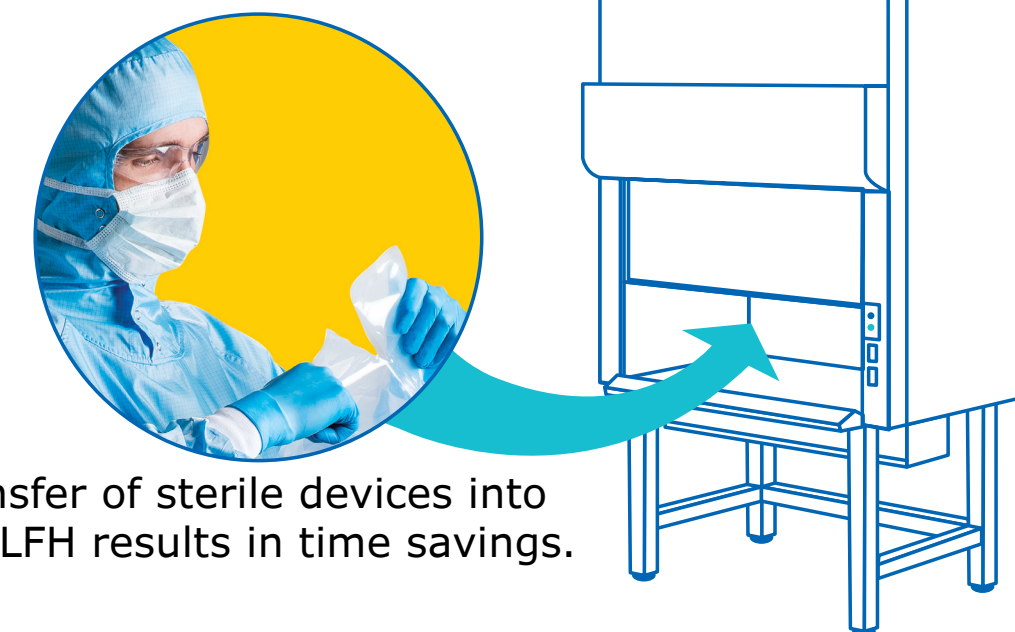


Bag with perfect cut sealing for an optimal decontamination.

Bag Transfer

Classified Room

Bag opening and transfer of devices



Transfer of sterile devices into the LFH results in time savings.

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Culture Media & Rinsing Fluids

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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 tailor-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.



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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.



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Culture Media and Diluting/Rinsing Fluids

Culture Media



Material Table

Solvent



Material Table

Rinsing Fluids



Material Table

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Pumps & Accessories

Benefits

Perfect Fit for Your Testing Environment

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Smart Accessories

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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.



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Pumps & Accessories

Benefits

Perfect Fit for Your Testing Environment

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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

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Pumps & Accessories

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Perfect Fit for Your Testing Environment

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Benefits



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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Pumps & Accessories

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Perfect Fit for Your Testing Environment

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Benefits



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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Pumps & Accessories

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Perfect Fit for Your Testing Environment

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Complete Sterility Testing Offer

Benefits



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

[Request information](#)



**Pumps &
Accessories**

Benefits

**Perfect Fit for Your
Testing Environment**

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**Complete Sterility
Testing Offer**

Benefits



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.

[Ordering information](#)

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 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).

[Ordering information](#)

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.

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Pumps & Accessories

Benefits

Perfect Fit for Your Testing Environment

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Pump Specifications

Onscreen Guidance

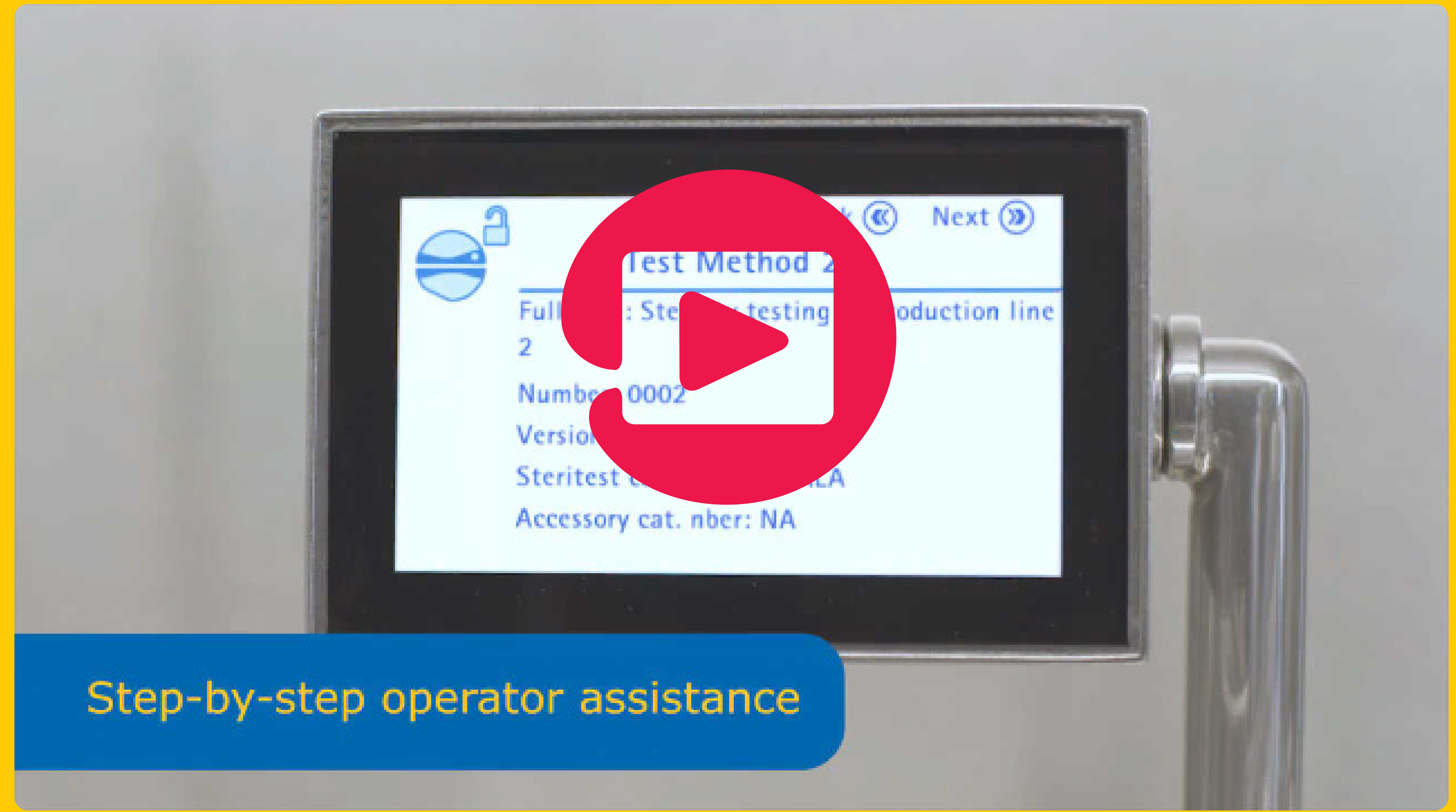
Software

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Step-by-step operator assistance

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Specifications - Steritest® Symbio Pumps

Isolator

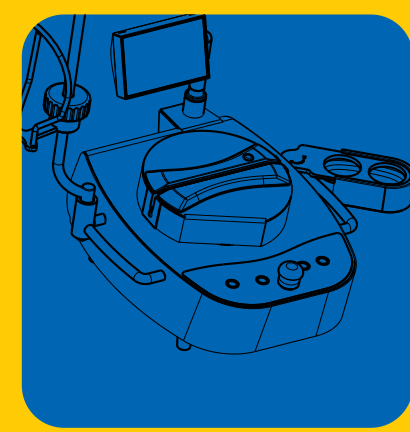
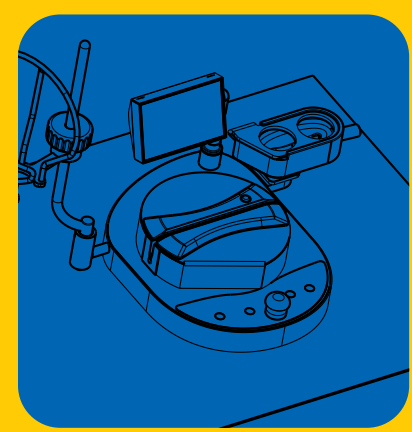
Laminar flow hood

Multiple ways (isolator or a laminar flow hood)

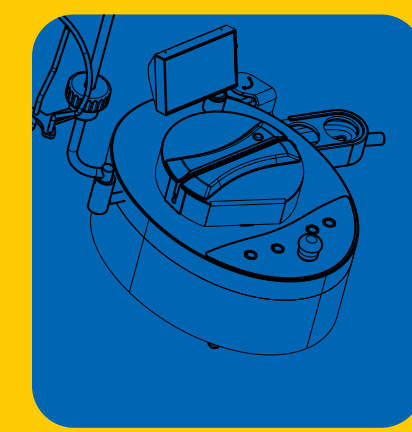
Steritest® Symbio ISL

Steritest® Symbio LFH

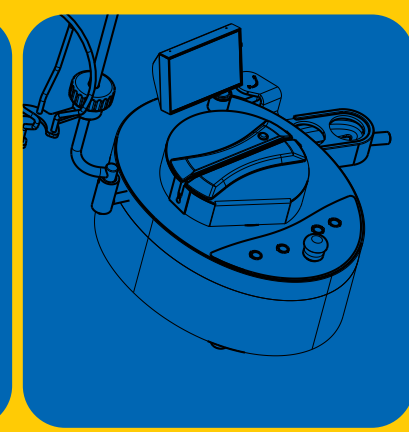
Steritest® Symbio FLEX



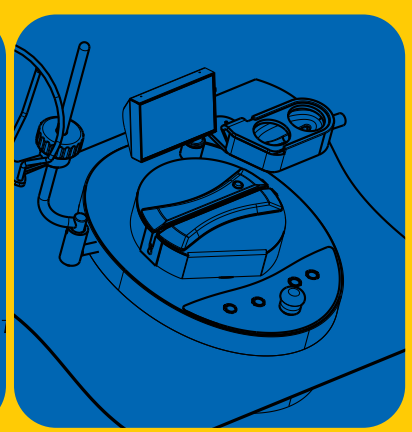
On feet in a laminar flow hood



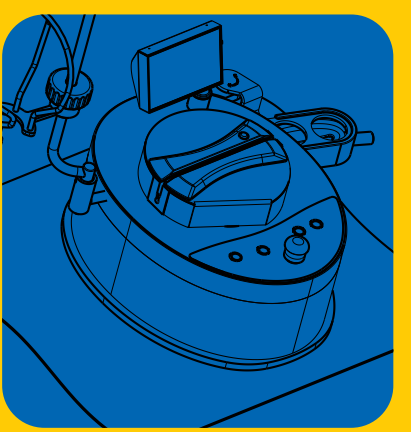
On feet in an isolator



Low integration in an isolator



High integration 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 & Pump head	316L Stainless steel					
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](#)

[Request information](#)



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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 accessory or pressure regulation mode.



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

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

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

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



[Download the software](#)

[Request Information](#)

[Request information](#)



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Perfect Fit for Your Testing Environment

Video

Pump Specifications

Onscreen Guidance

Software

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Smart accessories for streamlining your workflow and increasing safety

Procedure Step



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

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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

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Procedure Step



Steritest® Glass Ampoule Breaker



- Keep your bench clear of glass particles or droplets
- 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

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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

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Smart accessories for streamlining your workflow and increasing safety

Procedure Step



Steritest® Holder for Sterile Bags

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

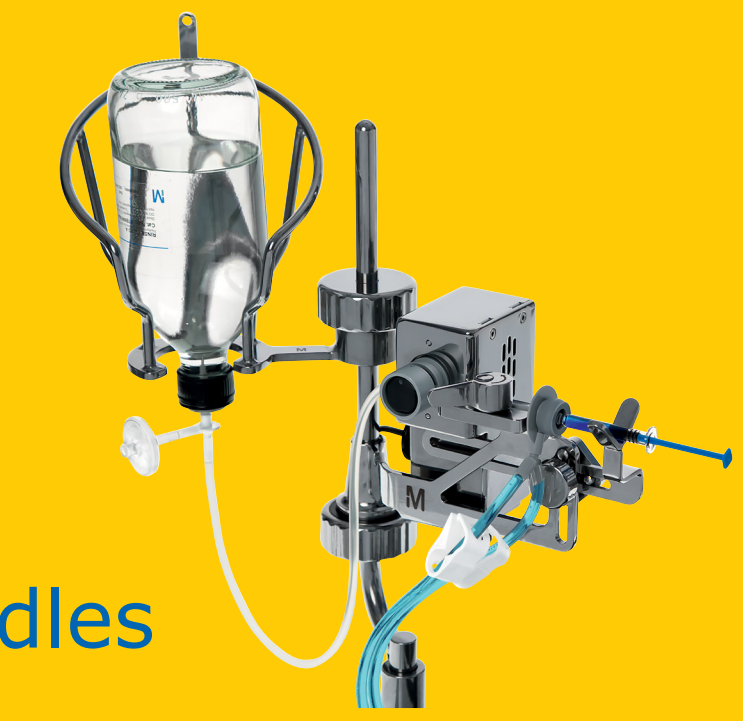


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Steritest® Syringe Support

- 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



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Procedure Step



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



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Procedure Step



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



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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		
Steritest® Communication Hub Holder for Hoods	SYMBCHH01		
Steritest® Communication Hub Holder for Isolators	SYMBCHI01		
Steritest® Connection Cable Extension with Tri-Clover® Clamp	SYMBXTC01		

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Services

Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

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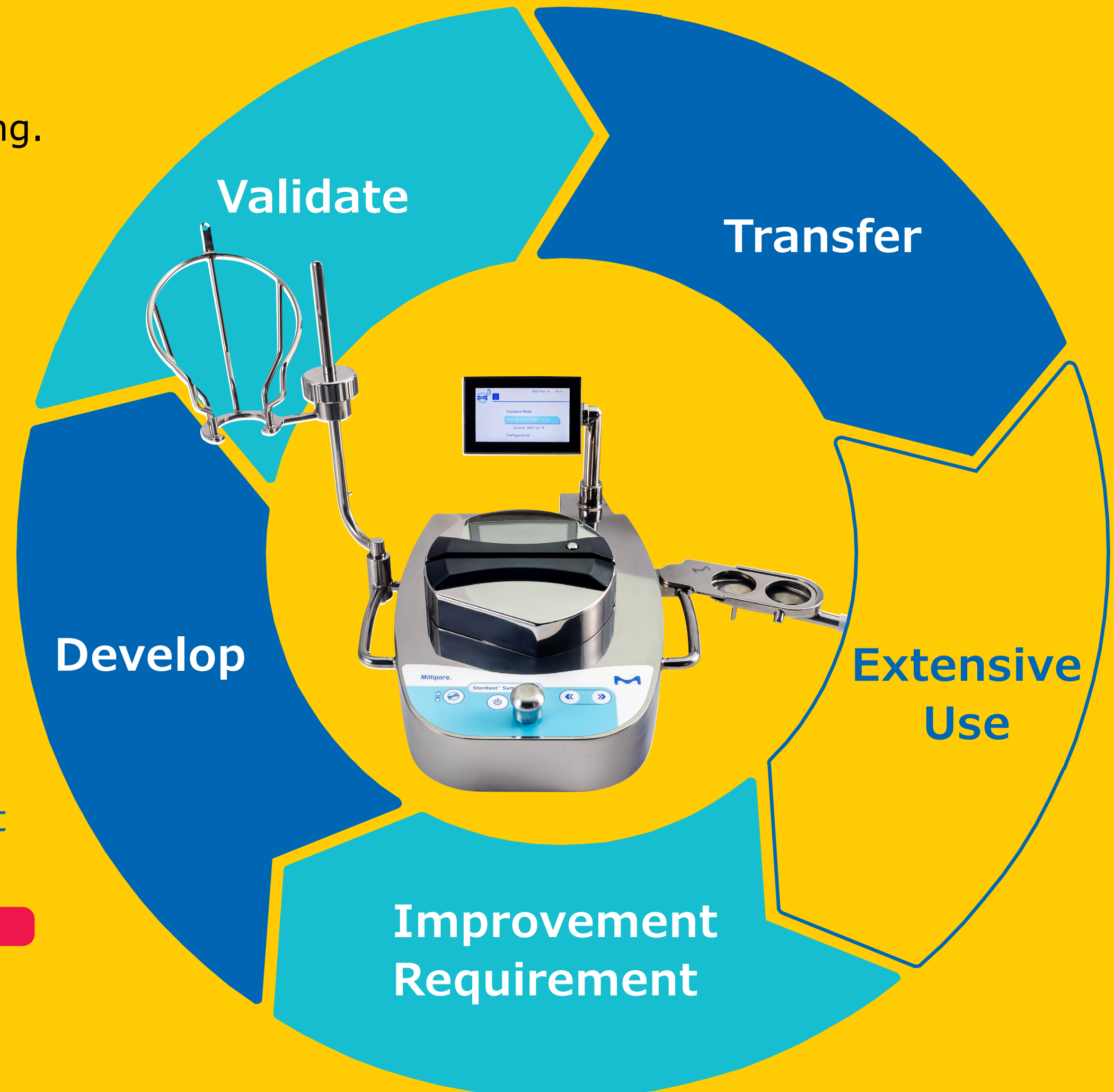
A team of experts

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



Request information



Services

Method
Development

Validation Protocols

Validation Services

Maintenance
& Service Plans

Training

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Consider it done

When a microbial test method (SOP) is set up for a new product, or improved for a product that demonstrates antimicrobial effects and/or filtration issues, our application scientists can develop a method that is compliant with international regulations (pharmacopoeias). Whether you need help with a new sterility test method, or to optimize an existing method, we are ready to lend a hand.

In addition, we can help you grow your expertise in method development through our method development consultation services.



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Validation protocols

Digital validation
protocols

Validation workflow
on Val@M™

Digital protocols on Val@M™ Application

Steritest® Symbio pumps digital validation protocol

Product #: SYMIQOQEP

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.

The digital validation protocol must be purchased together with the on-site IQ & OQ execution service.

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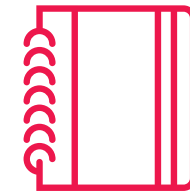
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Validation protocols

Digital validation protocols

Validation workflow on Val@M™



1. Validation Master Plan

- Defined structure, responsibilities for qualification



2. Installation Qualification (IQP)

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



3. Operational Qualification (OQP)

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



4. Performance Qualification (PQ guidelines)

- Test Method suitability verification (microbiology validation procedures)

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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

If having one of our experts on-site is not an option, we now offer remote IQ & OQ or PQ consulting services.

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Services

Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

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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.



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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 labour are covered during the service plan validity period (Total plans only).



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Services

Method Development

Validation Protocols

Validation Services

Maintenance & Service Plans

Training

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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

Request information



Services

Method
Development

Validation Protocols

Validation Services

Maintenance
& Service Plans

Training

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Training offer

Steritest® School - In Person

In depth theoretical training on sterility testing and applicable regulations covering:

- Result interpretation
- Method lifecycle
- Product portfolio
- Product demo
- Certificate of attendance

You can also attend an advanced practice module at the end of the Steritest® School.

Steritest® School - Remote

Our best Application Expert Trainers are now available for you remotely:

- Interactive lectures, hands-on demos and coaching sessions to your company participants.
- Certificate of attendance

Advanced Operator Training (AOT)

In-depth practical training on sterility testing covering:

- In depth hands-on session for each participant: assembling the pump, usage, cleaning, troubleshooting and common mistakes
- Certificate of attendance and examination form

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

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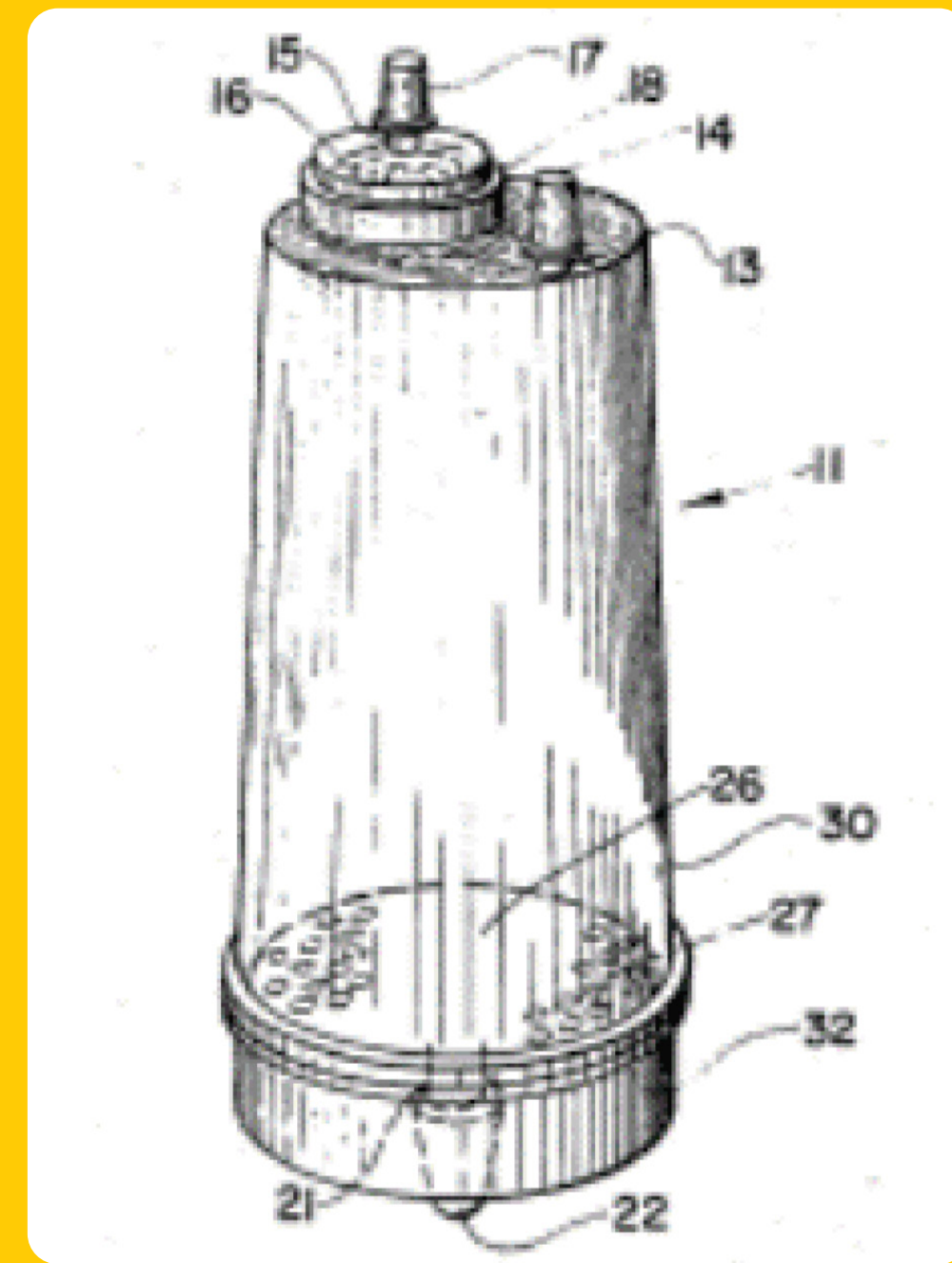


You all know the Steritest® system, but DO YOU KNOW THE STORY OF ITS INVENTION?



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 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.

In 1972, Jack Buch, Millipore founder and 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 >



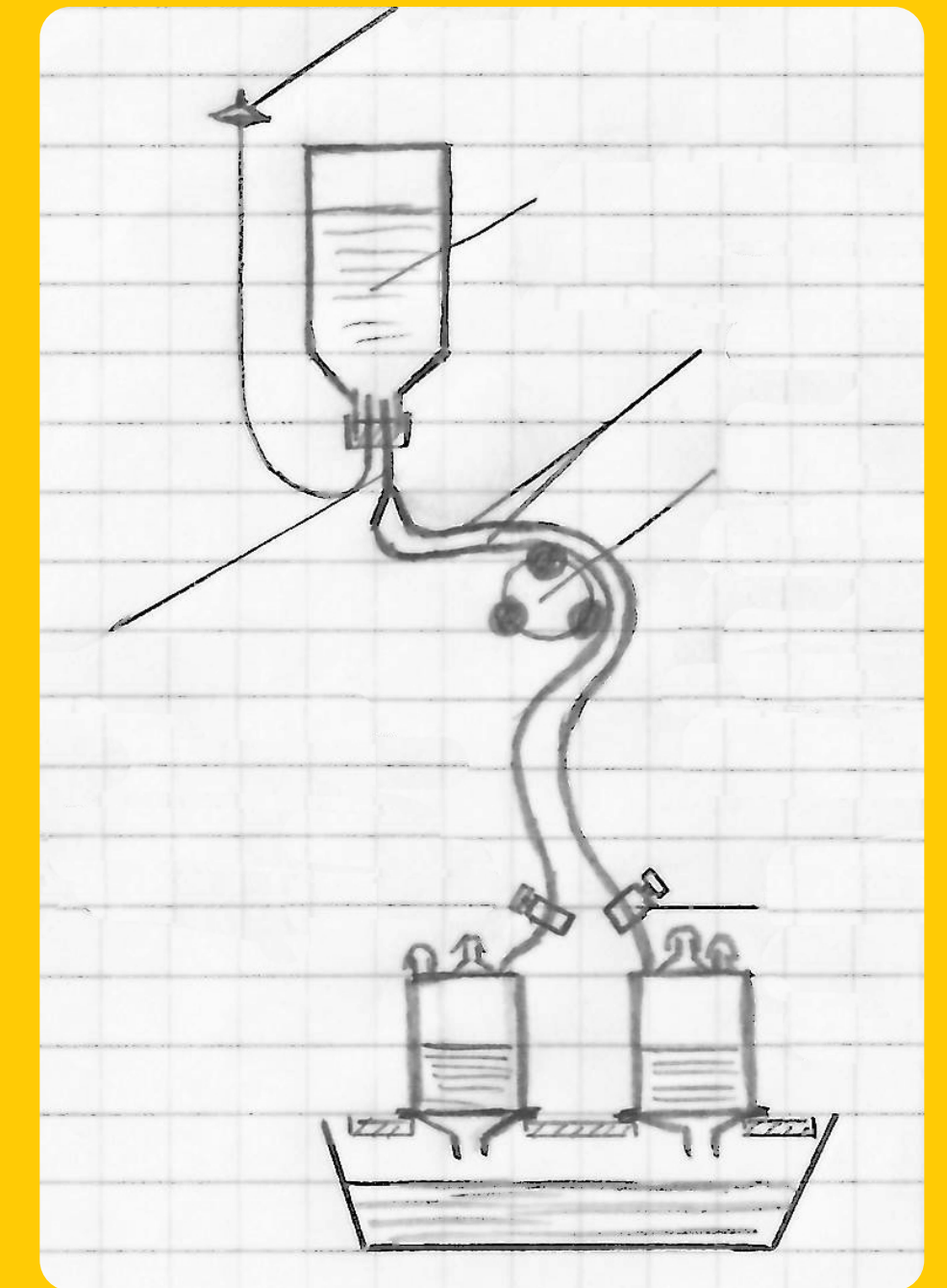
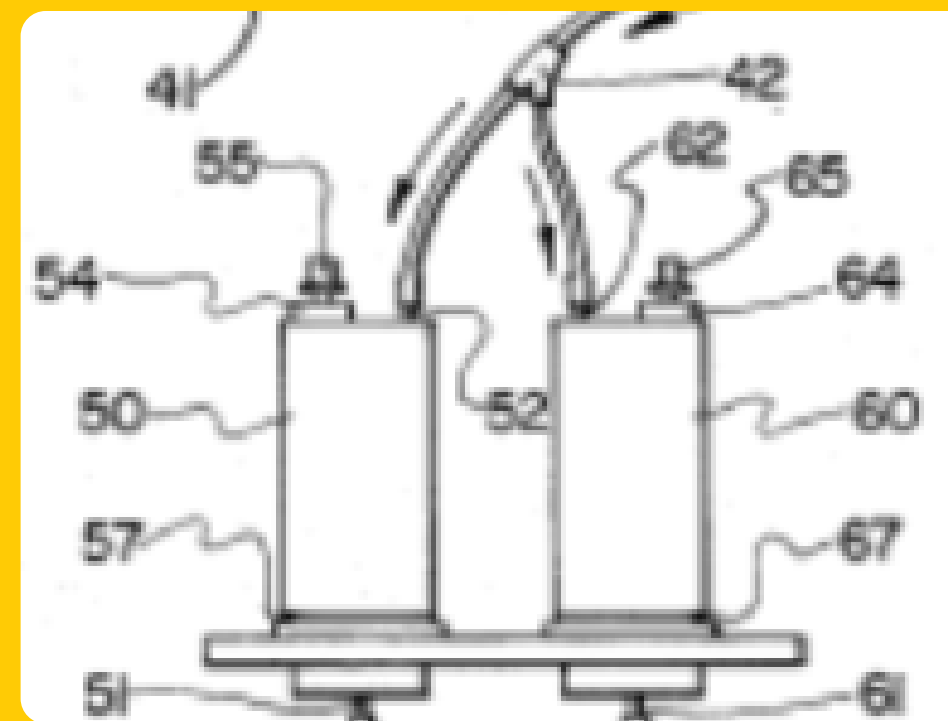
Is the Steritest® system the result of in-depth market research or of a gut feeling?



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.



Next >

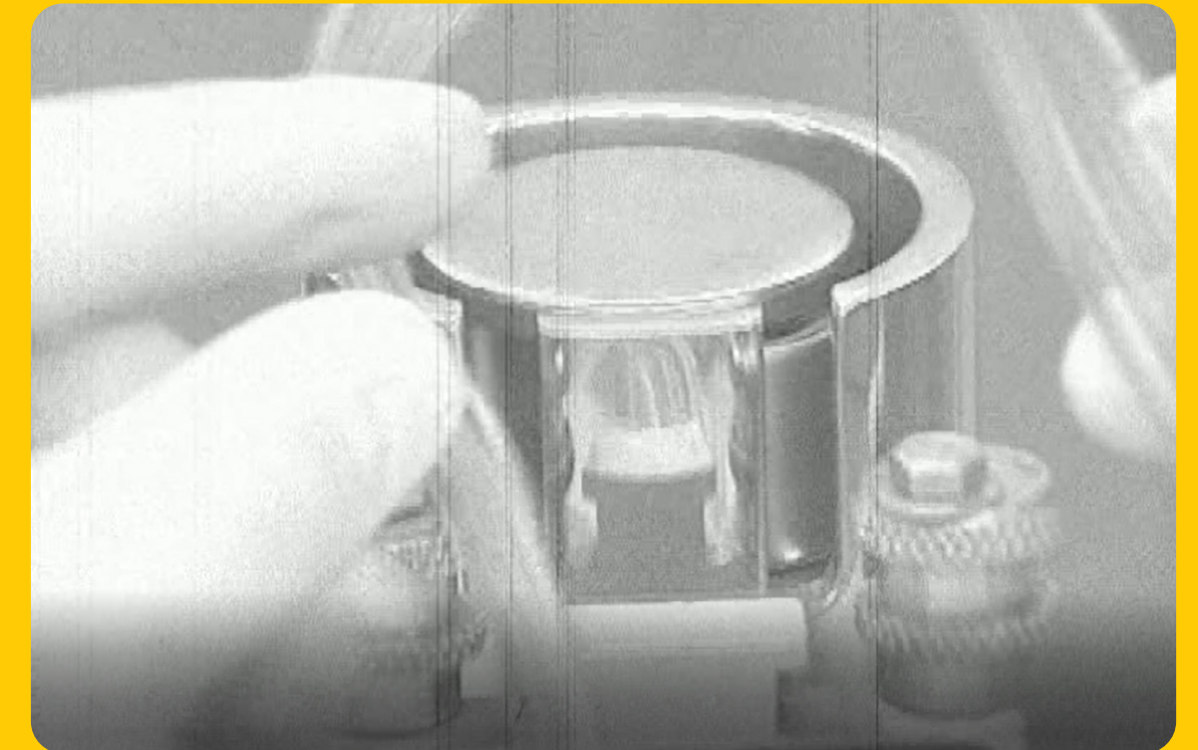


What was the biggest challenge during development, and how did you solve it?



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 Yoann Mainguy, Global Product Manager Sterility Testing



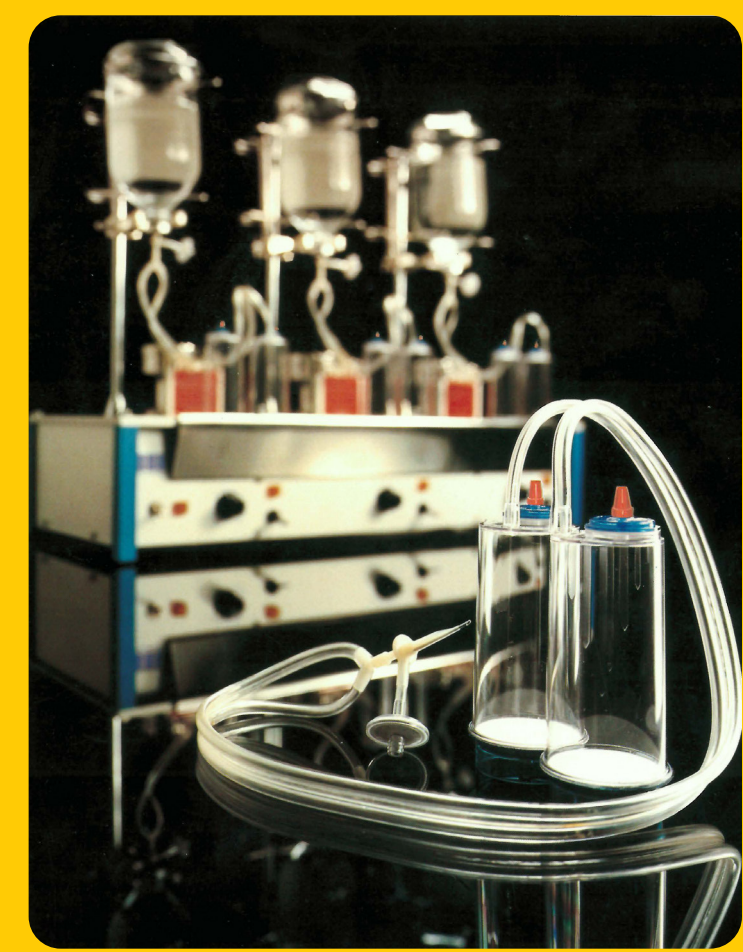
In 2020, the Steritest® system celebrated its 45th anniversary as a commercial product. Curiosity and innovation still motivate our teams.

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.





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Software**

**Your Digital QC
Companion**

How Does it Work?

**Boost Productivity
Ensure Compliance**

Shape your Future

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Testing Offer**

Your Digital QC Companion

M-Trace™ Electronic Test Record Software & Mobile App
Your 21 CFR Part 11 compliant Digital QC companion for Sterility Testing & other regulated processes, for trusted and efficient data recording!

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



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How Does it Work?

This is how a fully traceable, reliable and efficient sterility test performed with the assistance of the M-Trace™ software could look like at your site.



Transfer and digitalize your SOPs in the M-Trace™ software, optionally connect the system with your QC-IT environment such as LIMS and finally connect the M-Trace™ software with your Steritest® Symbio pump to be all set.

Watch the Video

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How Does it Work?

This is how a fully traceable, reliable and efficient sterility test performed with the assistance of the M-Trace™ software could look like at your site.



Scan LIMS label of sample with the M-Trace™ mobile device to register sample information in the M-Trace™ software. Collect and register consumables or equipment needed for testing based on item list provided by the M-Trace™ mobile device to make sure no item is forgotten.

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How Does it Work?

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How Does it Work?

This is how a fully traceable, reliable and efficient sterility test performed with the assistance of the M-Trace™ software could look like at your site.



Scan consumables for your work steps and be alerted if an expired or invalid consumable was selected. Get work instructions either by voice control or on the Steritest® Symbio pump and confirm proper execution real-time. In all this, the pump is controlled semi-automatically.

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**M-Trace™
Software**

**Your Digital QC
Companion**

How Does it Work?

**Boost Productivity
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How Does it Work?

This is how a fully traceable, reliable and efficient sterility test performed with the assistance of the M-Trace™ software could look like at your site.



Your personalized SOPs allow you to scan the test sample anywhere at your facility, so you can continuously document the results with the M-Trace™ mobile app. This app also lets you organize your sample management and reference a sample ID to a specific incubator.

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Software**

**Your Digital QC
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How Does it Work?

**Boost Productivity
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How Does it Work?

This is how a fully traceable, reliable and efficient sterility test performed with the assistance of the M-Trace™ software could look like at your site.



A comprehensive digital test report is automatically generated for convenient and reliable test record review.

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How Does it Work?

Boost Productivity
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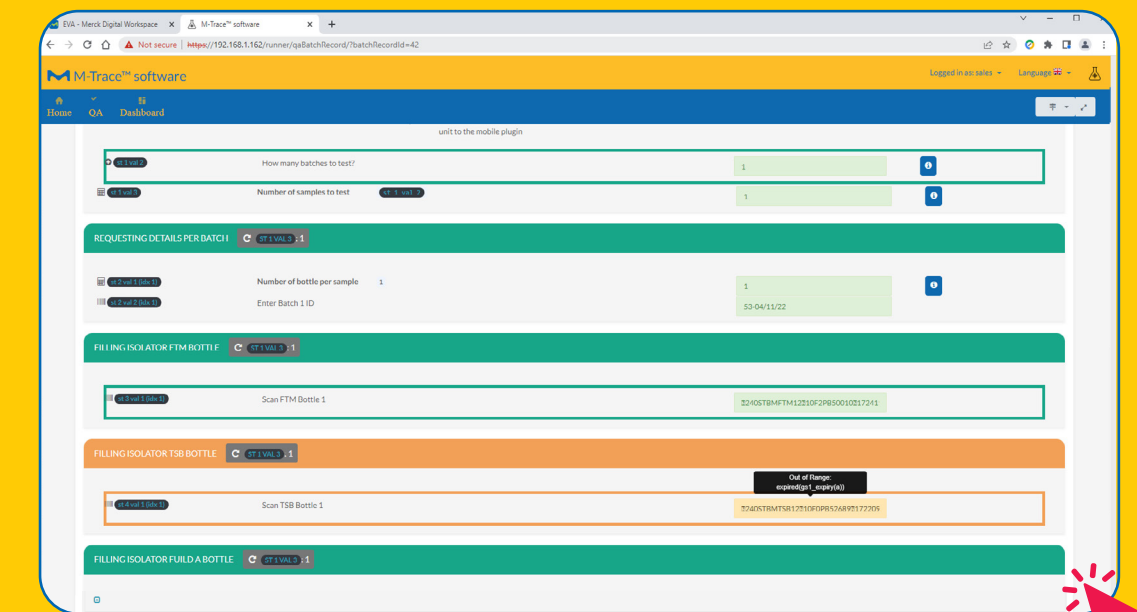
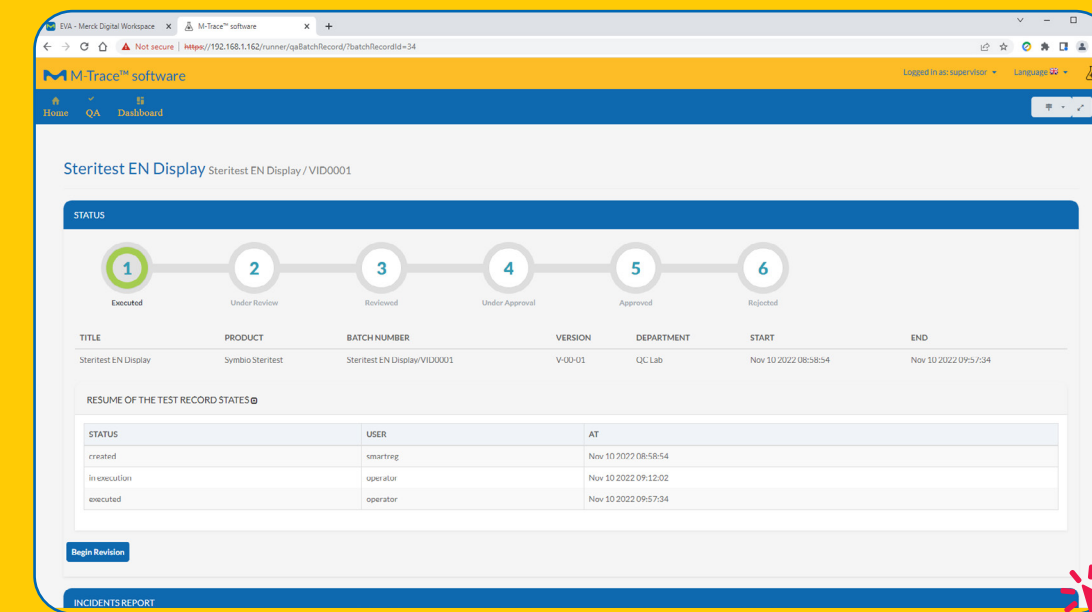
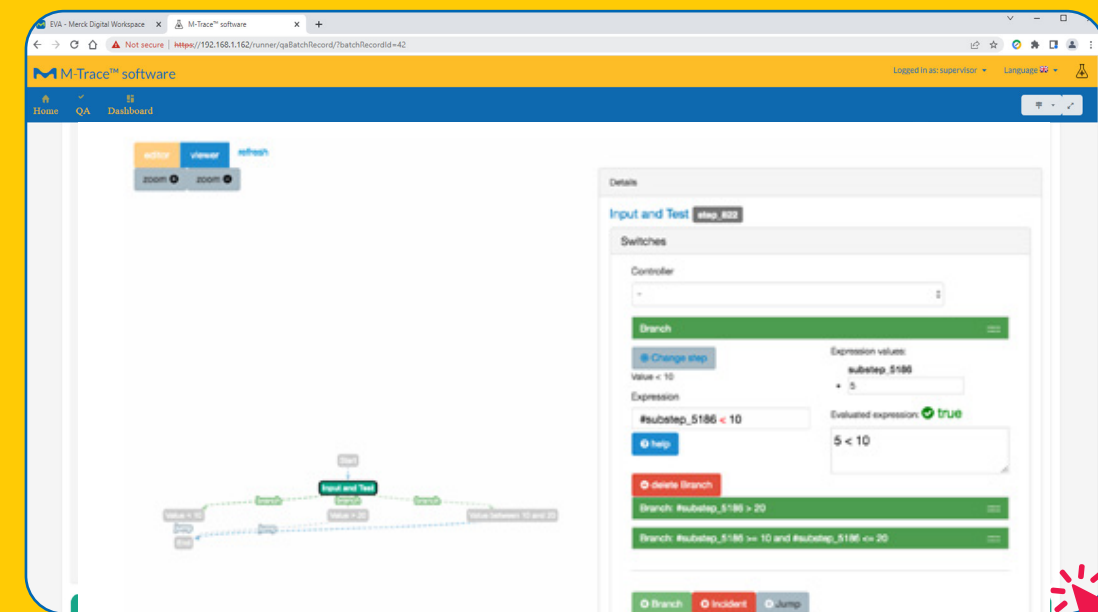
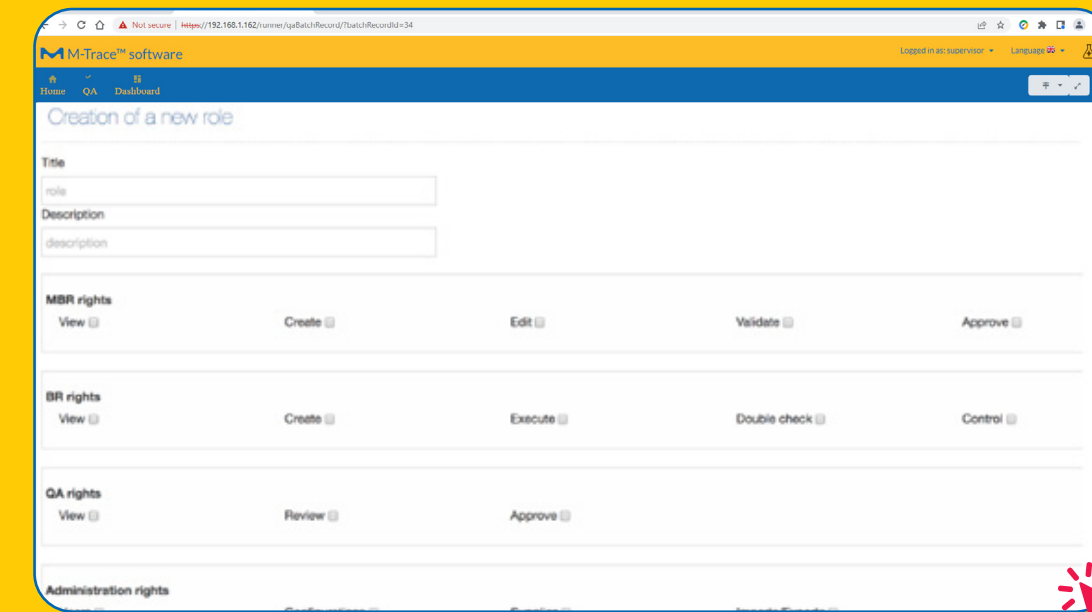
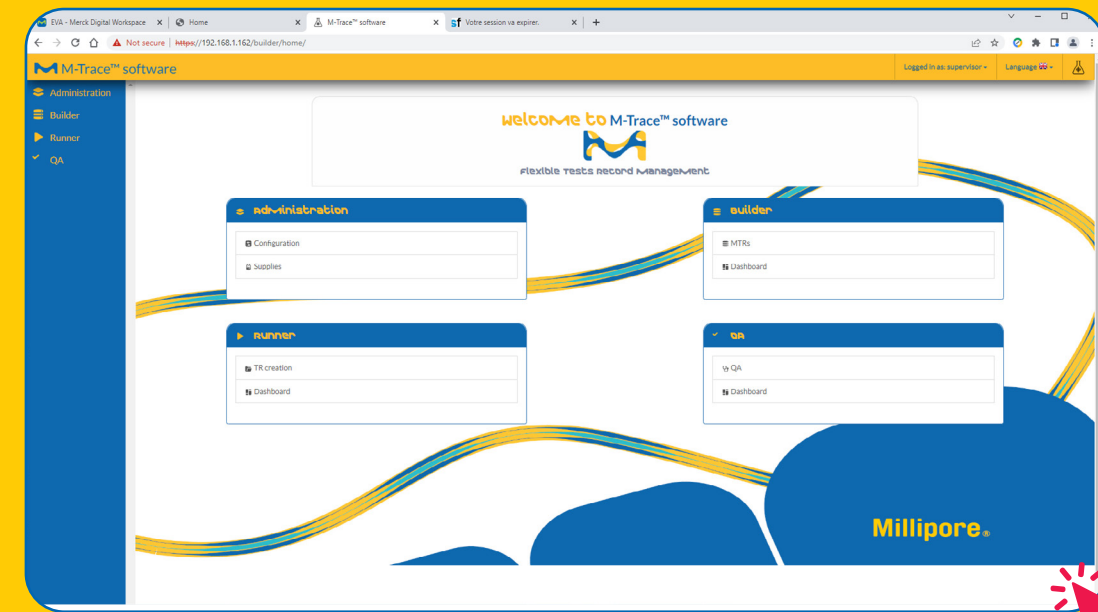
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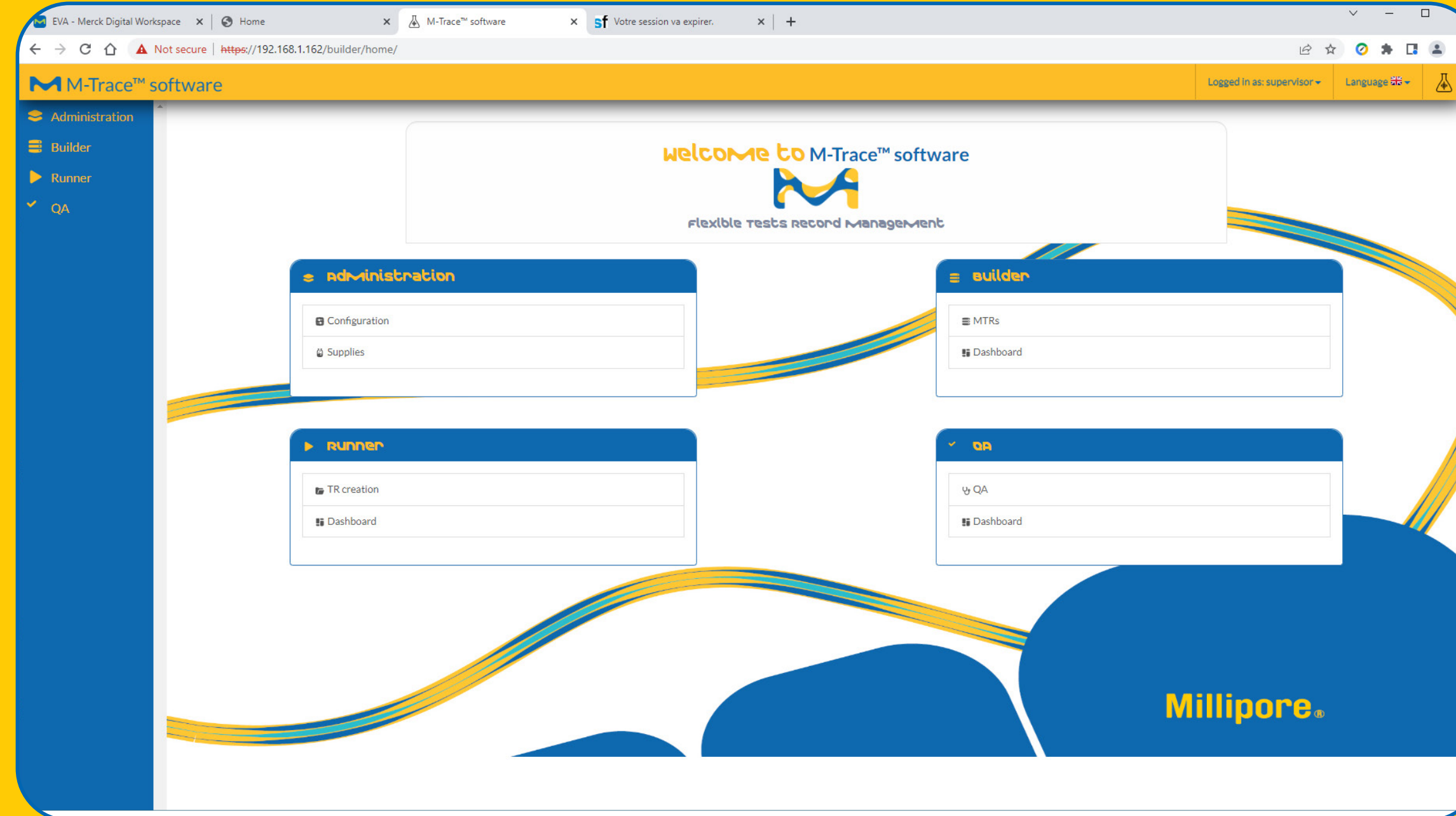
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Organize your lab material and users in the Administration module. Create your Master Test Records in the Builder, execute them in the Runner and organize the test records in the QA module.

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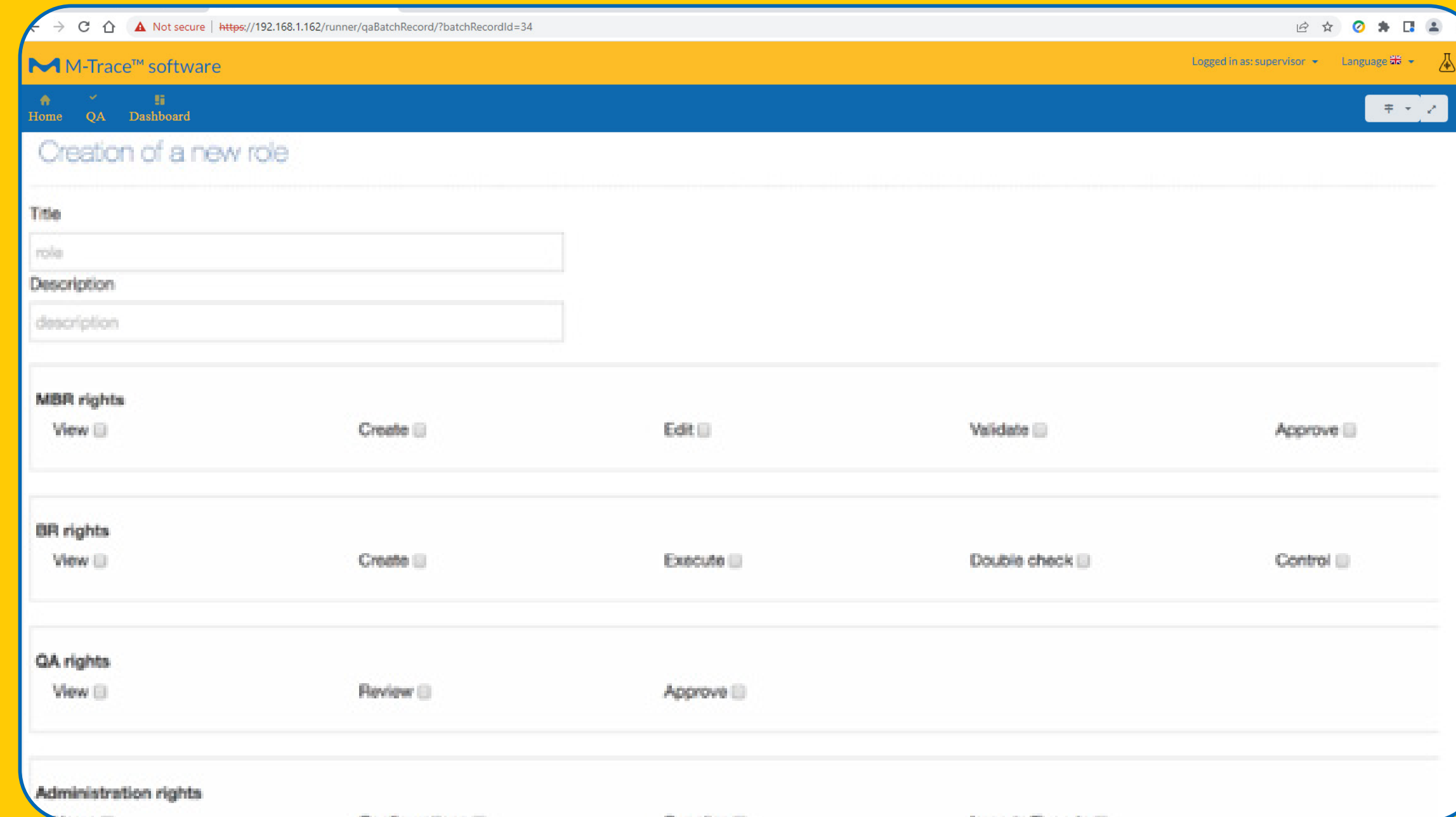
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Define roles and user rights in the comprehensive and convenient 21 CFR part 11 compliant user management system.

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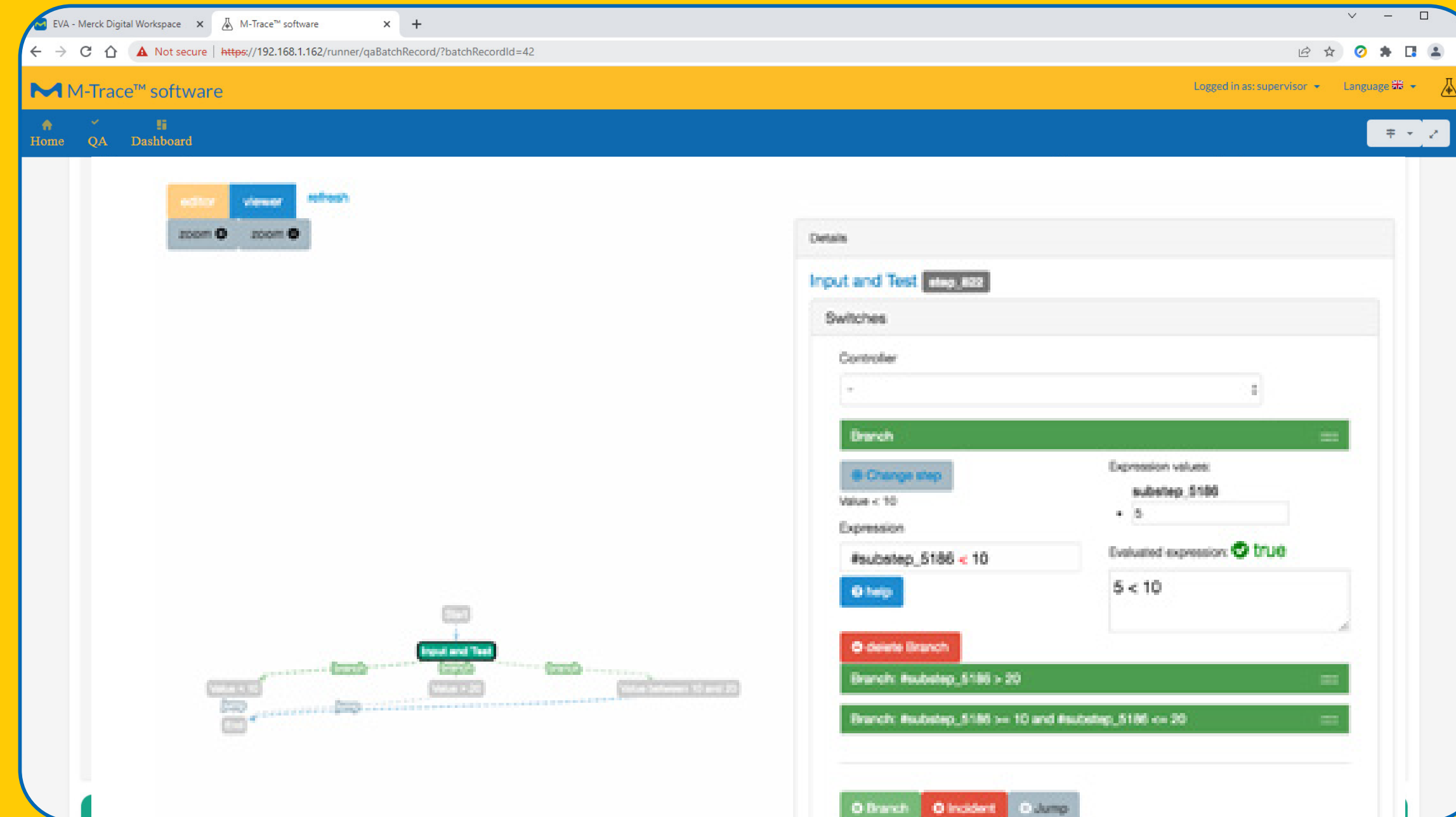
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Transfer your sterility testing SOP into the M-Trace™ software by creating fully customizable Master Test Records which will lead the operator through your workflow as defined. Thanks to the M-Trace™ software's versatility the Master Test Records are not limited to sterility testing but could also be created for any other workflow.

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Obtain comprehensive meta data form the Steritest® Symbio pump, for example pump speed, pressure or a detailed pump activity profile. This profile can prove that no overpressure has occurred and the Steritest® cannisters were not incubated under pressure that could harm microorganisms and thus lead to false negative results.

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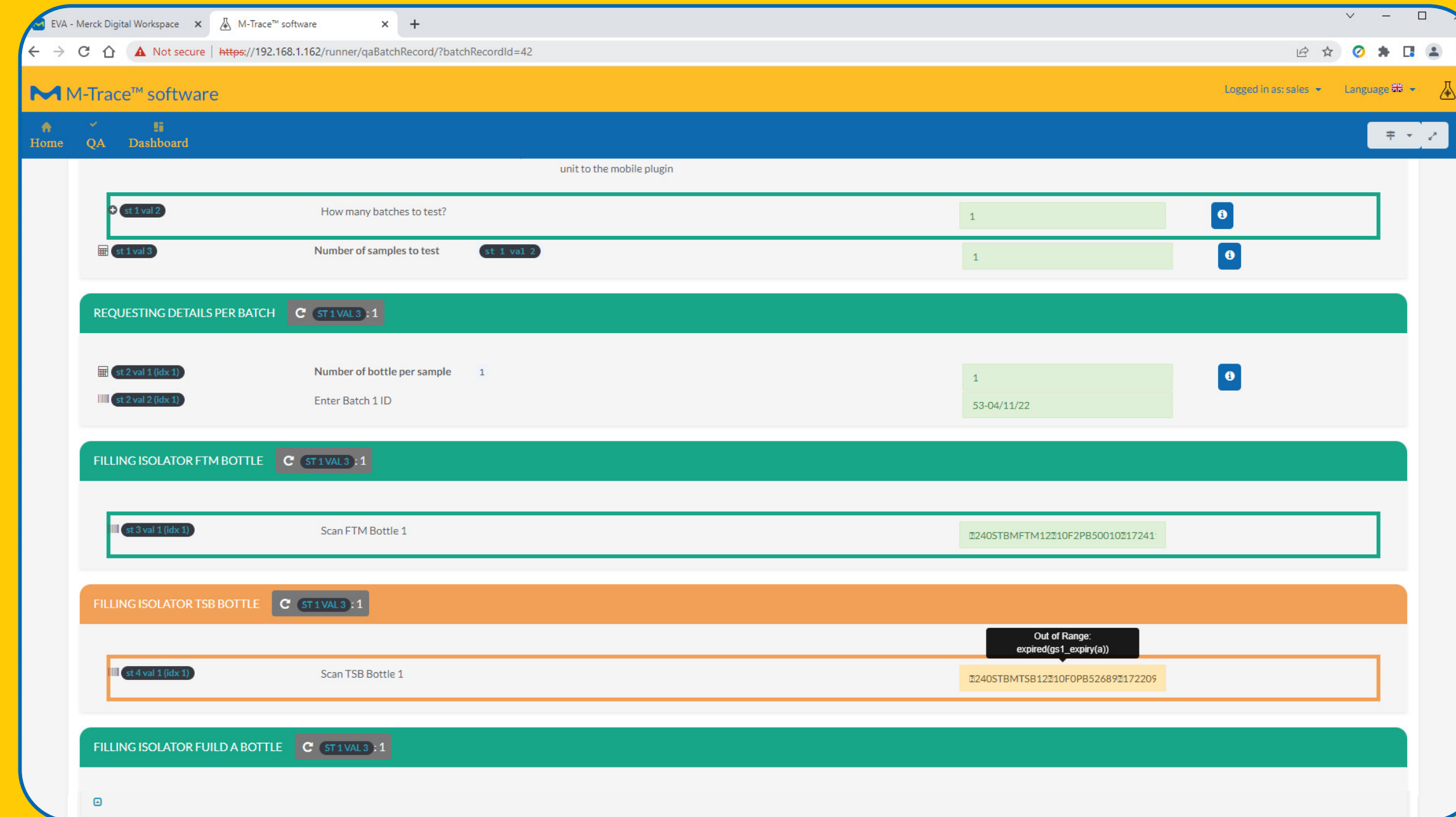
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In the test record potential incidents that occurred during the testing are clearly highlighted.

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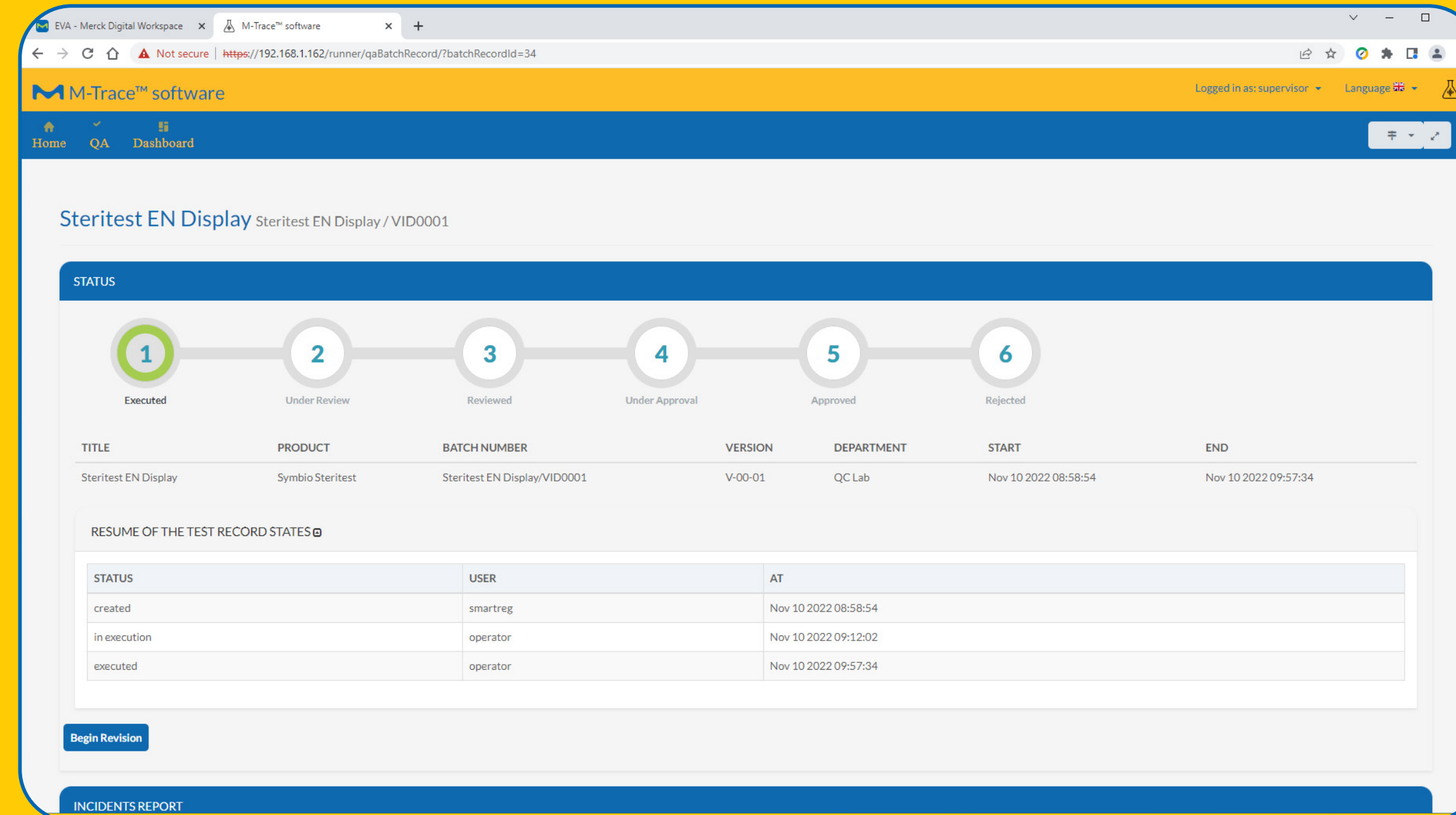
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The dedicated QA module facilitates structured review and approval of the test records.

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We help you bring robotics and automation together.

Our mission is to transform microbiology quality control processes to accelerate the release of safe pharmaceutical products.

We collaborate with the global scientific community to develop integrated automation and robotic solutions to improve QC testing reliability and data integrity.

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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:

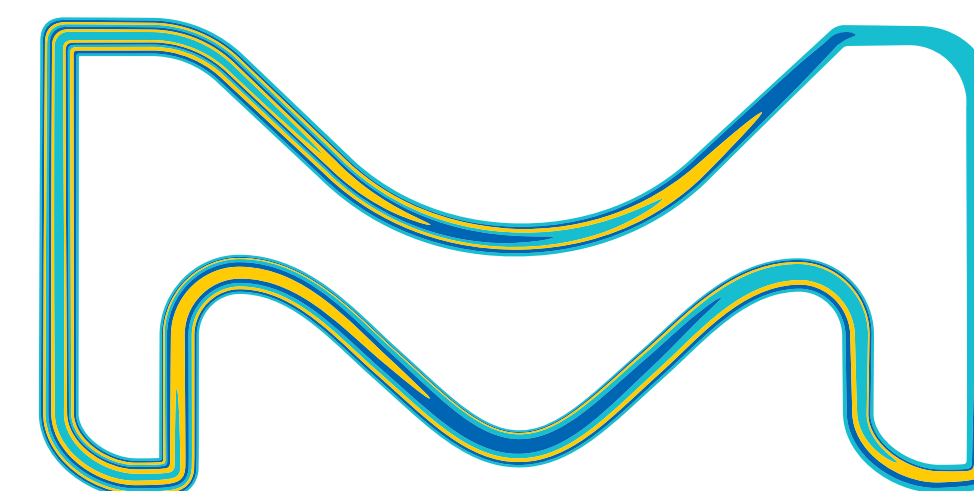
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Sterility testing is an essential part of validation for products manufactured according to GMP purporting to be sterile. Configure your Steritest® system to fit your sample, packaging, and controlled testing environment needs. Our large variety of 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

Story of the Steritest® system invention

Steritest® NEO Filtration Device

NEW M-Trace™ Software for Trusted & Efficient Data Recording

NEW Velax® cutting clamp

Culture Media & Rinsing Fluids

Peristaltic Steritest® Symbio Pump

Services & Training

Smart Accessories