



Millipore  
Sigma

For reliable sterility testing

# TRUST THE PIONEERS

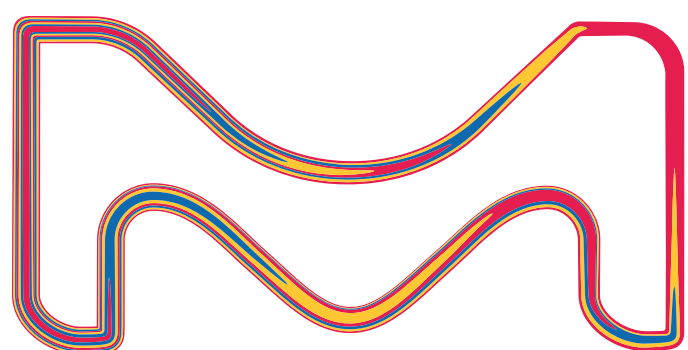
Complete sterility testing solutions  
for complete confidence.

MilliporeSigma is the U.S. and Canada  
Life Science business of Merck KGaA,  
Darmstadt, Germany.

**Millipore®**

Preparation, Separation,  
Filtration & Monitoring Products





Sterility testing is an essential part of validation for products manufactured according to GMP purporting to be sterile. Configure your Steritest® system to fit your sample, packaging, and controlled testing environment needs. Our large variety of devices and pumps, along with sterile culture media and rinsing fluids can help you to stay compliant, whether you use membrane filtration or direct inoculation methods.

## Workflow

### History

**Steritest® NEO  
Filtration Device**

**NEW Velax® cutting clamp**

**NEW Sampling Solutions**

**Culture Media  
& Rinsing Fluids**

**Services & Training**

### Story of the Steritest® system invention

**NEW M-Trace® Software**

**Peristaltic Steritest®  
Symbio Pump**

**NEW Rapid Sterility  
Testing System**

**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

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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.

[Request information](#)





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.

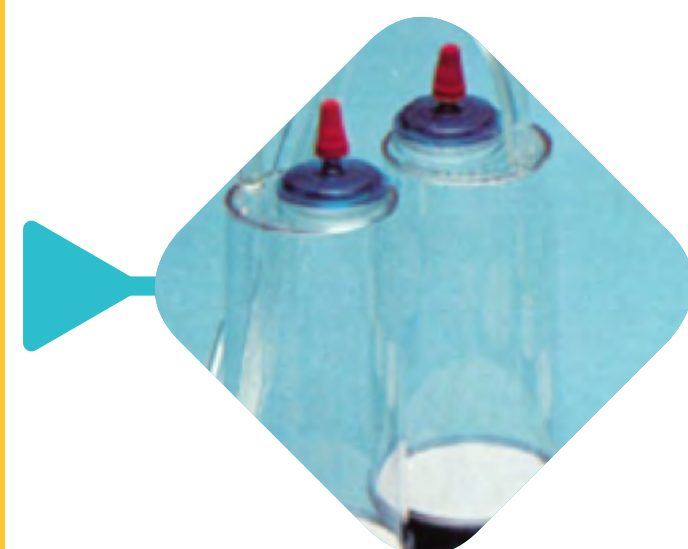
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History

# 50 years of **EXCELLENCE** in Sterility Testing



**1974**  
First Steritest®  
patent



**1985**  
New MCE  
membrane



**1986**  
New PVDF  
membrane



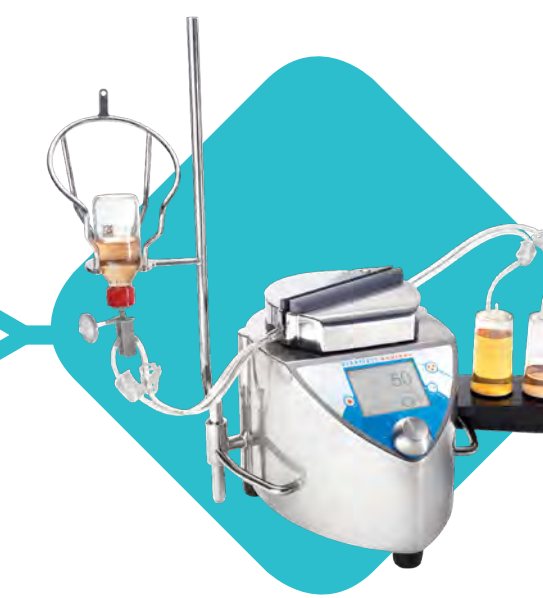
**1988**  
Steritest®  
Compact Pump



**1994**  
Steritest®  
device for oily  
samples



**1994**  
Steritest®  
Integral Pump



**2004**  
Steritest®  
Equinox  
Pumps

**CLICK**

to continue  
the journey



**2012**  
Double packed  
media



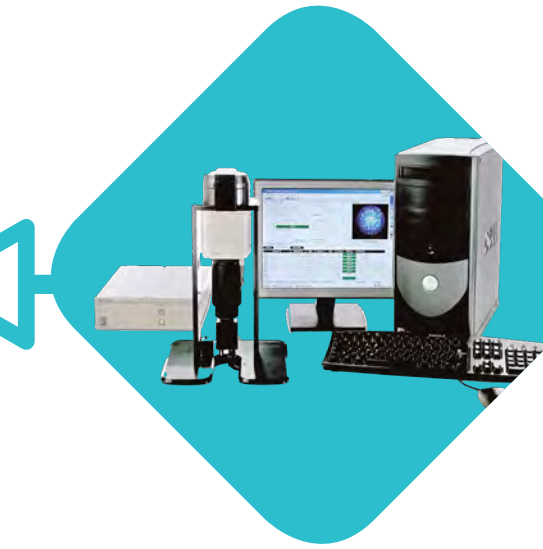
**2012**  
More choice of  
media & fluids



**2010**  
New media &  
fluid bottles



**2005**  
Steritest® EZ  
Devices



**2004**  
Milliflex®  
Rapid System

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History

# 50 years of **EXCELLENCE** in Sterility Testing



**2014**  
Steritest®  
Symbio Pumps



**2016**  
Complete  
range of  
Steritest®  
accessories



**2018**  
Steritest® NEO  
Device



**2023**  
M-Trace®  
Electronic Test  
Record  
Software



**2023**  
Milliflex® Rapid  
System 2.0



**2023**  
Velax® cutting  
clamp



**2024**  
New sampling  
solutions -  
Needle guide

**TO be  
continued**



**2024**  
New sampling  
solutions -  
Needle-free  
valve

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# 1974



The first patent for Steritest® devices is registered 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.

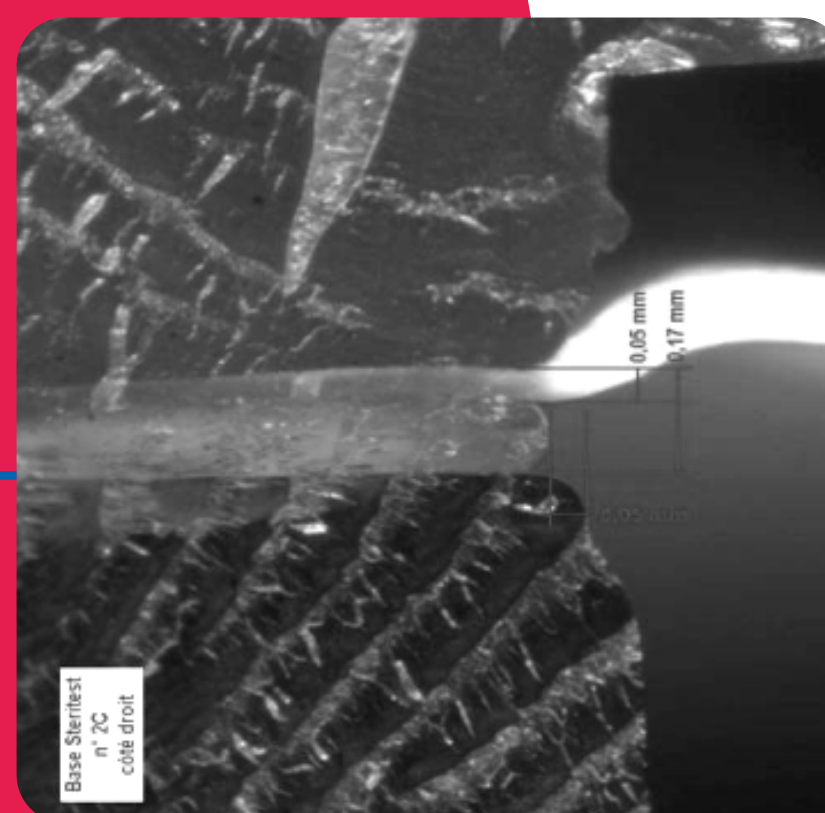




# 1985



## 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





## 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.



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## The Steritest® Integral pump



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







## 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.







History

# 2004



## The Steritest® Equinox pumps



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

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## Milliflex® Rapid System first generation

A complete system for rapid microbial detection reducing time-to-result, based on 3 proven technologies:

- Membrane filtration
- ATP bioluminescence
- Image Analysis for enumeration of microorganisms





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

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## 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







History

# 2014

## The Steritest® Symbio pumps

- Sterility testing becomes easier than ever.



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History

# 2016



## Complete range of Steritest® accessories

Streamline your workflow and increase safety with smart accessories.

### Sample Handling



**SYMBSVB01**

Steritest® Holder for  
Steridilutor® NEO  
Vent Chamber



**SYMBABR01**

Steritest® Glass  
Ampoule Breaker



**SYMBSVB01**

Steritest® Holder for  
Sterile Bags

### Filtration



**SYMBSYS01**

Steritest® Syringe  
Support



**SYMBWFS01**

Steritest® Waste  
Overfilling Sensor  
for Solid Containers



**SYMBCAN08**

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

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History

# 2018



## 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**

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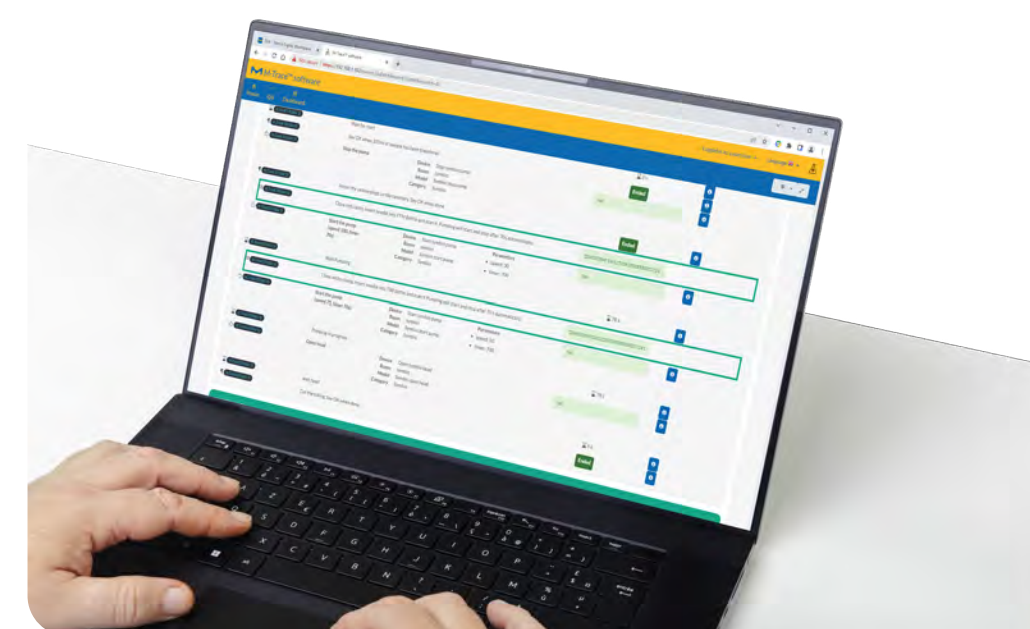
History

# 2023



## M-Trace® Electronic Test Record Software & Mobile App

A digital solution to provide 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.



[Request information](#)





History

# 2023



## Milliflex® Rapid System 2.0

An automated solution for accurate detection and enumeration of microorganisms 75% faster than traditional methods.

The new generation comes with:

- Improved camera technology for image analysis
- Data integrity thanks to 21 CFR Part 11 compliant software
- Perfect compatibility with the latest generation of our Milliflex Oasis® filtration pumps
- A full range of services



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History

# 2023

## Velax® cutting clamp



A new feature readily mounted on all Steritest® NEO Devices to enable a clean and safe cut of the tubings.



[Request information](#)





History

# 2024



## New solutions for sampling or injection into Steritest® NEO Devices



Needle guide for unplanned sampling or injection into your Steritest® NEO Device



Needle-free Valve for planned sampling or injection into your Steritest® NEO Device

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**Steritest® NEO**

**Benefits**

**New Features**

**Video - New Features**

**Video - New Devices**

**Video - Velax® Cutting  
Clamp**

**Video - Manufacturing  
Made in France**

**Specifications**

**Regulations**

**Double Packed**

**Sampling Solutions**

**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**

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**Video - New Features**

**Video - New Devices**

**Video - Velax® Cutting Clamp**

**Video - Manufacturing Made in France**

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**Regulations**

**Double Packed**

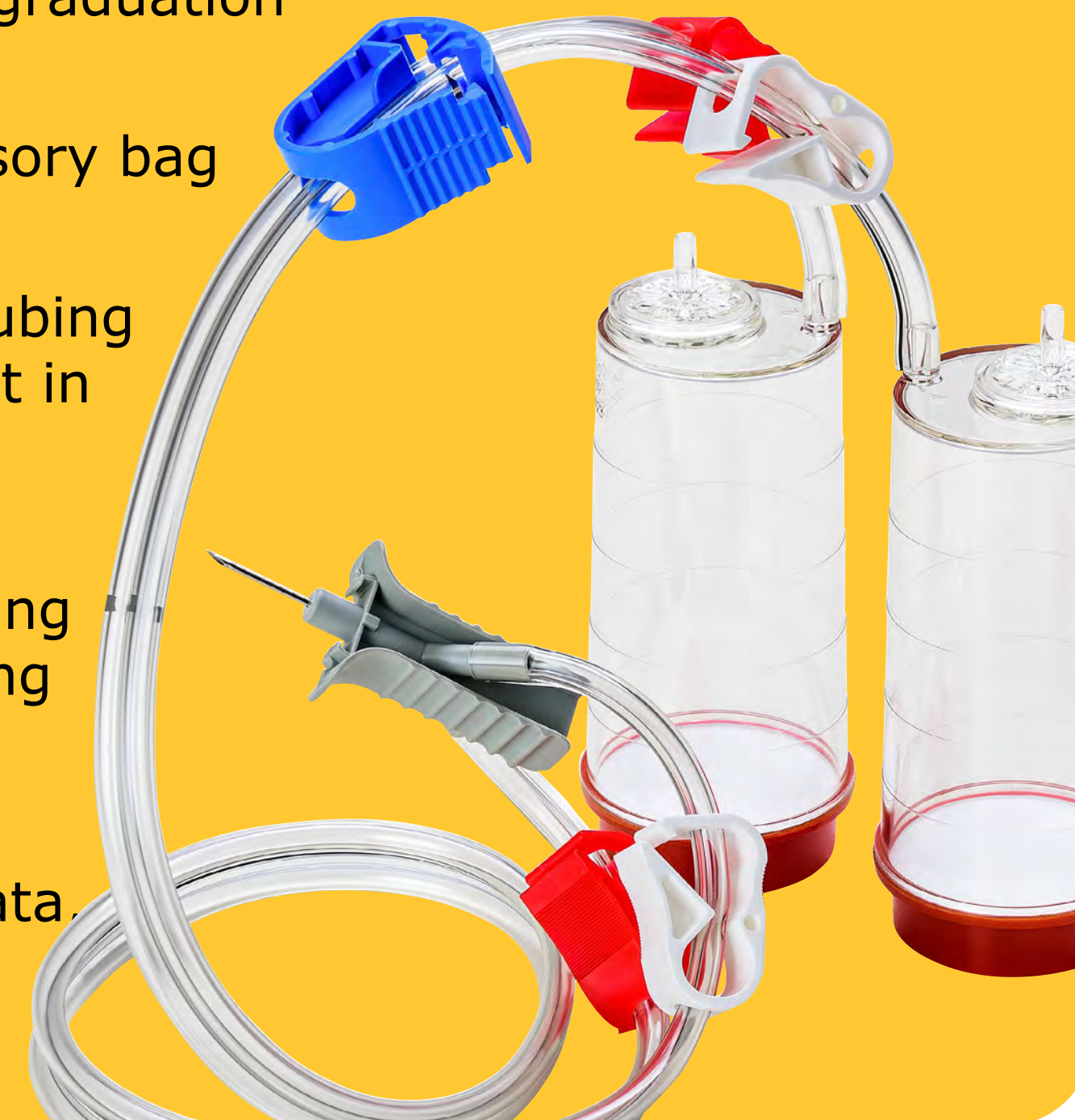
**Sampling Solutions**

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## 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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Steritest® NEO

Benefits

New Features

Video - New Features

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Testing Offer

## New features of the 4<sup>th</sup> generation of Steritest® devices

### EVOLUTION OF CONVENIENCE



[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.

### EVOLUTION OF SAFETY

### EVOLUTION OF RELIABILITY

[Request information](#)





Steritest® NEO

Benefits

New Features

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Testing Offer

## New features of the 4<sup>th</sup> generation of Steritest® devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY

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



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**Steritest® NEO**

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**New Features**

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## New features of the 4<sup>th</sup> generation of Steritest® devices

**EVOLUTION OF CONVENIENCE**

**EVOLUTION OF SAFETY**

**EVOLUTION OF RELIABILITY**

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



**Request information**



**Steritest® NEO**

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## New features of the 4<sup>th</sup> generation of Steritest® devices

**EVOLUTION OF CONVENIENCE**

**EVOLUTION OF SAFETY**

**EVOLUTION OF RELIABILITY**

**Feel free: easy to open accessory bag**



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Steritest® NEO

Benefits

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## New features of the 4<sup>th</sup> generation of Steritest® devices

EVOLUTION OF CONVENIENCE

EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY

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



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Steritest® NEO

Benefits

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## New features of the 4<sup>th</sup> generation of Steritest® devices

### EVOLUTION OF CONVENIENCE



[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.

### EVOLUTION OF SAFETY

### EVOLUTION OF RELIABILITY

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**Steritest® NEO**

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## New features of the 4<sup>th</sup> generation of Steritest® devices

**EVOLUTION OF CONVENIENCE**

**EVOLUTION OF SAFETY**

**EVOLUTION OF RELIABILITY**

**Feel confident: colored clamps**



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**Steritest® NEO**

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## New features of the 4<sup>th</sup> generation of Steritest® devices

**EVOLUTION OF CONVENIENCE**

**EVOLUTION OF SAFETY**

**EVOLUTION OF RELIABILITY**

**Feel safer: newly designed needle guard and needle protector**



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Steritest® NEO

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## New features of the 4<sup>th</sup> generation of Steritest® devices

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. ✕



Watch the Video

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Steritest® NEO

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### EVOLUTION OF CONVENIENCE



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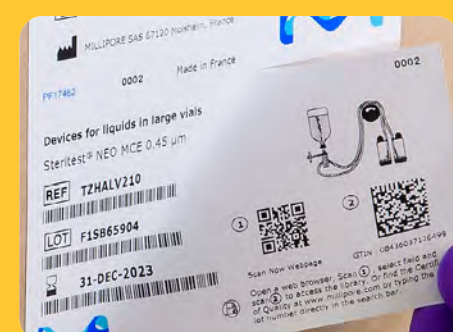
#### Feel secure: optimized identification and traceability

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](https://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

New Features

Video - New Features

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Clamp

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EVOLUTION OF SAFETY

EVOLUTION OF RELIABILITY

Feel secure: optimized identification and traceability



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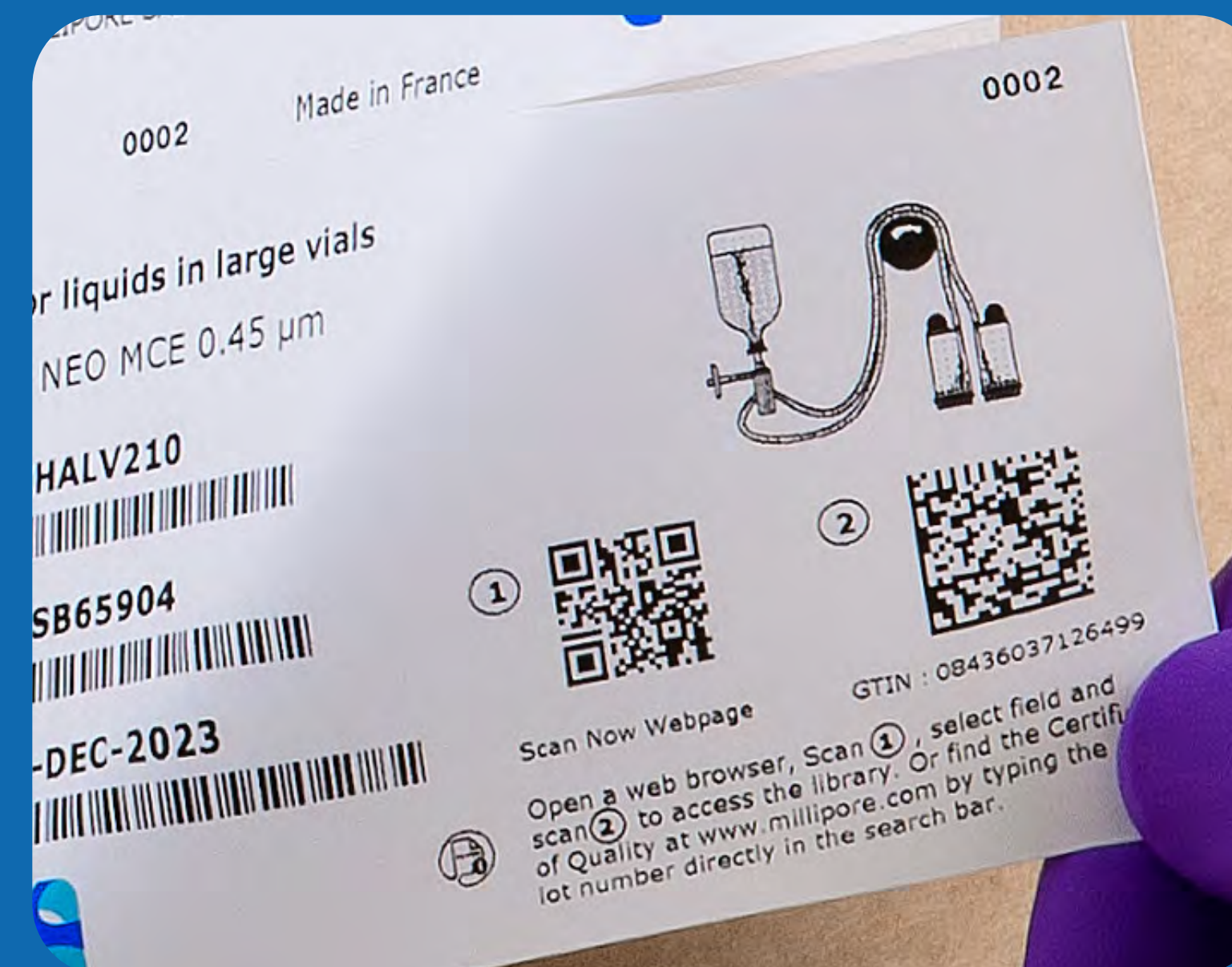
## New features of the 4<sup>th</sup> generation of Steritest® devices

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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**Video - New Devices**

**Video - Velax® Cutting  
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## New features of the 4<sup>th</sup> generation of Steritest® devices

**EVOLUTION OF CONVENIENCE**

**EVOLUTION OF SAFETY**

**EVOLUTION OF RELIABILITY**

**Feel confident: volume graduation on the canisters**



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**Steritest® NEO**

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## Video

Steritest® NEO devices: new features

**Select your needle length**  
protective cap in 2 parts



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**Steritest® NEO**

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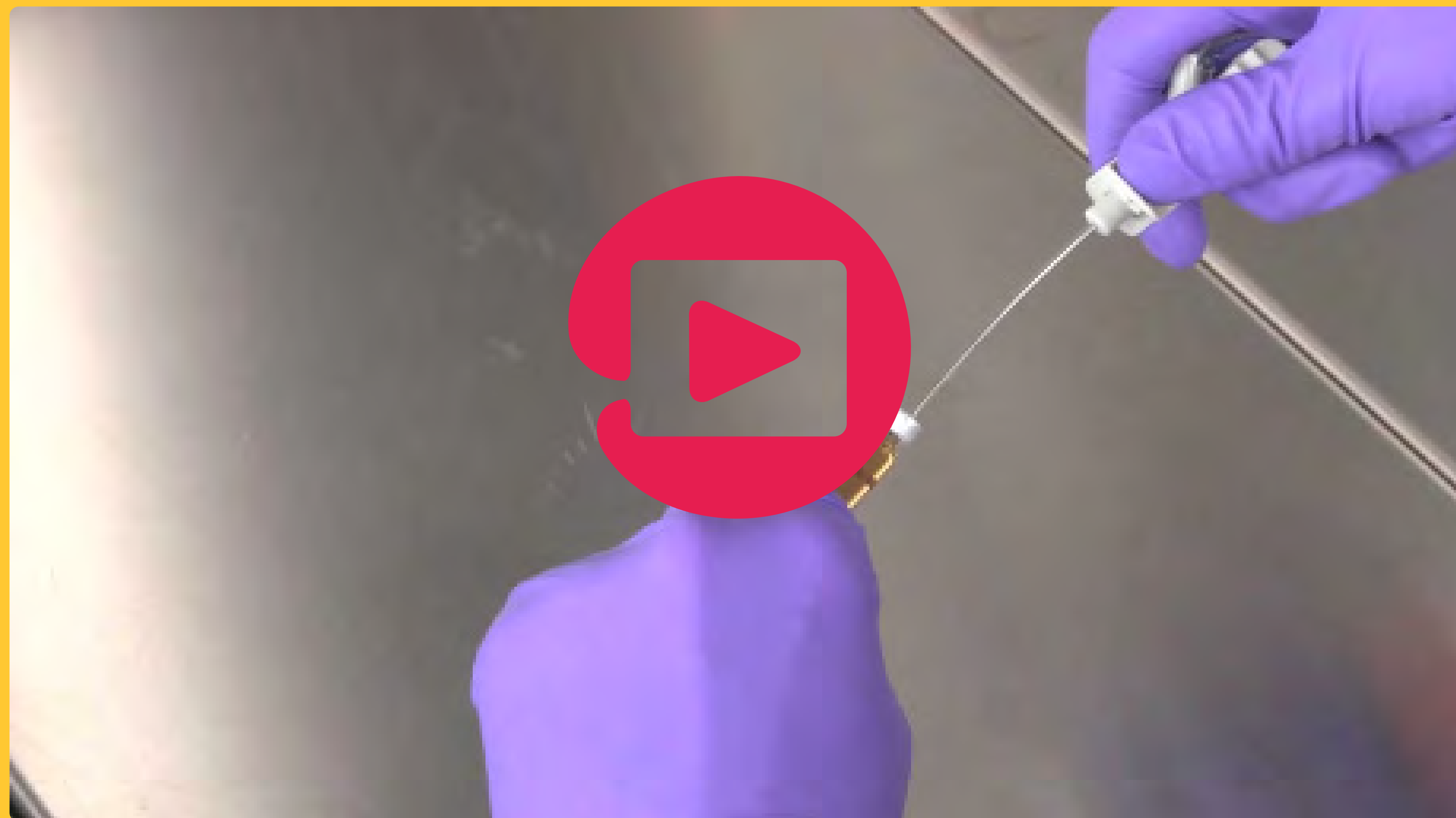
**Sampling Solutions**

**Ordering Information**

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Testing Offer**

## Video

Steritest® NEO devices for cartridges and small soft plastic containers



**Request information**



**Steritest® NEO**

**Benefits**

**New Features**

**Video - New Features**

**Video - New Devices**

**Video - Velax® Cutting Clamp**

**Video - Manufacturing Made in France**

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**Complete Sterility Testing Offer**

## Video

Steritest® NEO Velax Cutting Clamp for a Scissor Free Sterility Testing Workflow



**Request information**





**Steritest® NEO**

**Benefits**

**New Features**

**Video - New Features**

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**Video - Manufacturing  
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## Video

Production of Steritest® NEO devices in our Center of Excellence,  
Molsheim, France



**Request information**





Steritest® NEO

Benefits

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Video - Velax® Cutting  
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## Specifications

### Steritest® NEO "Blue Base" devices

for products WITHOUT  
antimicrobial agents and  
medical devices



|  |  |
|--|--|
| Canister Base Color  | Blue   |
| Canister Base Membrane   | Mixed Esters of Cellulose (HA) membrane, 0.45 µm                                 |
| Materials of Construction<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Styrene acrylonitrile<br>PVC, 850 mm length<br>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  |
| Ordering Information   | <a href="#">Click here</a>   |

### Steritest® NEO "Red Base" devices

for antibiotics, products  
WITH antimicrobial agents  
and medical devices



|  |  |
|--|--|
| Canister Base Color  | Red  |
| Canister Base Membrane   | Low adsorption Durapore® membrane (HV), 0.45 µm hydrophilic PVDF                       |
| Materials of Construction<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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  |
| Ordering Information   | <a href="#">Click here</a>   |

### Steritest® NEO "Green Base" devices

for products dissolved in  
solvents requiring increased  
chemical compatibility



|  |  |
|--|--|
| Canister Base Color  | Green  |
| Canister Base Membrane   | Low adsorption Durapore® membrane (HV), 0.45 µm hydrophilic PVDF                 |
| Materials of Construction<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | polyamide 6-6 (nylon)<br>PVC, 850 mm length<br>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  |
| Ordering Information   | <a href="#">Click here</a>   |

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**Regulations**

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**Regulations**

**Closed  
Environment**

**Consistent  
Performance**

**Certificates  
of Quality**

**Documented  
Qualification**



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## Regulations and Industry benchmark

**Regulations**

**Closed  
Environment**

**Consistent  
Performance**

**Certificates  
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**Documented  
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### 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>.

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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.

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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

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## 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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## Regulations and Industry benchmark



### Documented Qualification

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

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## **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**



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**Benefits**

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## **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.

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## **Steritest® Sampling Solutions**

For unplanned or occasional sampling  
or injection into your Steritest® NEO Device

During incubation of our Steritest® NEO Devices, it may be necessary to access the container, for example to subculture, reincubate, identify microorganisms or for positive controls. When this is performed, it is pivotal that sterility is not compromised.

We have developed two safe solutions for this purpose—simply choose the one that best suits your needs:

### **Needle Guide**



### **Needle-free Valve**



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## Steritest® Needle Guide

For unplanned sampling or injection into your Steritest® NEO Device



When needed, install the needle guide onto the top of the canister.

Attach the provided needle to a syringe and guide the needle into and through the canister's chimney, thereby piercing the tubing of the canister.



After sampling, close the clamp of the needle guide to keep your canister safe from external contamination.

Once closed, the canister can be further incubated or kept for investigation purposes.



Watch the Video

### Ordering information

Steritest® needle guide  
+ needle



TZSPLKT10

Box of 10 guides + 10 needles

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## Steritest® Needle-free Valve

For planned sampling or injection into your Steritest® NEO Device  
(to be installed on the canister before incubation)



At the end of the sterility assay workflow, close the clamps and cut the tubing.

Install the needle-free valve onto the cut tubing of each canister and place the red plug onto the vent.

Incubate the canisters with the needle free valve readily installed.



Take off the red plug and the valve's cover. Open the clamp and connect a lure lock syringe to the needle free valve and sample the media. Once done, detach the syringe and place the red plug and the valve cover back on the canister. The canister can now be returned to incubation.



Watch the Video

### Ordering information

Steritest® sampling  
needle-free valve



TZNFVSP20

box of 10 units (2 valves per package)

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**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 “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

**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

**Accessories** for sample preparation,  
dilution, sampling and injection.

Tubing and needle assembly to dissolve powders,  
or for the transfer of liquids, or sterile vent  
needles.  
Sampling solutions for sampling or injection into  
your Steritest® NEO device.

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### 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 <b>DP</b>         | TZHALA205 |                  |             |
| Steritest® NEO Devices for Liquids in Collapsible Bags           | TZHALA210 |                  |             |
| Steritest® NEO Devices for Liquids in Collapsible Bags <b>DP</b> | TZHALA205 |                  |             |
| Steritest® NEO Devices for Liquids in Large Vials                | TZHALV210 |                  |             |
| Steritest® NEO Devices for Liquids in Large Vials <b>DP</b>      | TZHALV205 |                  |             |
| Steritest® NEO Devices for Liquids in Small Vials                | TZHASV210 |                  |             |
| Steritest® NEO Devices for Liquids in Small Vials <b>DP</b>      | 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 |                  |             |
| <b>NEW</b> Steritest® NEO Devices for Liquids in Cartridges      | TZHACA210 |                  |             |

**DP** = Double Packed

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### Steritest® NEO “Blue Base” Devices

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#### Application

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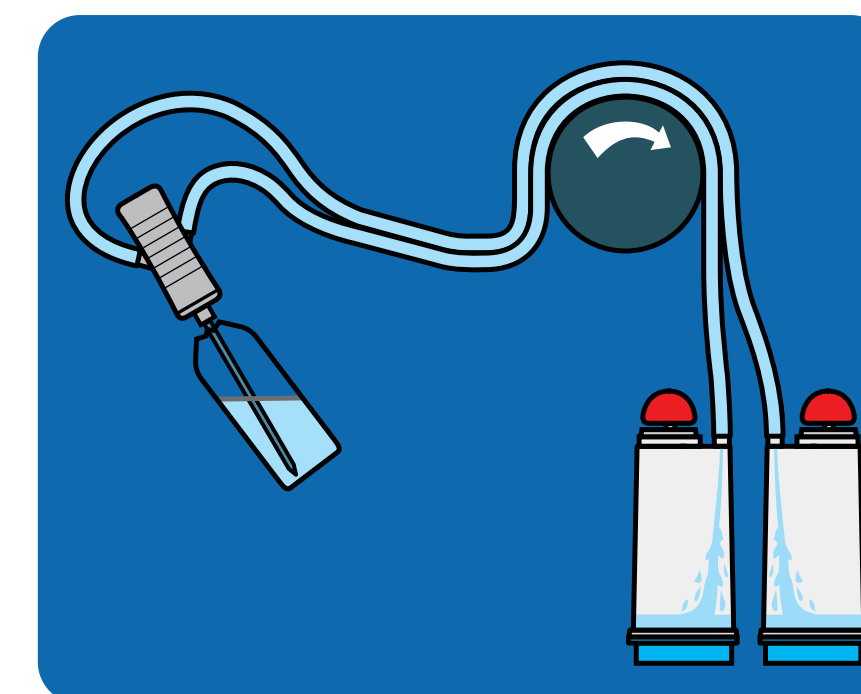
### Steritest® NEO Devices for Liquids in Ampoules (TZHALA210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>Stainless steel and polyamide 6-6 |
| Sample Container Capacity  | 120 mL (graduation marks at 25, 50, 75 and 100 mL)  |
| Minimum Flow Rate (for water)  | 300 mL/min at 690 mbar (10 psi)   |
| Maximum Temperature  | 45 °C   |
| Maximum Operating Pressure   | 3.15 bars at 25 °C (45 psi at 77 °F)  |
| Sterilization  | Gamma irradiation   |

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### Steritest® NEO “Blue Base” Devices

for products WITHOUT antimicrobial agents and medical devices



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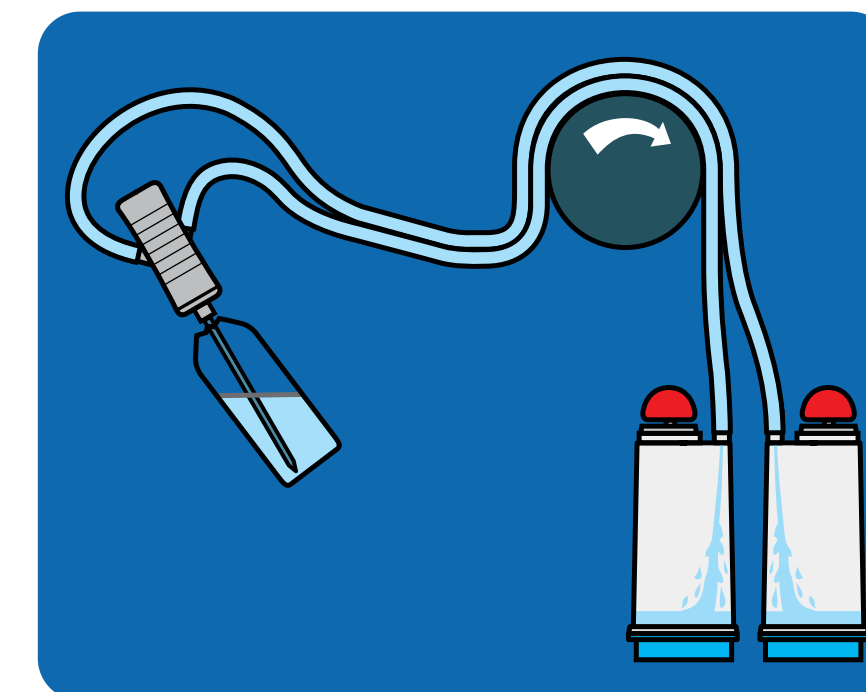
### Steritest® NEO Devices for Liquids in Ampoules - Double-Packed (TZHALA205)

- 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 “Blue Base” Devices

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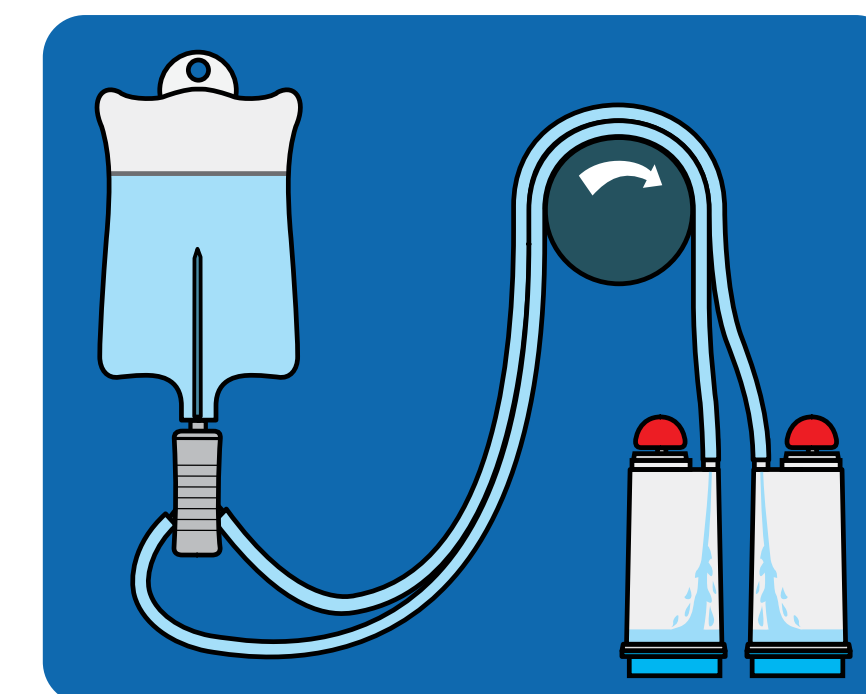
### Steritest® NEO Devices for Liquids in Collapsible Bags (TZHALA210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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

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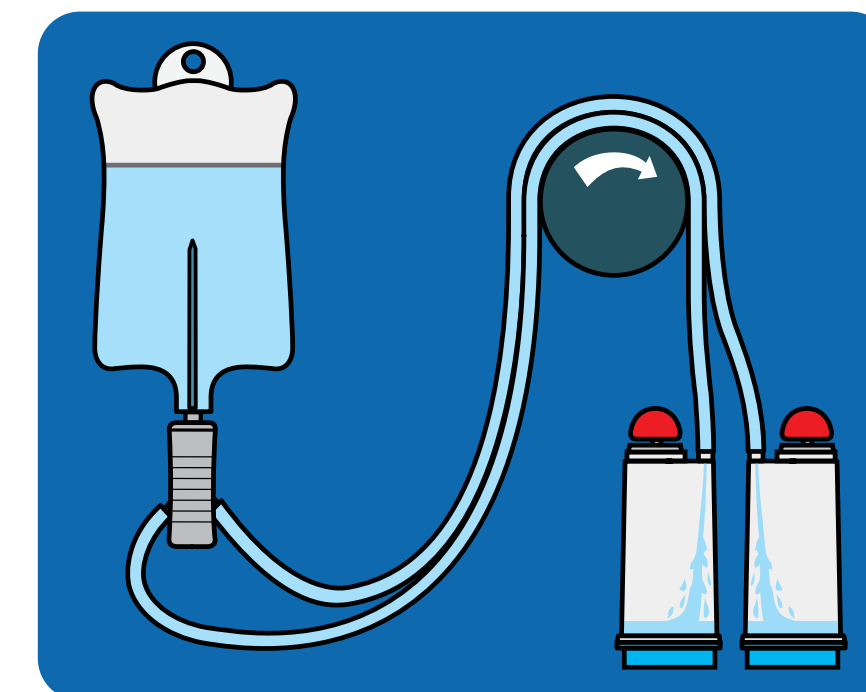
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### Steritest® NEO Devices for Liquids in Collapsible Bags - Double-Packed (TZHALA205)

- 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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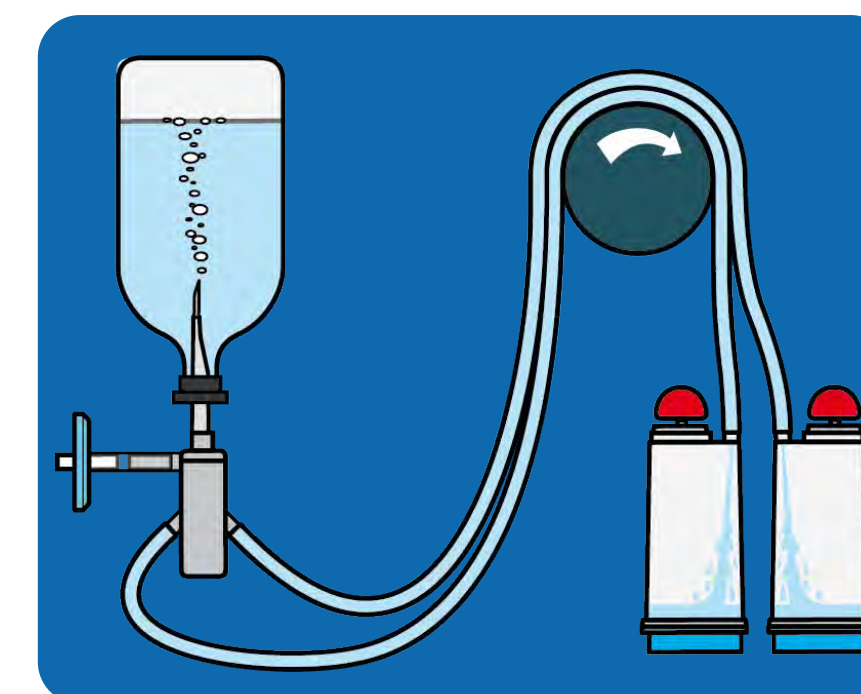
### Steritest® NEO Devices for Liquids in Large Vials (TZHALV210)



- Vented double needle for large glass containers with septa

|  |   |
|--|---|
| Canister Base Membrane   | Mixed Esters of Cellulose (HA) membrane, 0.45 µm  |
| Materials of Construction<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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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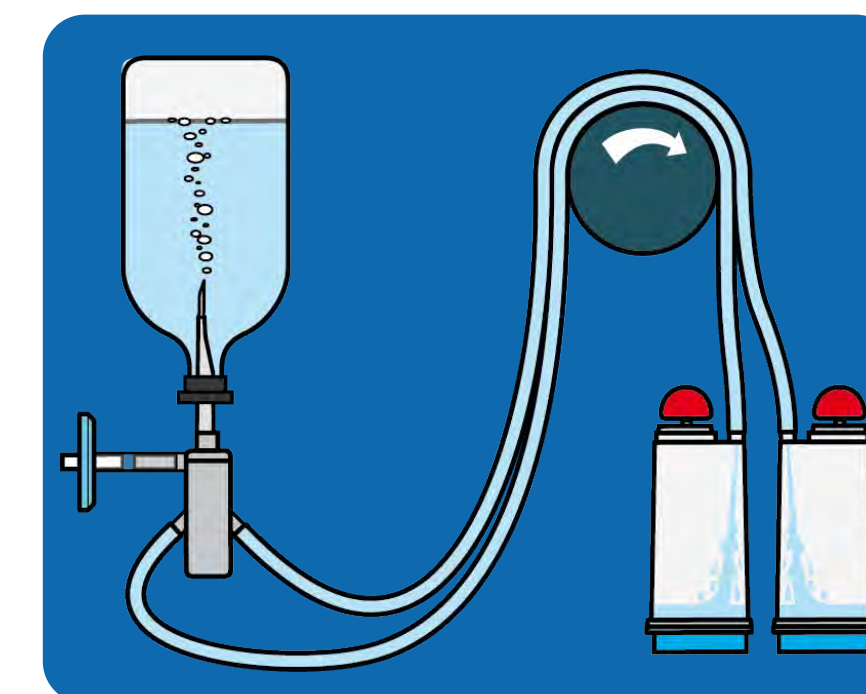
### Steritest® NEO Devices for Liquids in Large Vials - Double-Packed (TZHALV205)



- 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 “Blue Base” Devices

for products WITHOUT antimicrobial agents and medical devices



#### Application

Steritest® NEO Devices for Liquids

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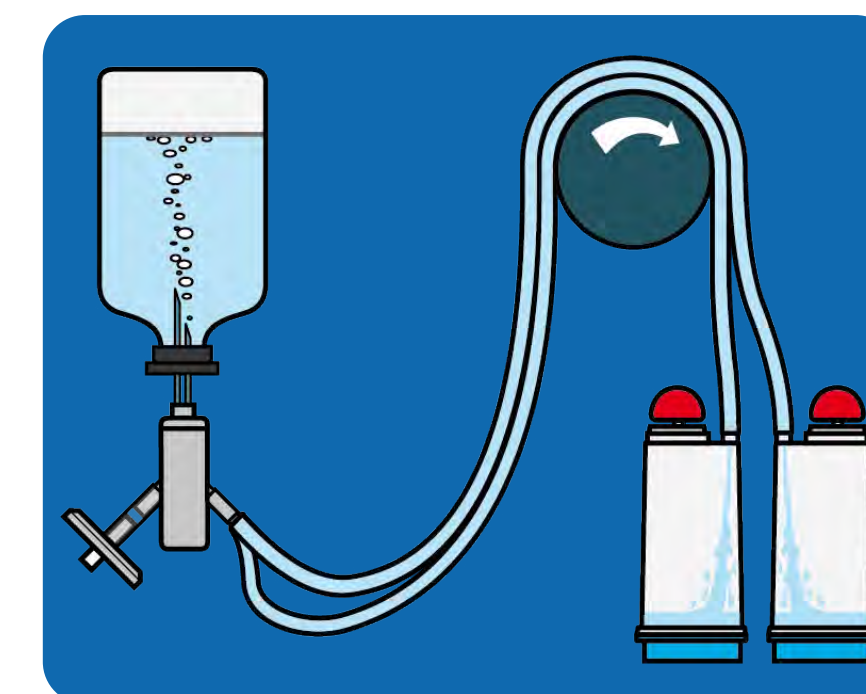
### Steritest® NEO Devices for Liquids in Small Vials (TZHASV210)



- Vented double needle for small vials with septa

|  |   |
|--|---|
| Canister Base Membrane   | Mixed Esters of Cellulose (HA) membrane, 0.45 µm  |
| Materials of Construction<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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 Liquids

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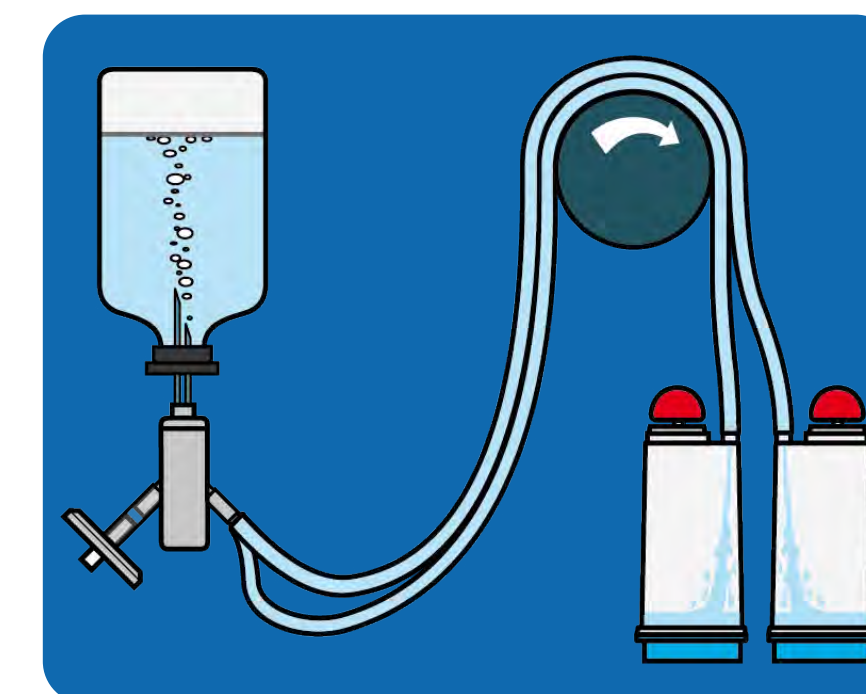
### Steritest® NEO Devices for Liquids in Small Vials - Double-Packed (TZHASV205)



- 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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#### Application

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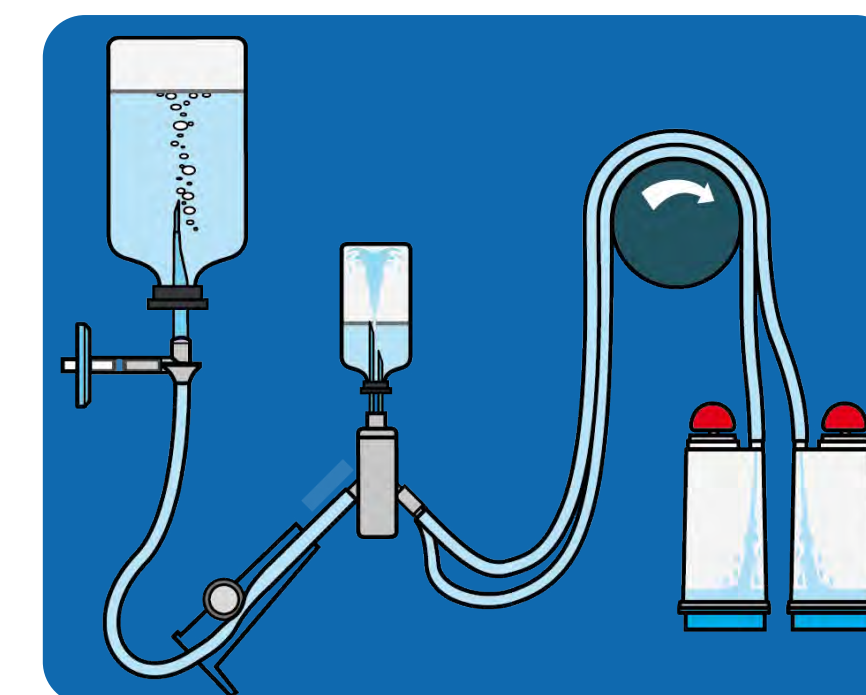
### Steritest® NEO Devices for Soluble Powders in Vials (TZHADV210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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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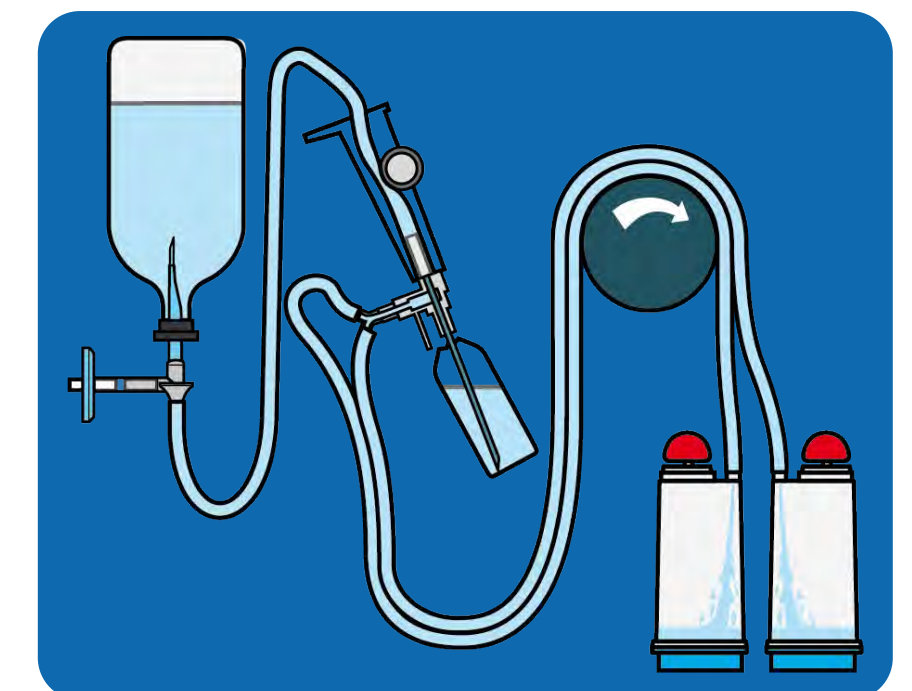
### Steritest® NEO Devices for Soluble Powders in Ampoules (TZHADA210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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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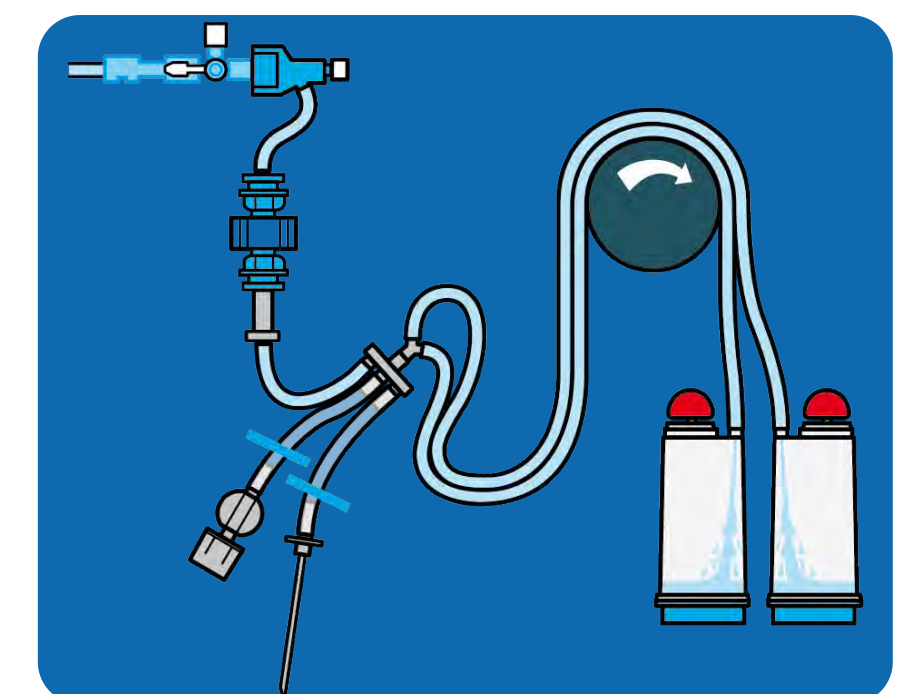
### Steritest® NEO Devices for Medical Devices and Collapsible Bags (TZHAMD210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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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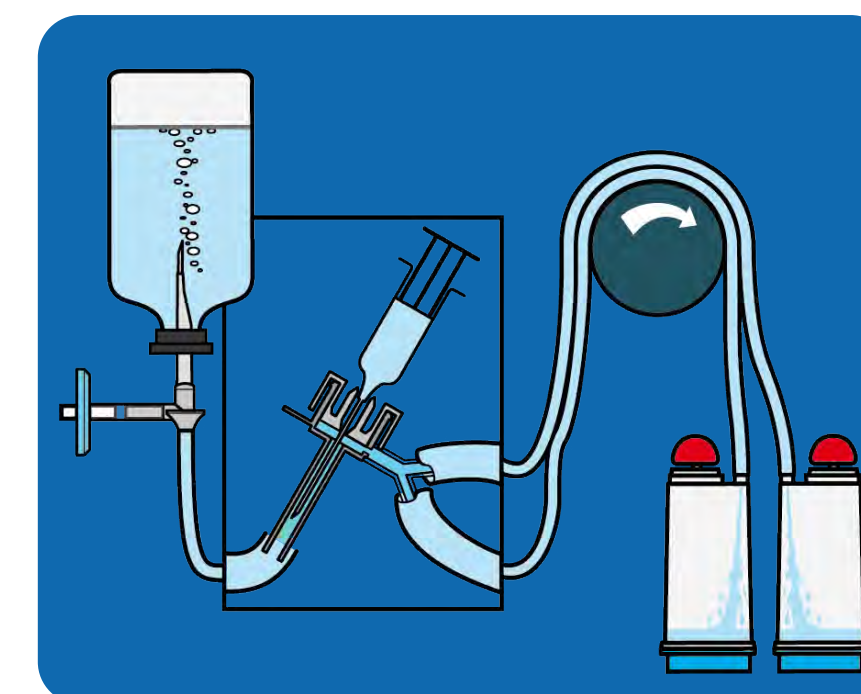
### Steritest® NEO Devices for Liquids in Syringes (TZHASY210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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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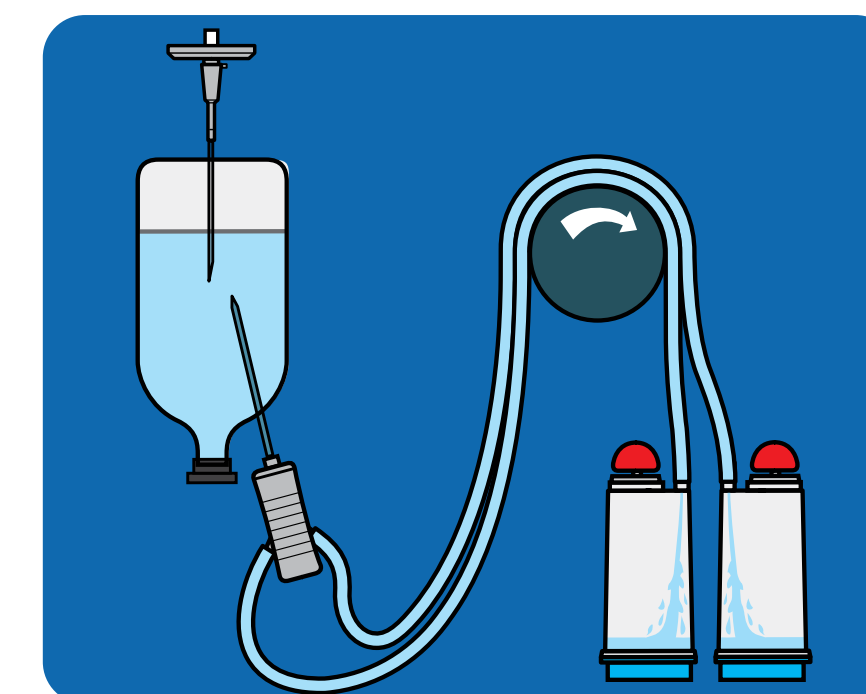
### Steritest® NEO Devices for Liquids in Plastic Containers (TZHAPC210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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 Cartridges and Small Soft Plastic Containers (TZHACA210)

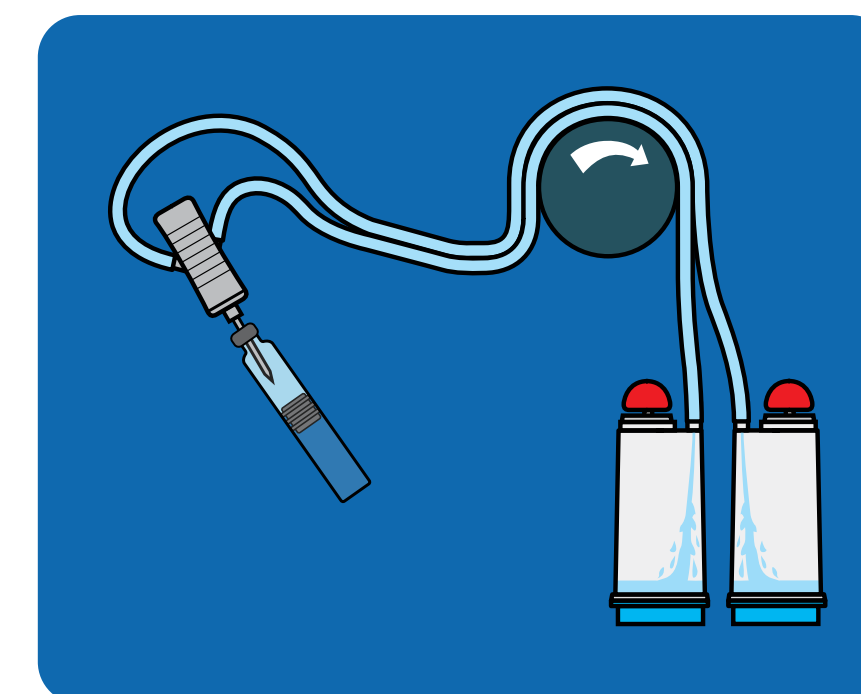
- Single short (20 mm) needle for easy access to cartridges and small soft plastic containers
- Separate vent needle

|  |   |
|--|---|
| Canister Base Membrane   | Mixed Esters of Cellulose (HA) membrane, 0.45 µm  |
| Materials of Construction<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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



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|--|------------|------------------|-------------|
| Steritest® NEO Devices for Liquids in Ampoules                   | TZHVAB210  |                  |             |
| Steritest® NEO Devices for Liquids in Ampoules <b>DP</b>         | TZHVAB205  |                  |             |
| Steritest® NEO Devices for Liquids in Collapsible Bags           | TZHVAB210  |                  |             |
| Steritest® NEO Devices for Liquids in Collapsible Bags <b>DP</b> | TZHVAB205  |                  |             |
| Steritest® NEO Devices for Liquids in Large Vials                | TZHVLV210  |                  |             |
| Steritest® NEO Devices for Liquids in Large Vials <b>DP</b>      | TZHVLV205  |                  |             |
| Steritest® NEO Devices for Liquids in Small Vials                | TZHVSV210  |                  |             |
| Steritest® NEO Devices for Liquids in Small Vials <b>DP</b>      | TZHVSV205  |                  |             |
| Steritest® NEO Devices for Soluble Powders in Vials              | TZHVVDV210 |                  |             |
| Steritest® NEO Devices for Soluble Powders in Vials <b>DP</b>    | TZHVVDV205 |                  |             |
| Steritest® NEO Devices for Medical Devices and Collapsible Bags  | TZHVMD210  |                  |             |
| Steritest® NEO Devices for Powders and Superpotent Antibiotics   | TZHVAB210  |                  |             |
| <b>NEW</b> Steritest® NEO Devices for Liquids in Cartridges      | TZHVCA210  |                  |             |

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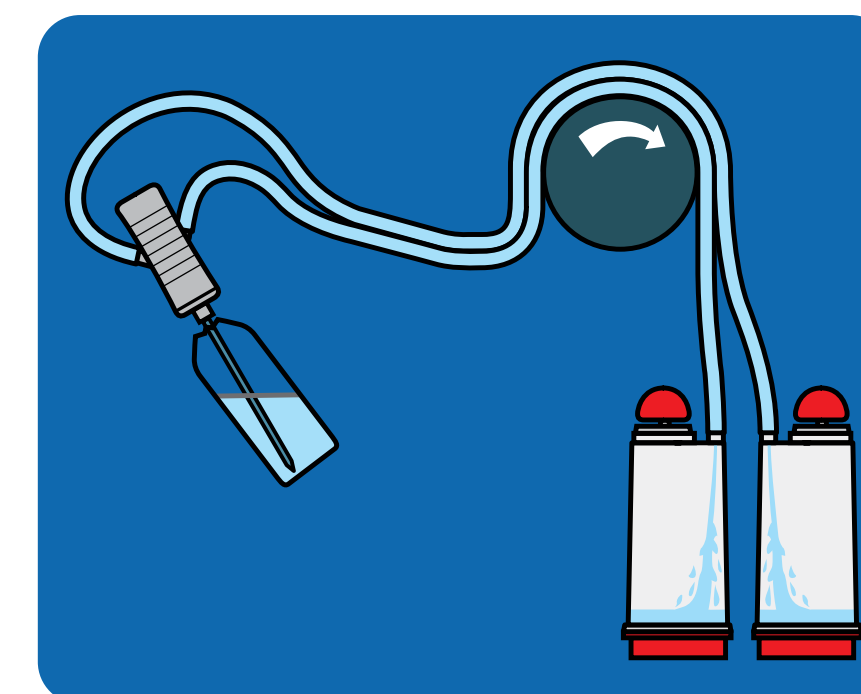
### Steritest® NEO Devices for Liquids in Ampoules (TZHVAB210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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 Ampoules - Double-Packed (TZHVB205)

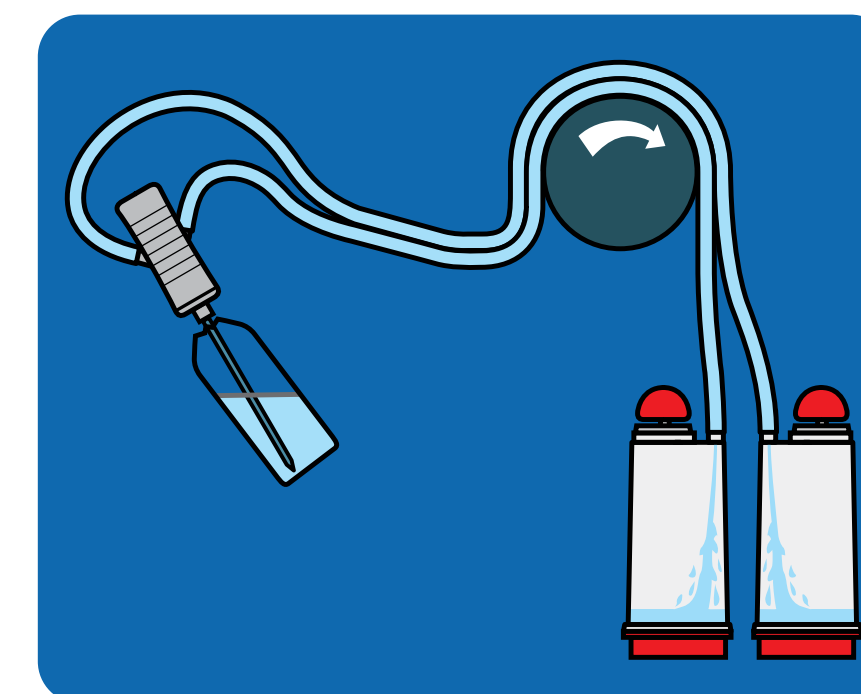


- Single needle for easy access to ampoules
- Separate vent needle
- Double-packed for quick transfer into sterility testing environments

|                                |   |
|--------------------------------|---|
| 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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### 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 Powder

**NEW** Steritest® NEO Devices for L

#### Product #

#### More Information

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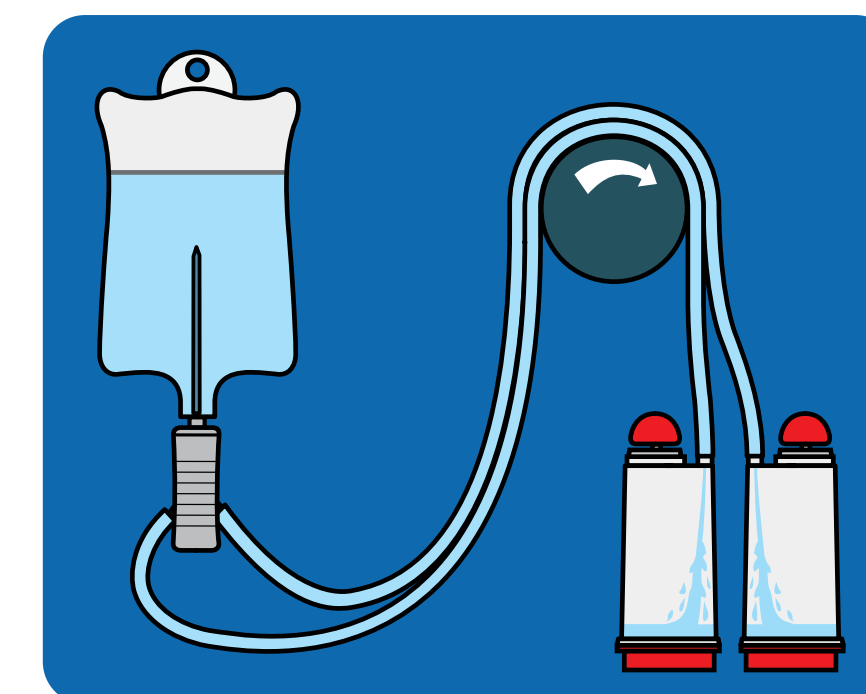
### Steritest® NEO Devices for Liquids in Collapsible Bags (TZHVAB210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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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Regulations

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### 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

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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 Powder

**NEW** Steritest® NEO Devices for L

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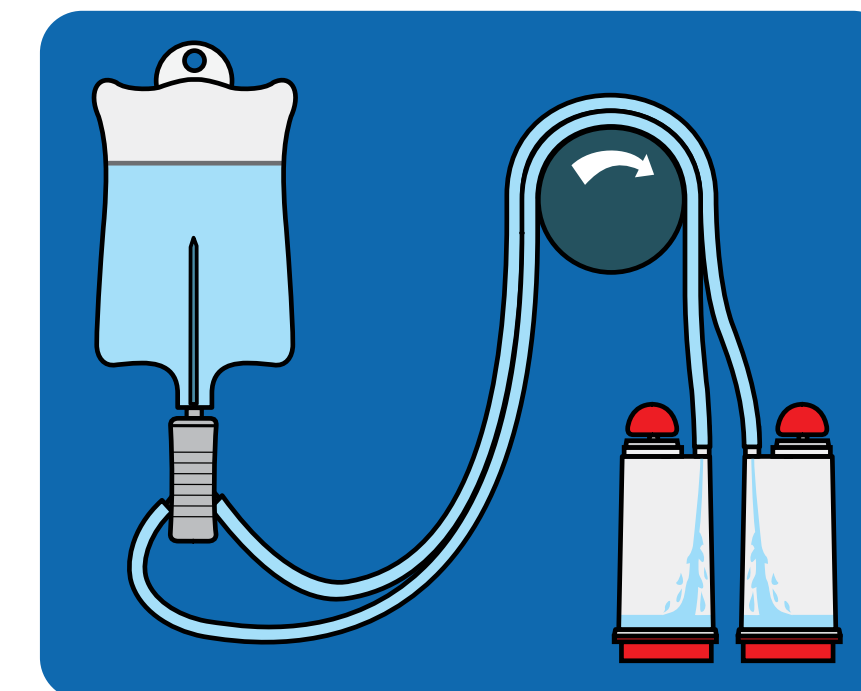
### Steritest® NEO Devices for Liquids in Collapsible Bags - Double-Packed (TZHVAB205)



- 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 “Red Base” Devices

for antibiotics, products WITH antimicrobial agents and medical devices



#### Application

Steritest® NEO Devices for Liquids

Steritest® NEO Devices for Liquids

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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 Powder

**NEW** Steritest® NEO Devices for L

#### Product #

#### More Information

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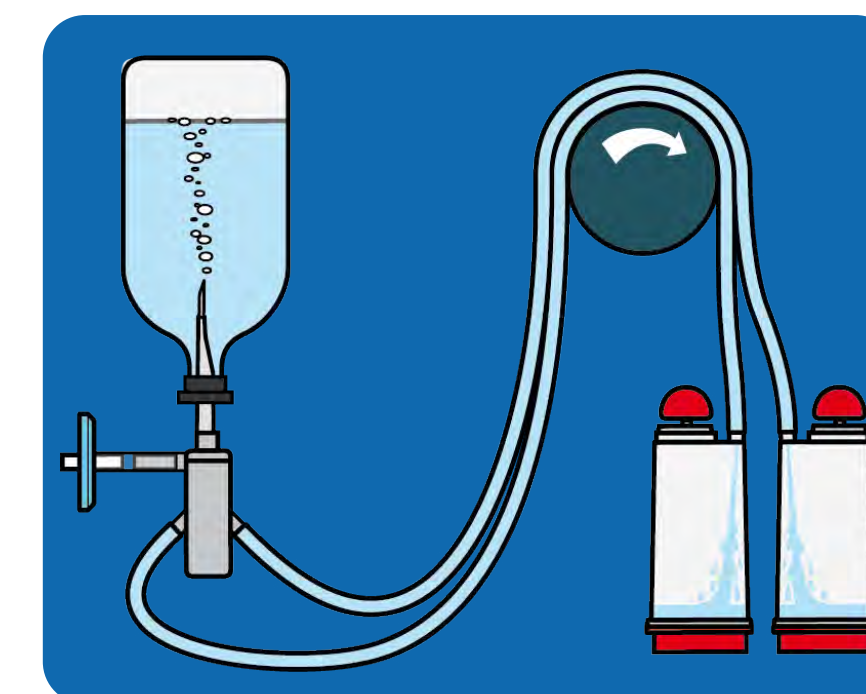
### Steritest® NEO Devices for Liquids in Large Vials (TZHVLV210)



- Vented double needle for large glass containers with septa

|  |   |
|--|---|
| Canister Base Membrane   | Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF   |
| Materials of Construction<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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

Steritest® NEO Devices for Liquids

Steritest® NEO Devices for Liquids

Steritest® NEO Devices for Liquids

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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 Powder

**NEW** Steritest® NEO Devices for L

#### Product #

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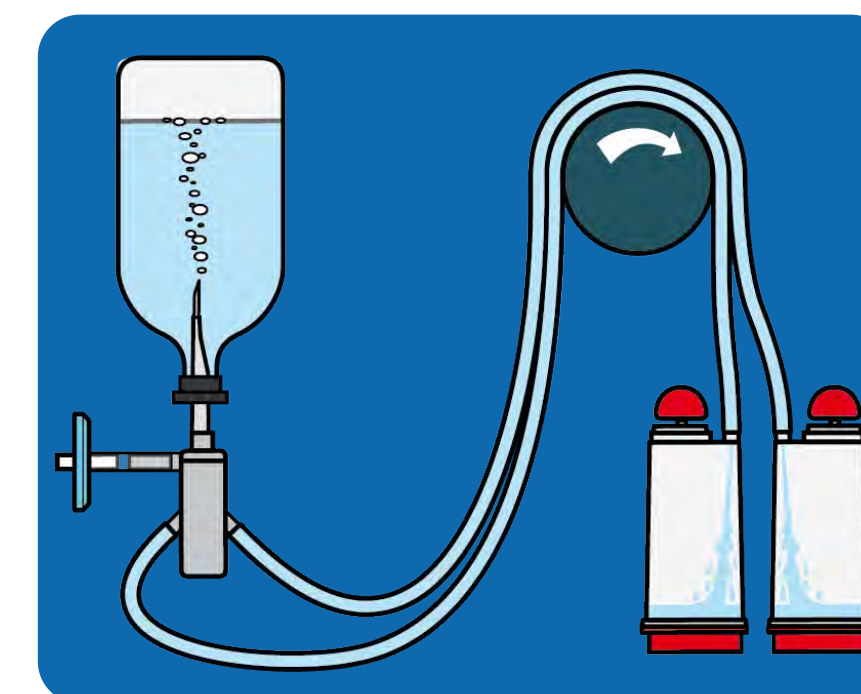
### Steritest® NEO Devices for Liquids in Large Vials - Double-Packed (TZHVLV205)



- 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 “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

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Steritest® NEO Devices for Liquids

Steritest® NEO Devices for Soluble

Steritest® NEO Devices for Soluble

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Steritest® NEO Devices for Powder

**NEW** Steritest® NEO Devices for L

#### Product #

#### More Information

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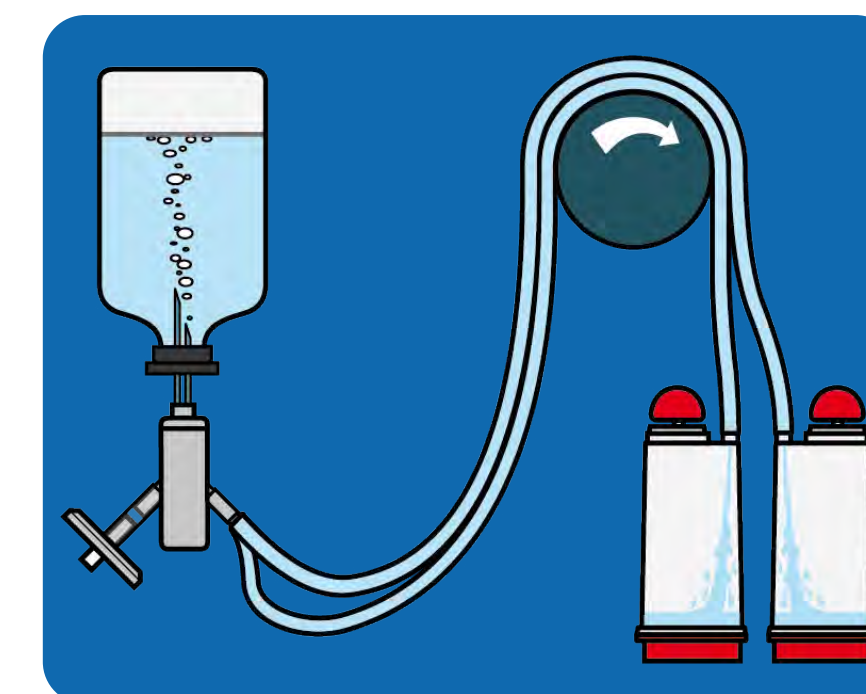
### Steritest® NEO Devices for Liquids in Small Vials (TZHVS210)



- Vented double needle for small vials with septa

|  |   |
|--|---|
| Canister Base Membrane   | Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF   |
| Materials of Construction<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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

Steritest® NEO Devices for Liquids

Steritest® NEO Devices for Liquids

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Steritest® NEO Devices for Soluble

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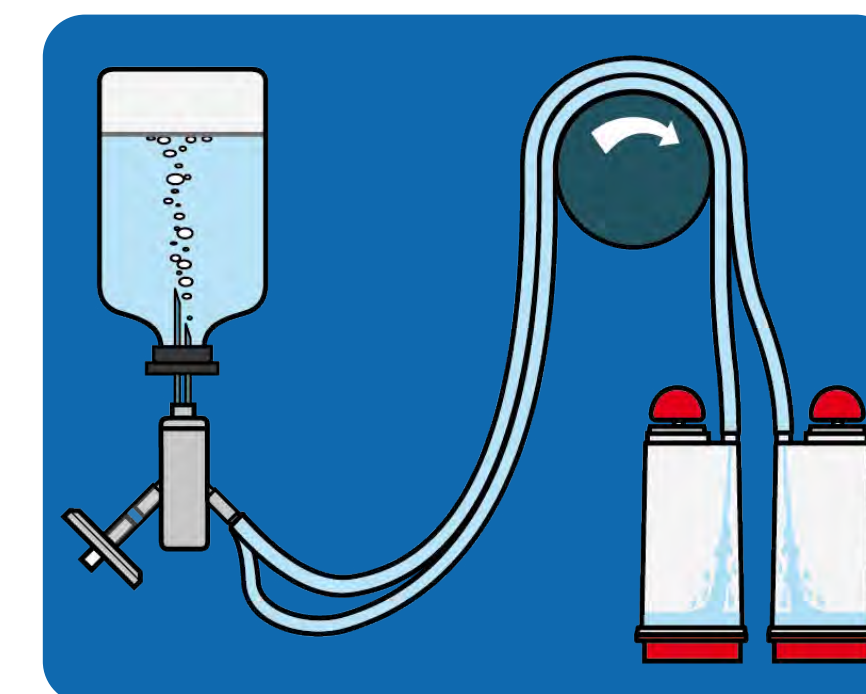
### Steritest® NEO Devices for Liquids in Small Vials - Double-Packed (TZHVS205)



- 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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### Steritest® NEO “Red Base” Devices

for antibiotics, products WITH antimicrobial agents and medical devices



#### Application

Steritest® NEO Devices for Liquids

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Steritest® NEO Devices for Liquids

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**NEW** Steritest® NEO Devices for L

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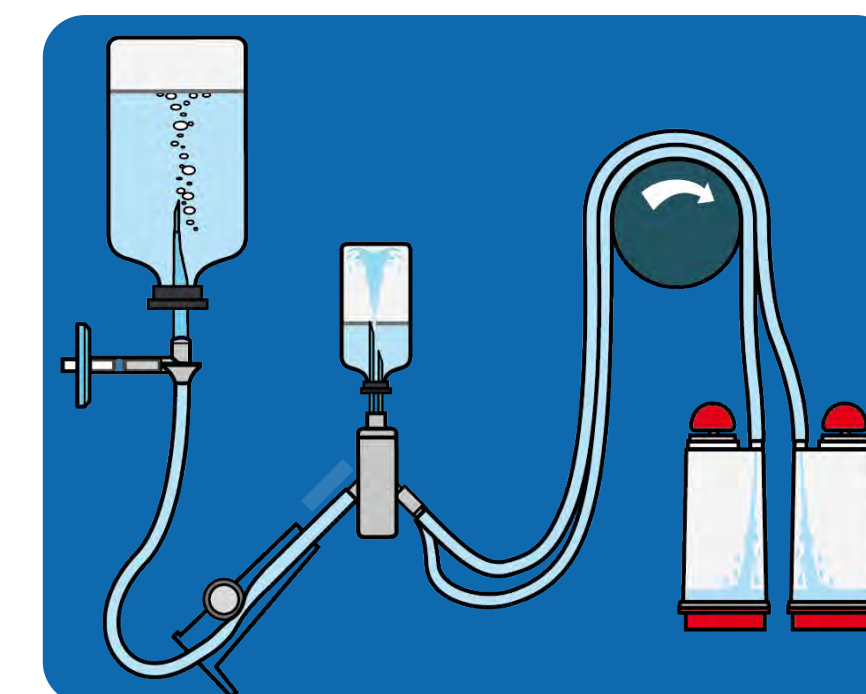
### Steritest® NEO Devices for Soluble Powders in Vials (TZHVDV210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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

Steritest® NEO Devices for Liquids

Steritest® NEO Devices for Liquids

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Steritest® NEO Devices for Liquids

Steritest® NEO Devices for Soluble

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Steritest® NEO Devices for Powder

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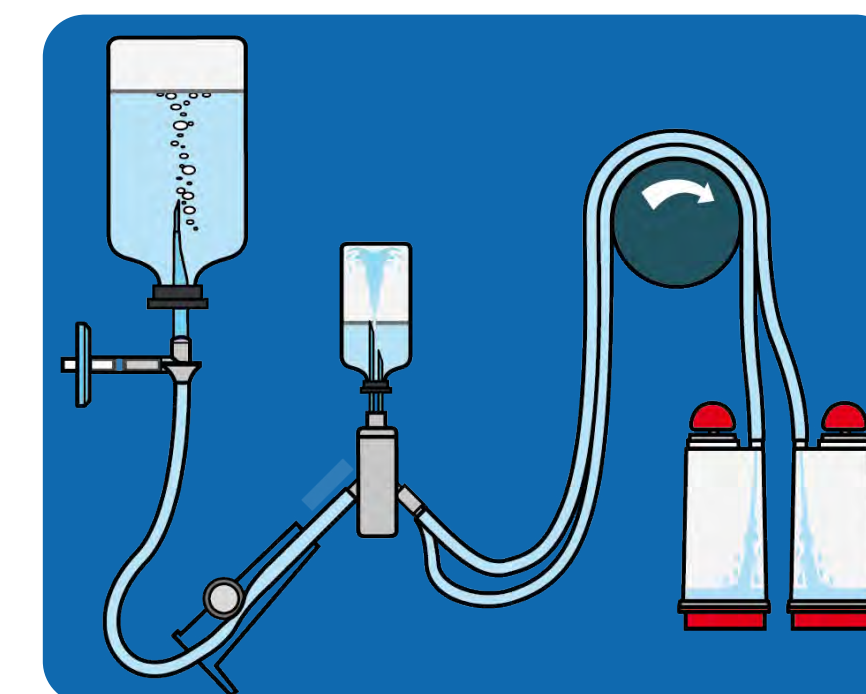
### Steritest® NEO Devices for Soluble Powders in Vials - Double-Packed (TZHVDV205)



- 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 “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

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Steritest® NEO Devices for Powder

**NEW** Steritest® NEO Devices for L

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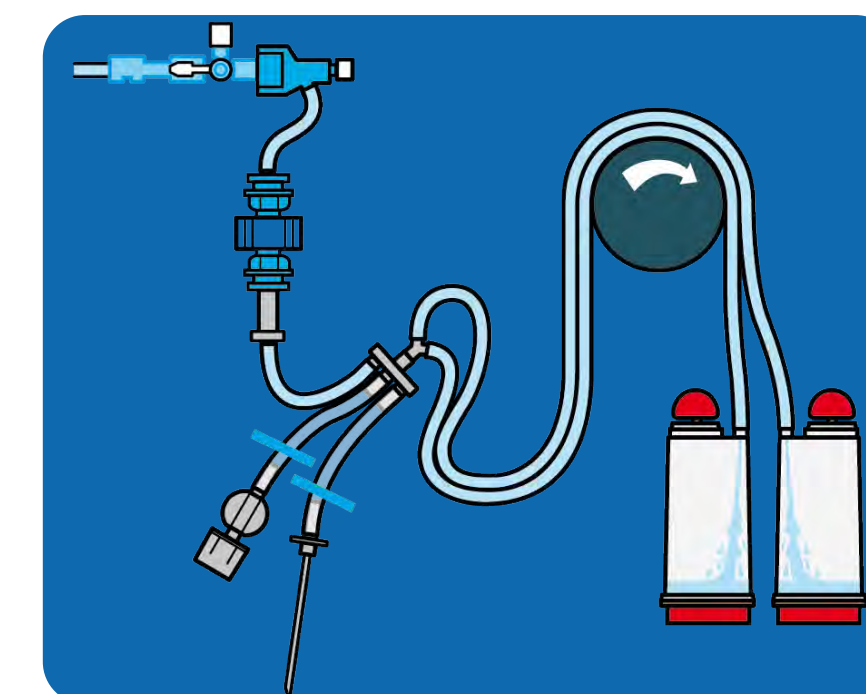
### Steritest® NEO Devices for Medical Devices and Collapsible Bags (TZHVM210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>Styrene acrylonitrile (SAN)<br>PVC, 850 mm length<br>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

Steritest® NEO Devices for Liquids

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Steritest® NEO Devices for Liquids

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#### Product #

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### 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 “Red Base” Devices

for antibiotics, products WITH antimicrobial agents and medical devices



#### Application

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Steritest® NEO Devices for Soluble

Steritest® NEO Devices for Soluble

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Steritest® NEO Devices for Powder

**NEW** Steritest® NEO Devices for L

#### Product #

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



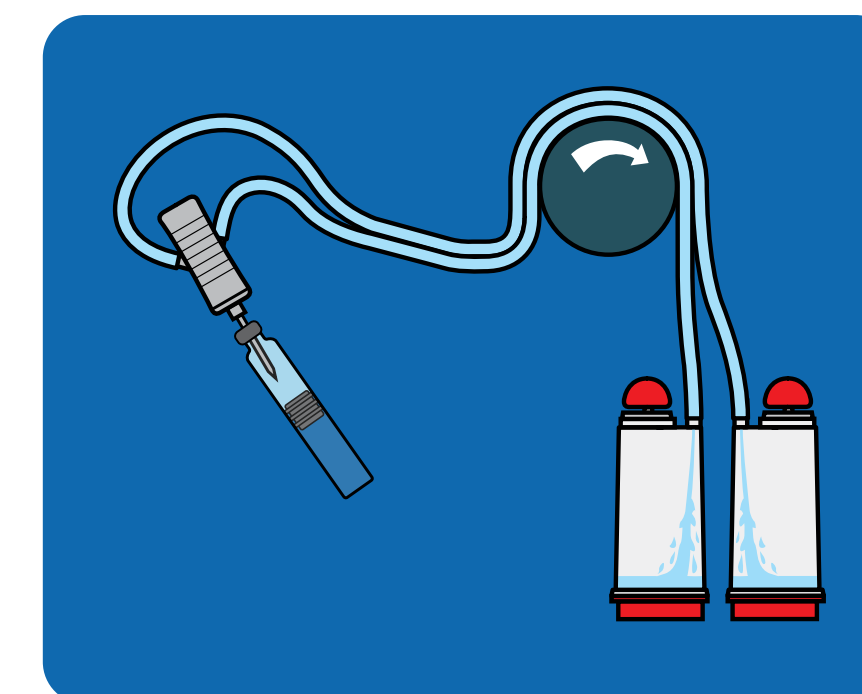
- Single short (20 mm) needle for easy access to cartridges and small soft plastic containers
- Separate vent needle



Watch the Video

|                                |   |
|--------------------------------|---|
| Canister Base Membrane         | Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF |
| Materials of Construction      |   |
| Primary blister:               | Shell made of PET, Cover made of Tyvek® paper               |
| Filtration Chamber (Canister): | Styrene acrylonitrile (SAN)                                 |
| Double Lumen Tubing:           | PVC, 850 mm length  |
| 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 “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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### 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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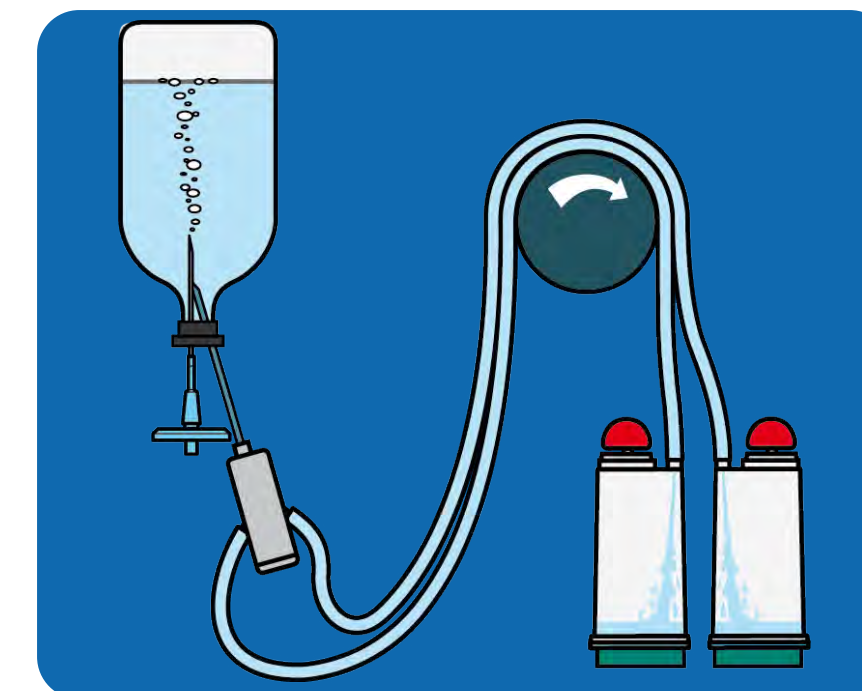
### Steritest® NEO Devices for Solvents, Creams, Ointments, and Veterinary Injectables (TZHVSL210)



- 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<br>Primary blister:<br>Filtration Chamber (Canister):<br>Double Lumen Tubing:<br>Needle: | Shell made of PET, Cover made of Tyvek® paper<br>polyamide 6-6 (nylon)<br>PVC, 850 mm length<br>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

Steritest® NEO Devices for Solvent  
and Veterinary Injectables

Sterile Irradiated Isopropyl Myristate

### Product #

### More Information

### Add to Cart

### 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 |                  |             |
| Steritest® needle guide + needle  | TZSPLKT10 |                  |             |
| Steritest® sampling needle-free valve   | TZNFVSP20 |                  |             |

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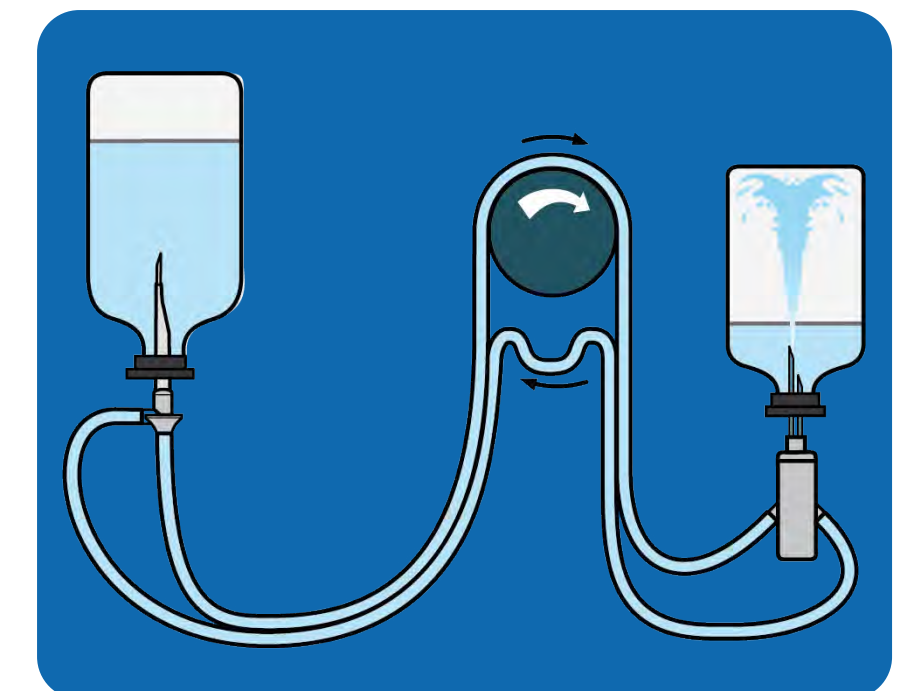
## Ordering Information

### 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   |           |                  |             |
| Steritest® needle guide + needle  |           |                  |             |
| Steritest® sampling needle-free vials   |           |                  |             |

### 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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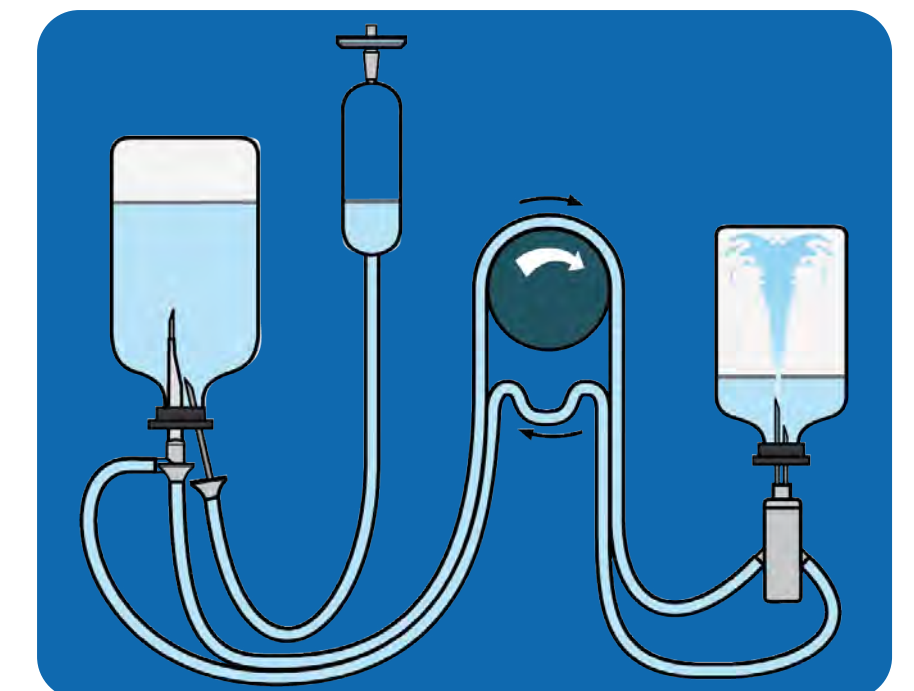
## Ordering Information

### 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   |           |                  |             |
| Steritest® needle guide + needle  |           |                  |             |
| Steritest® sampling needle-free vials   |           |                  |             |

### 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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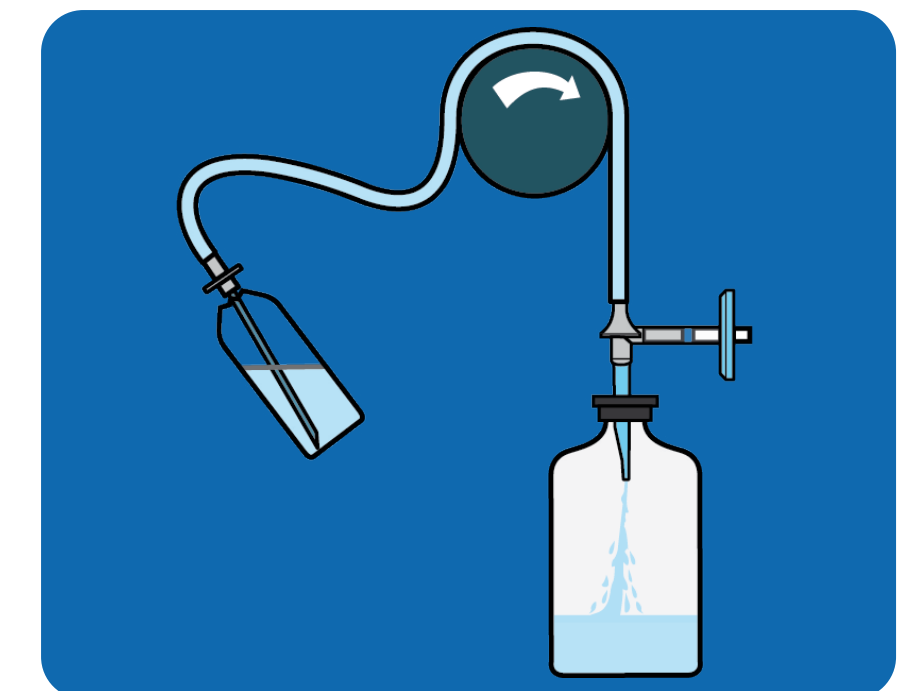
## Ordering Information

### Sterility Testing Accessories for Liquid Transfer and Dilution

| Application  | Product # | More Information | Add to Cart |
|--|-----------|------------------|-------------|
| Steridilutor® NEO Devices without Excess for Sample Preparation and Dilution |           |                  |             |
| Steridilutor® NEO Devices with Excess for Sample Preparation and Dilution    |           |                  |             |
| Steridilutor® NEO Devices for Liquid Transfer                                |           |                  |             |
| Steritest® Vent Needles  |           |                  |             |
| Steritest® needle guide + needle   |           |                  |             |
| Steritest® sampling needle-free vial   |           |                  |             |

### 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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## Ordering Information

### Sterility Testing Accessories for Liquid Transfer and Dilution

| Application  | Product # | More Information | Add to Cart |
|--|-----------|------------------|-------------|
| Steridilutor® NEO Devices without Excess for Sample Preparation and Dilution |           |                  |             |
| Steridilutor® NEO Devices with Excess for Sample Preparation and Dilution    |           |                  |             |
| Steridilutor® NEO Devices for Liquid Transfer                                |           |                  |             |
| Steritest® Vent Needles  |           |                  |             |
| Steritest® needle guide + needle   |           |                  |             |
| Steritest® sampling needle-free vials  |           |                  |             |

### 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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## Benefits

## Regulations

## Culture Media

## Rinsing Fluids

## Double Packed

## Customized Culture Media

## Closure Caps

## Ordering Information

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## Complete Sterility Testing Offer

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

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



## Request information





Culture Media &  
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## 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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**Culture Media &  
Rinsing Fluids**

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## Video

Production of Sterility Testing Culture Media & Fluids in our  
Center of Excellence, Molsheim, France



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**Culture Media &  
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## 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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**Culture Media &  
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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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**Culture Media &  
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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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## Regulations and Industry benchmark



### 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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## 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

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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 | 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 | 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 | 100 mL      | 12     | STBMCTM12DP |                  |             |
|  | Crimp cap with septum                 | 100 mL      | 10     | 1.46456     |                  |             |

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Culture Media & Rinsing Fluids

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# Ordering Information

## Sterility Testing Culture Media

| Culture Media bottle | Closure | Volume (mL) | Qty/pk | Product # | More Information | Add to Cart |
|----------------------|---------|-------------|--------|-----------|------------------|-------------|
|----------------------|---------|-------------|--------|-----------|------------------|-------------|

Soybean-Casein Digest Medium (Tryptcase Soy Broth, TSB)

Screw cap with septum

100 mL

12

STBMTSB12



Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

## Tryptcase 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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# 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



### 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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# Ordering Information

## Sterility Testing Culture Media

| Culture Media bottle | Closure | Volume (mL) | Qty/pk | Product # | More Information | Add to Cart |
|----------------------|---------|-------------|--------|-----------|------------------|-------------|
|----------------------|---------|-------------|--------|-----------|------------------|-------------|

Soybean-Casein Digest Medium (Tryptcase Soy Broth, TSB)

Screw cap with septum

100 mL

12

STBMTSB12



Fluid Thioglycollate Medium, FTM

Clear Thioglycollate Medium, CTM

### Tryptcase 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 |
|----------------------|---------|-------------|--------|-----------|------------------|-------------|
|----------------------|---------|-------------|--------|-----------|------------------|-------------|

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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# 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



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 |
|----------------------|---------|-------------|--------|-----------|------------------|-------------|
|----------------------|---------|-------------|--------|-----------|------------------|-------------|

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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# 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



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 |
|----------------------|---------|-------------|--------|-----------|------------------|-------------|
|----------------------|---------|-------------|--------|-----------|------------------|-------------|

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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# 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



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 | 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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## Sterility Testing Rinsing Fluids

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

### Rinsing Fluid USP Rinse Fluid A (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

## Solvent

Rinse fluid solution bottle

Sterile Isopropyl Myristate (IPM)

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## Sterility Testing Rinsing Fluids

| Rinse fluid solution bottle | Closure | Volume (mL) | Qty/pk | Product # | More Information | Add to Cart |
|-----------------------------|---------|-------------|--------|-----------|------------------|-------------|
|-----------------------------|---------|-------------|--------|-----------|------------------|-------------|

USP Rinse Fluid A

900 mL

4

STBMRFA94



### Rinsing Fluid USP Rinse Fluid A (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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USP Rinse Fluid D

USP Rinse Fluid K

### Solvent

Rinse fluid solution bottle

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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 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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## Sterility Testing Rinsing Fluids

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

### Rinsing Fluid USP Rinse Fluid A (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) |



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USP Rinse Fluid D

USP Rinse Fluid K

## Solvent

Rinse fluid solution bottle

Sterile Isopropyl Myristate (IPM)

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## Sterility Testing Rinsing Fluids

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

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

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

|                        |  |
|------------------------|--|
| Closure                | Screw cap with septum – double packed  |
| Volume (mL)            | 100 mL   |
| Packaging              | 12 per pack  |
| Sterilization          | Autoclaving + Ethylene oxide   |
| Color                  | Clear, with no precipitate and free of visible particles   |
| Shelf life             | 12 months  |
| pH at 25 °C            | pH 7.1 ±0.2  |
| Storage conditions     | Room Temperature (2 to 25 °C)  |
| Regulatory conformance | USP <71>, EP <2.6.1>, JP <4.06>  |
| QC organisms           | <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

## Solvent

Rinse fluid solution bottle

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## Sterility Testing Rinsing Fluids

| Rinse fluid solution bottle | Closure | Volume (mL) | Qty/pk | Product # | More Information | Add to Cart |
|-----------------------------|---------|-------------|--------|-----------|------------------|-------------|
|-----------------------------|---------|-------------|--------|-----------|------------------|-------------|

USP Rinse Fluid A

900 mL

4

STBMRFA94



### Rinsing Fluid USP Rinse Fluid A (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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USP Rinse Fluid D

USP Rinse Fluid K

### Solvent

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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 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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## 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 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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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 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) |



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USP Rinse Fluid K

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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 D

USP Rinse Fluid K

## Solvent

Rinse fluid solution bottle

Sterile Isopropyl Myristate (IPM)

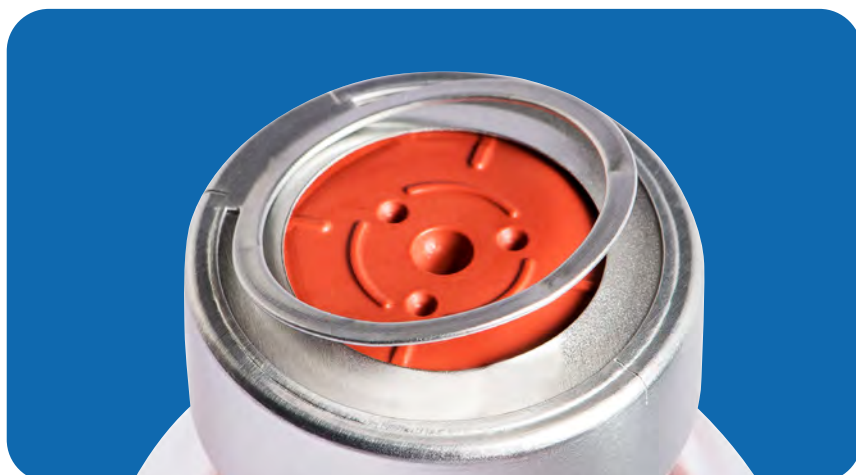
## Sterile Isopropyl myristate (IPM) (146628)

- Improve dissolution of viscous products, ointments and creams prior to membrane filtration
- Sterilized and ready-to-use
- To be use in combination of the Steritest® NEO Green base (TZHVSL210)

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

Order Now

DP = Double Packed



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Benefits

Regulations

Culture Media

Rinsing Fluids

Double Packed

Customized  
Culture Media

Closure Caps

Ordering Information

Video - Manufacturing

Complete Sterility  
Testing Offer

## Double-Packed Sterility Testing Media & Rinse Fluids

### Gamma Sterilized

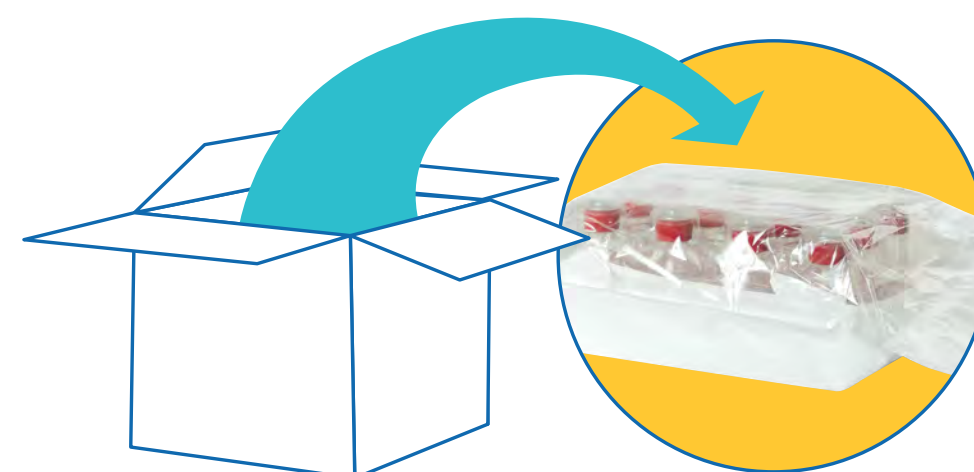
Sterility testing culture media and rinsing fluids are also available in a double-packed format. The sterilized double Tyvek® packaging helps to minimize the risk of cross-contamination in laminar flow hoods and to secure an efficient decontamination of isolator chambers. These products are supplied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

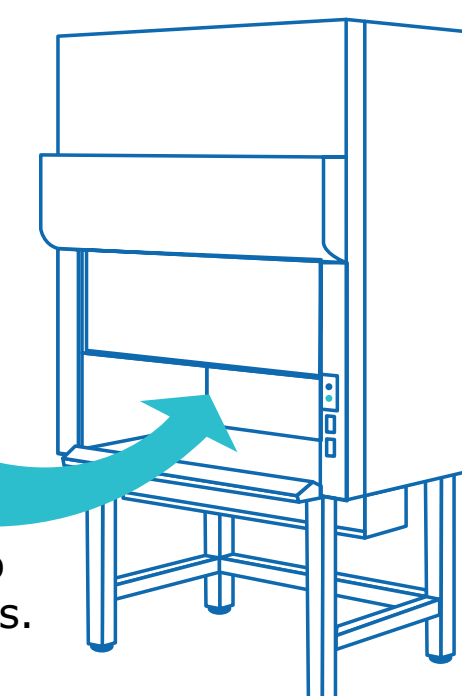
Bag Transfer

##### Classified Room

Bag opening and  
transfer of devices



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



Request information



Culture Media &  
Rinsing Fluids

Benefits

Regulations

Culture Media

Rinsing Fluids

Double Packed

Customized  
Culture Media

Closure Caps

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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.



Make a request

Request information





Culture Media &  
Rinsing Fluids

Benefits

Regulations

Culture Media

Rinsing Fluids

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Customized  
Culture Media

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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.



Request information





Culture Media & Rinsing Fluids

Benefits

Regulations

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Rinsing Fluids

Double Packed

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Culture Media and Diluting/Rinsing Fluids

Culture Media



Material Table

Solvent



Material Table

Rinsing Fluids



Material Table





**Pumps &  
Accessories**

**Benefits**

**Perfect Fit for Your  
Testing Environment**

**Video**

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**Onscreen Guidance**

**Software**

**Smart Accessories**

**Ordering Information**

**Complete Sterility  
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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.



**Request information**



**Pumps &  
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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 &  
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## Benefits

**Easy-to-Use**

**Reliable**

**Safe**

**Ergonomic**

**User-Friendly**

### Reliable

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

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**Pumps &  
Accessories**

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## Benefits

**Easy-to-Use**

**Reliable**

**Safe**

**Ergonomic**

**User-Friendly**

### Safe

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

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## Benefits

**Easy-to-Use**

**Reliable**

**Safe**

**Ergonomic**

**User-Friendly**

### Ergonomic

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

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## Benefits

**Easy-to-Use**

**Reliable**

**Safe**

**Ergonomic**

**User-Friendly**

### User-Friendly

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

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## 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.

Ordering information

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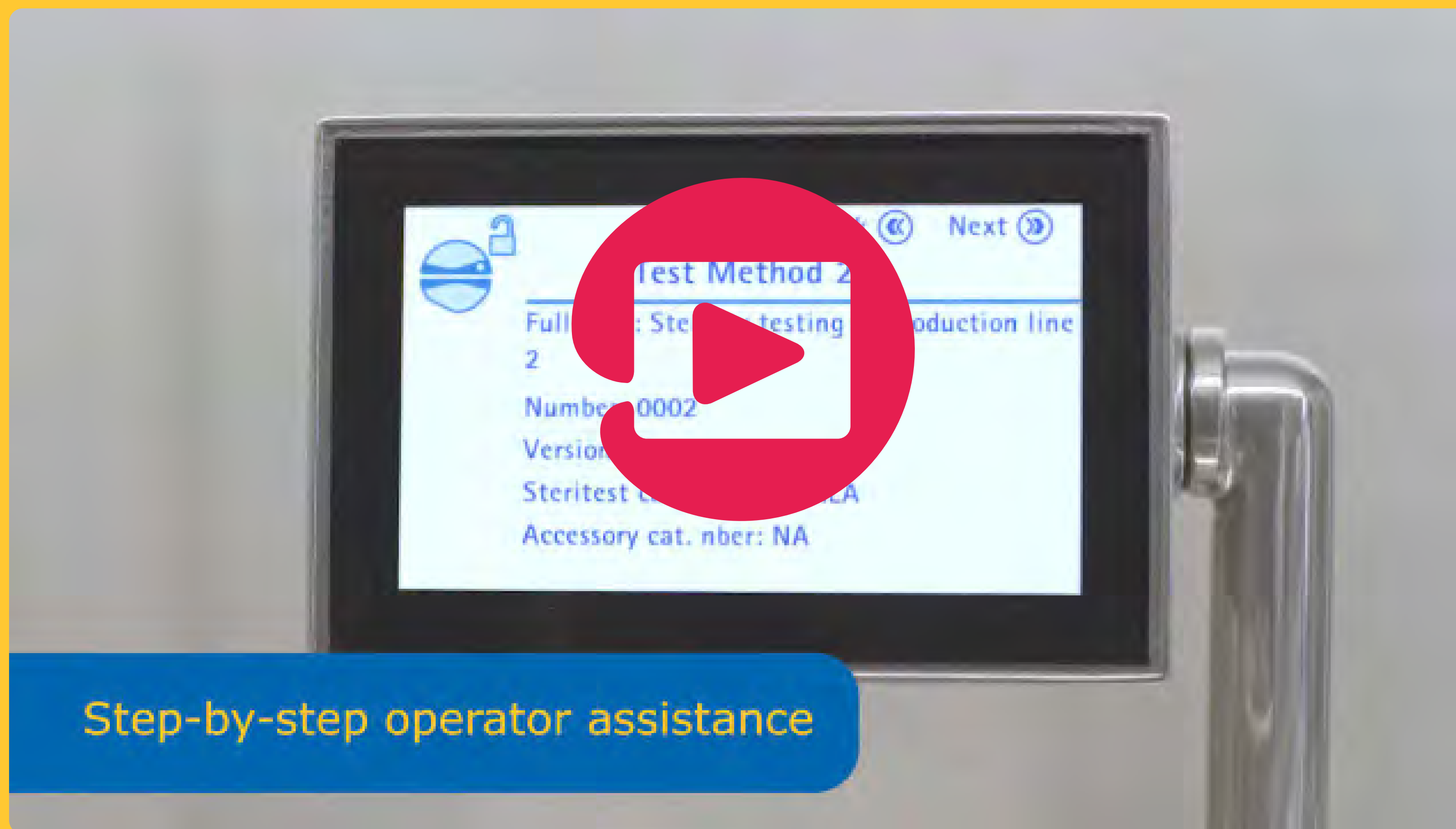
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## Video



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Pumps & Accessories

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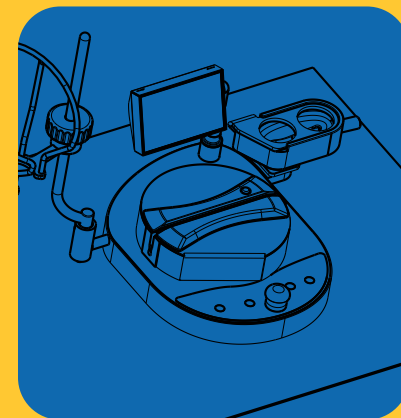
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## Specifications - Steritest® Symbio Pumps

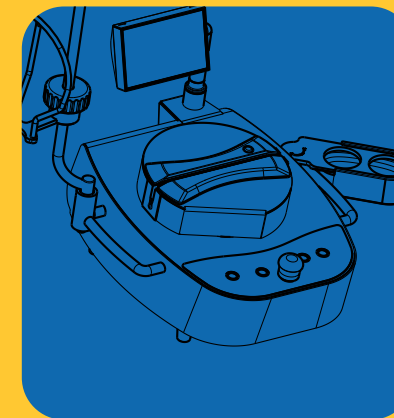
### Isolator

Steritest® Symbio ISL



### Laminar flow hood

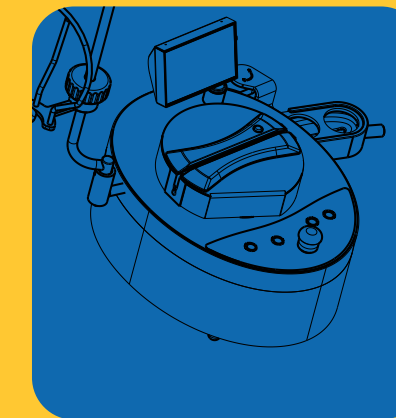
Steritest® Symbio LFH



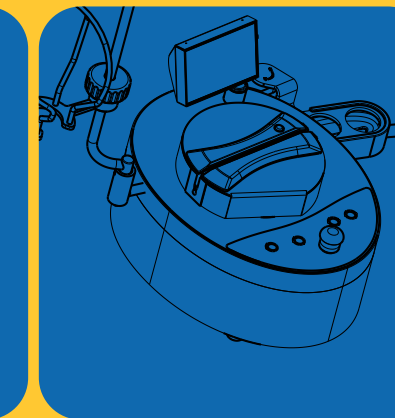
### Multiple ways (isolator or a laminar flow hood)

Steritest® Symbio FLEX

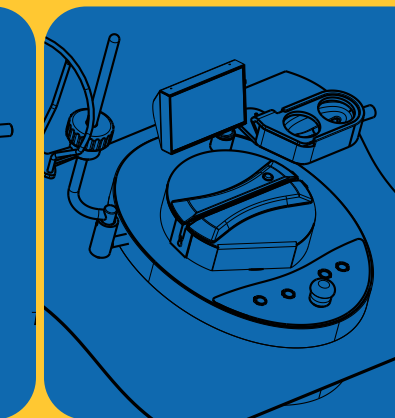
On feet in a laminar flow hood



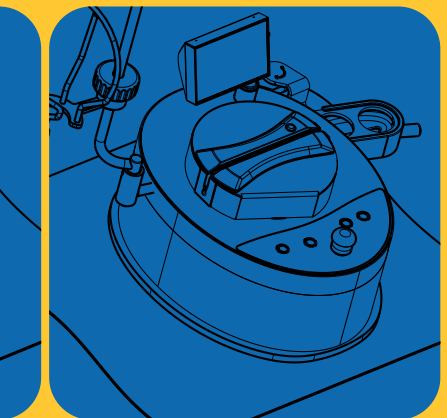
On feet in an isolator



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



**Pumps &  
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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](http://SigmaAldrich.com/steritest-software) and install it on your laboratory computer

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

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

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

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



[Download the software](#)

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[Request information](#)



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## Smart accessories for streamlining your workflow and increasing safety

### Procedure Step

**Testing  
Environment  
Setup**

**Sample  
Handling**

**Filtration**

**Waste  
Management**

**Transport and  
Incubation**

### **Steritest® Communication Hub Holder for Hoods**



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

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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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## Smart accessories for streamlining your workflow and increasing safety

### Procedure Step

Testing  
Environment  
Setup

Sample  
Handling

Filtration

Waste  
Management

Transport and  
Incubation



Watch the Video

### 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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**Pumps &  
Accessories**

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## Smart accessories for streamlining your workflow and increasing safety

### Procedure Step

Testing  
Environment  
Setup

Sample  
Handling

**Filtration**

Waste  
Management

Transport and  
Incubation

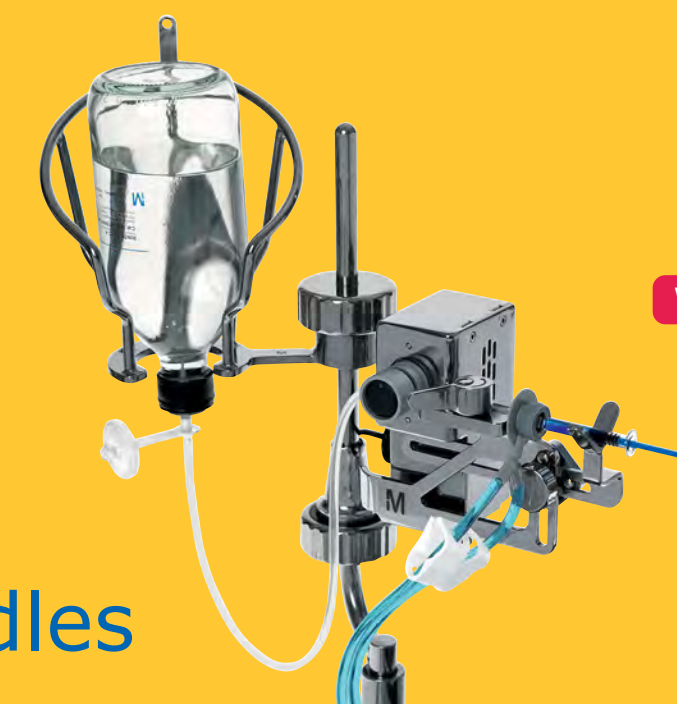
### Steritest® Holder for Sterile Bags

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



### Steritest® Syringe Support

- Safe handling of syringes with needles
- Automatic dispensing of sterile fluid to dilute the content of the syringes, eliminating the need to turn the dilution bottle between syringes during testing



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**Order Now**

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**Pumps &  
Accessories**

**Benefits**

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## Smart accessories for streamlining your workflow and increasing safety

### Procedure Step

Testing  
Environment  
Setup

Sample  
Handling

Filtration

Waste  
Management

Transport and  
Incubation

### Steritest® Waste Overfilling Sensor for Solid Containers

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



**Watch the Video**



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**Pumps &  
Accessories**

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## Smart accessories for streamlining your workflow and increasing safety

### 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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Pumps & Accessories

Benefits

Perfect Fit for Your Testing Environment

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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  
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Training

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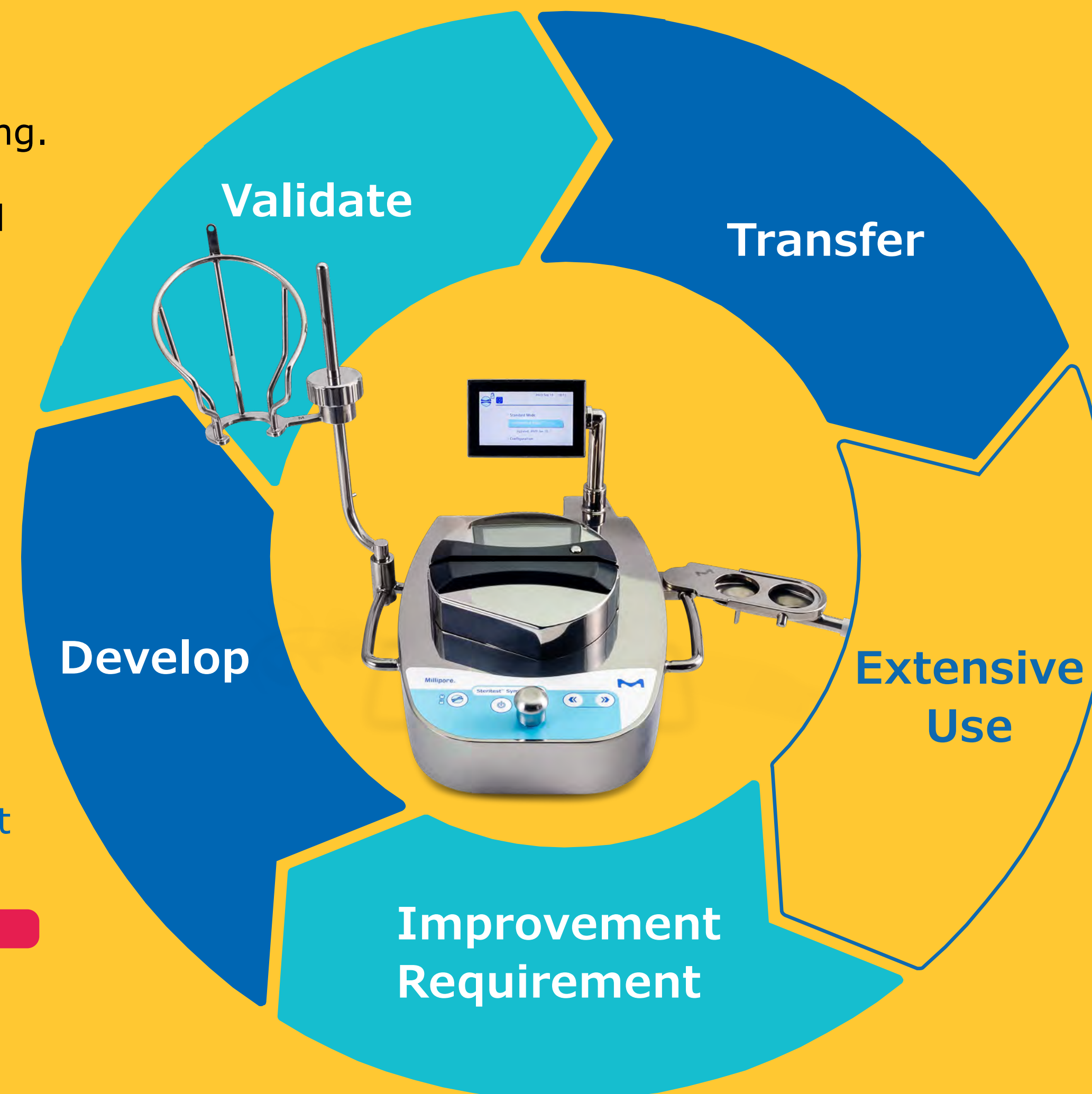
## A team of experts

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





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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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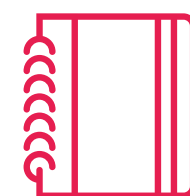
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## Validation protocols

Digital validation  
protocols

Validation workflow  
on Val@M™



### 1. Validation Master Plan

- Defined structure, responsibilities for qualification



### 3. Operational Qualification (OQP)

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



### 2. Installation Qualification (IQP)

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



### 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

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



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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

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## Training offer

### BEST training

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

- Result interpretation
- Method lifecycle
- Product portfolio
- Product demo
- Hands-on training
- Take preventive actions to avoid false positive or false negative test results
- Develop and optimize testing procedures
- Understand and identify root causes for common issues
- Certificate of attendance

Our best Application Expert Trainers now also run a series of remote training events.

For availability of BEST training and services, contact us

### 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 BEST training and services, contact us

Request information



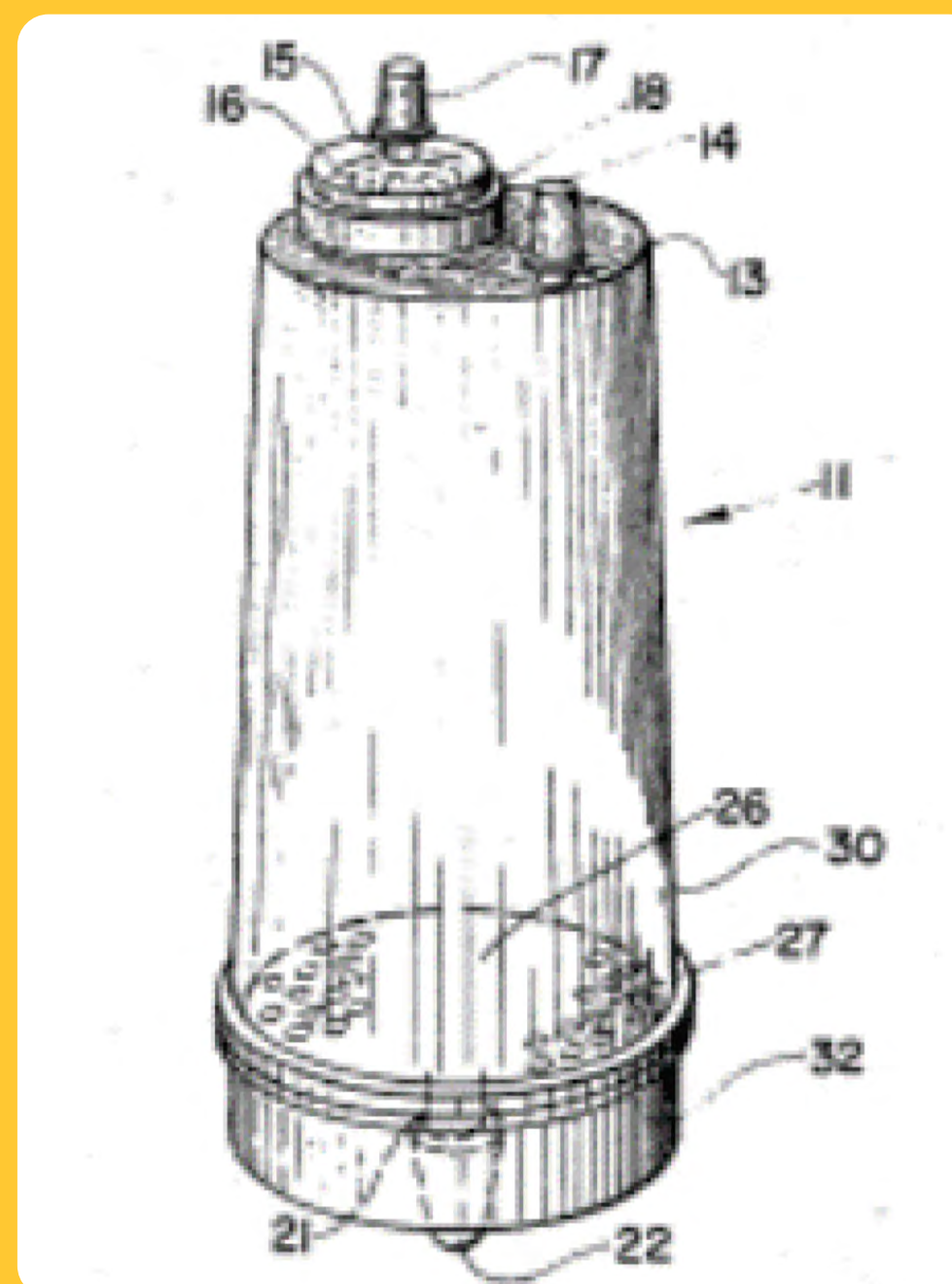


## You all know the Steritest® system, but DO YOU KNOW THE STORY OF ITS INVENTION?



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 >





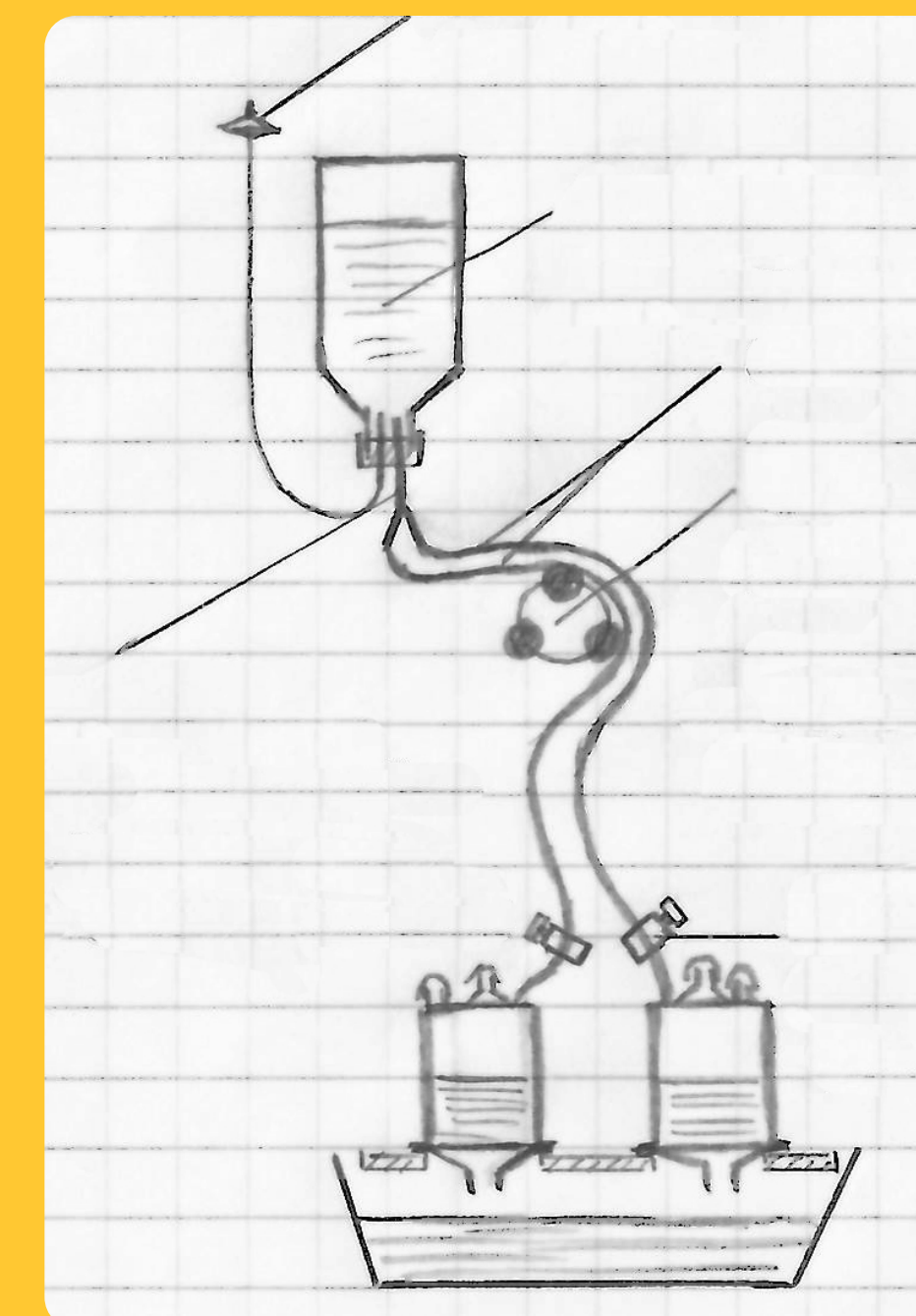
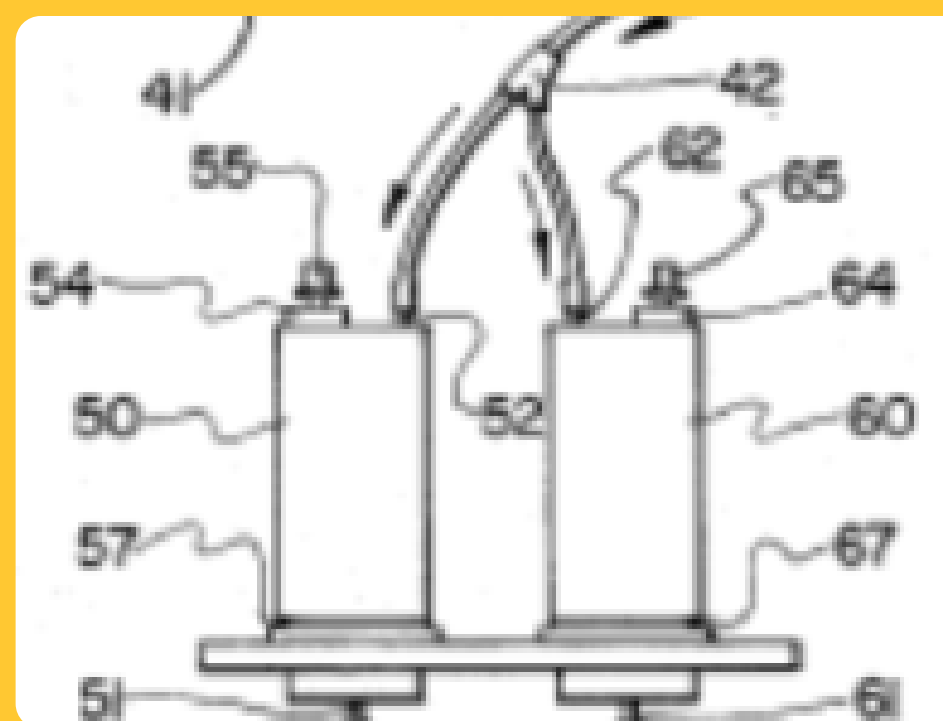
## Is the Steritest® system the result of in-depth market research or of a gut feeling?



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.



**50 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



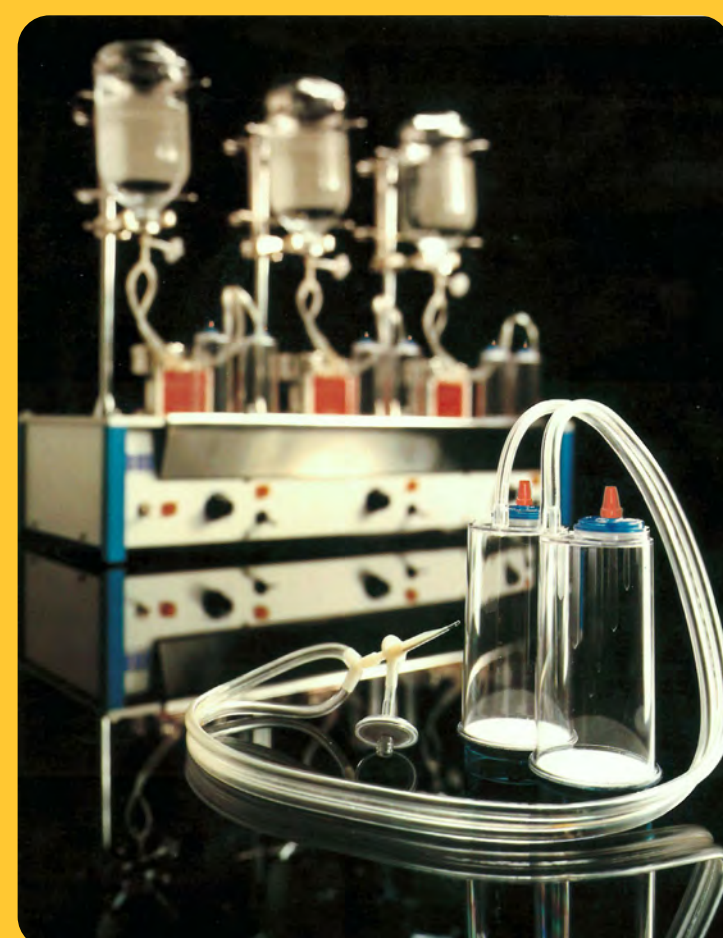
In 2024, the Steritest® system is celebrating its 50<sup>th</sup> anniversary as a commercial product. Curiosity and innovation still motivate our teams.

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 50 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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## 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?

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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## 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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## 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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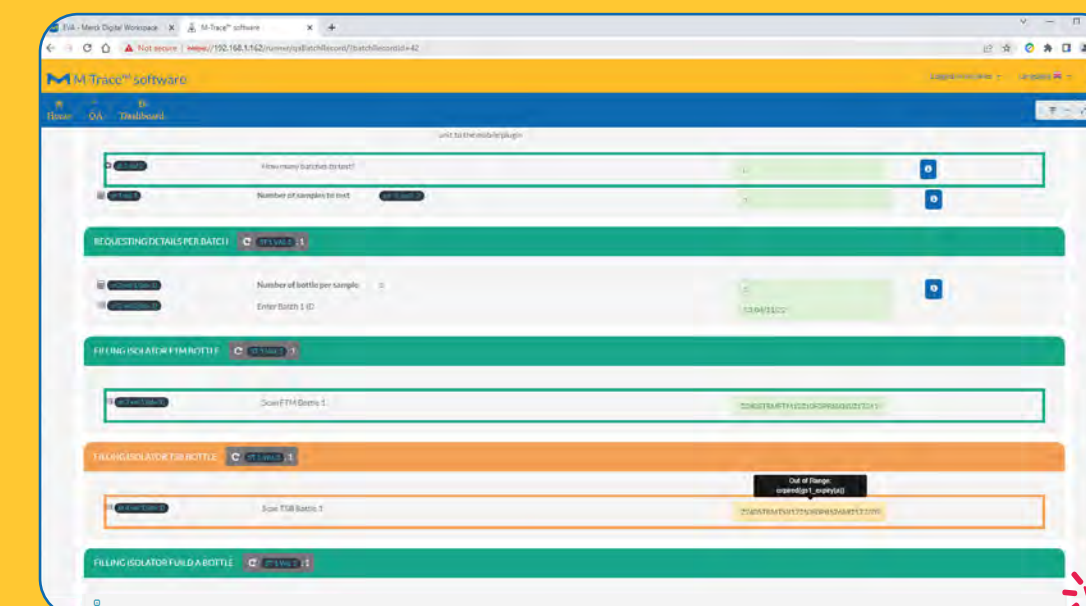
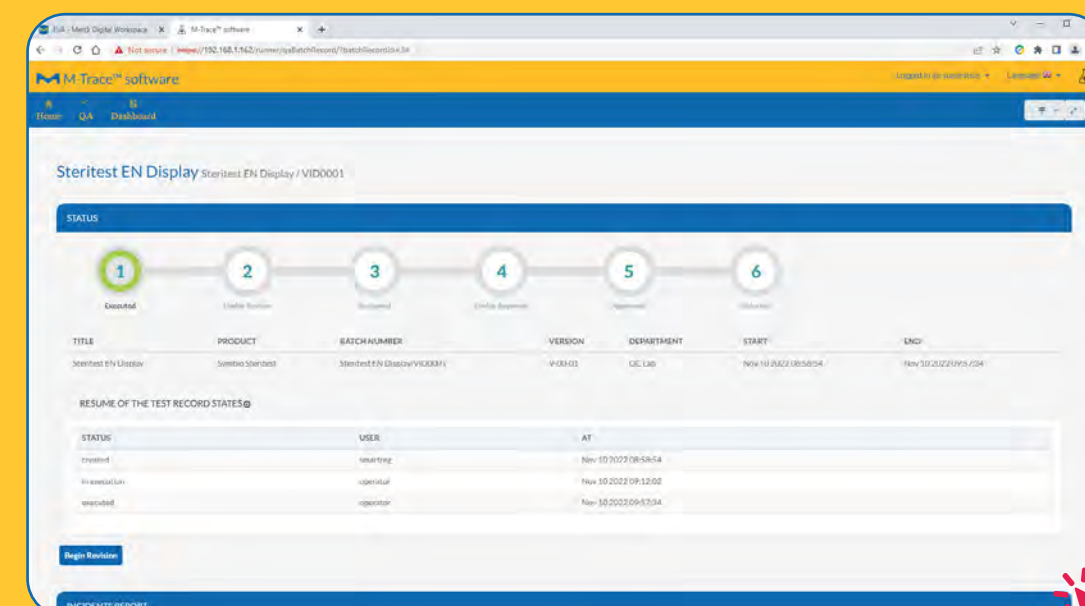
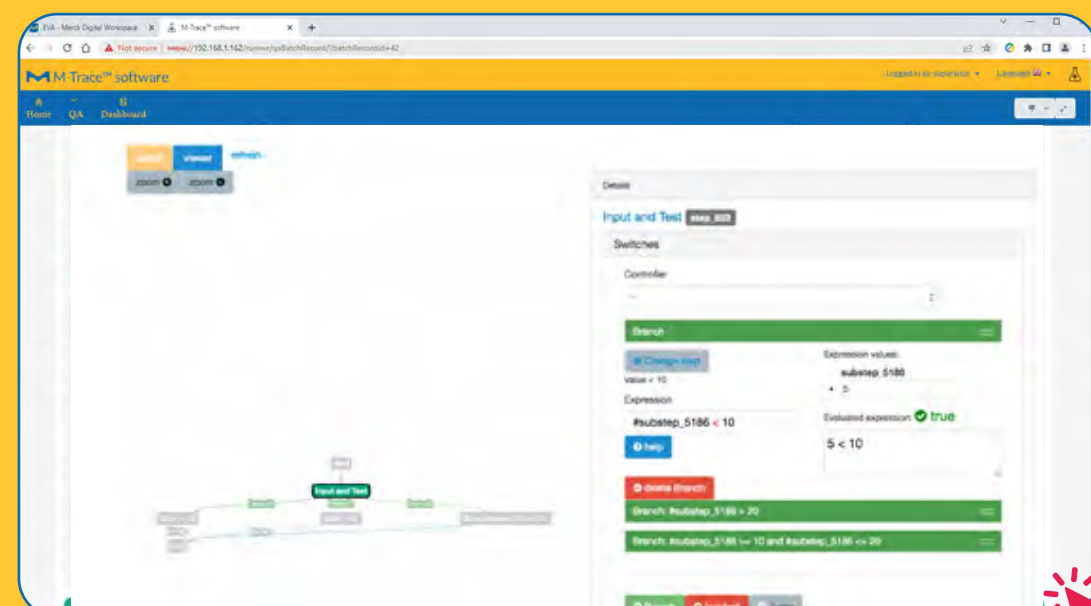
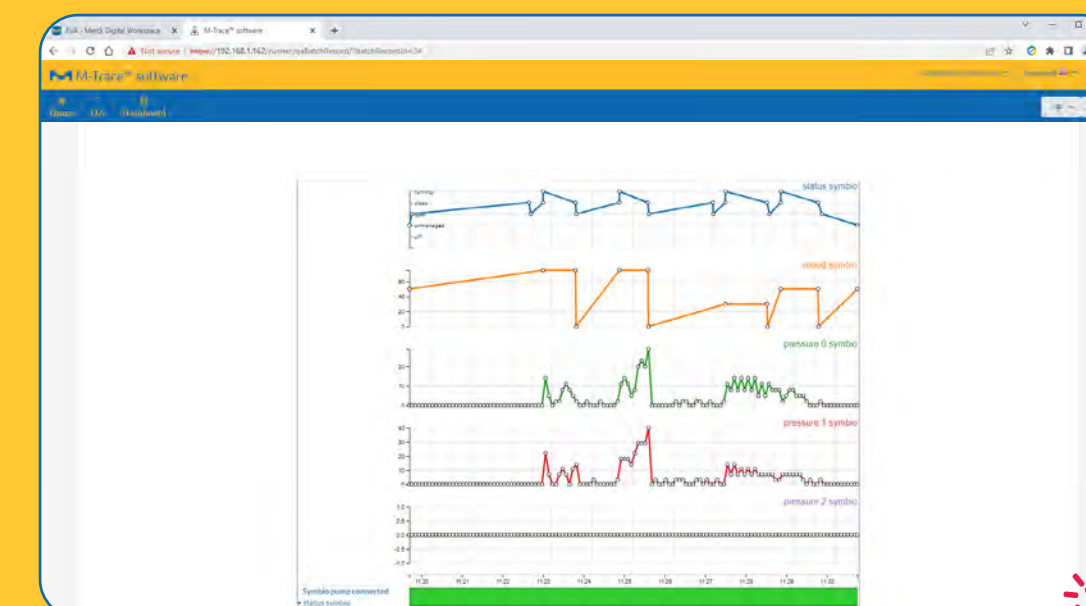
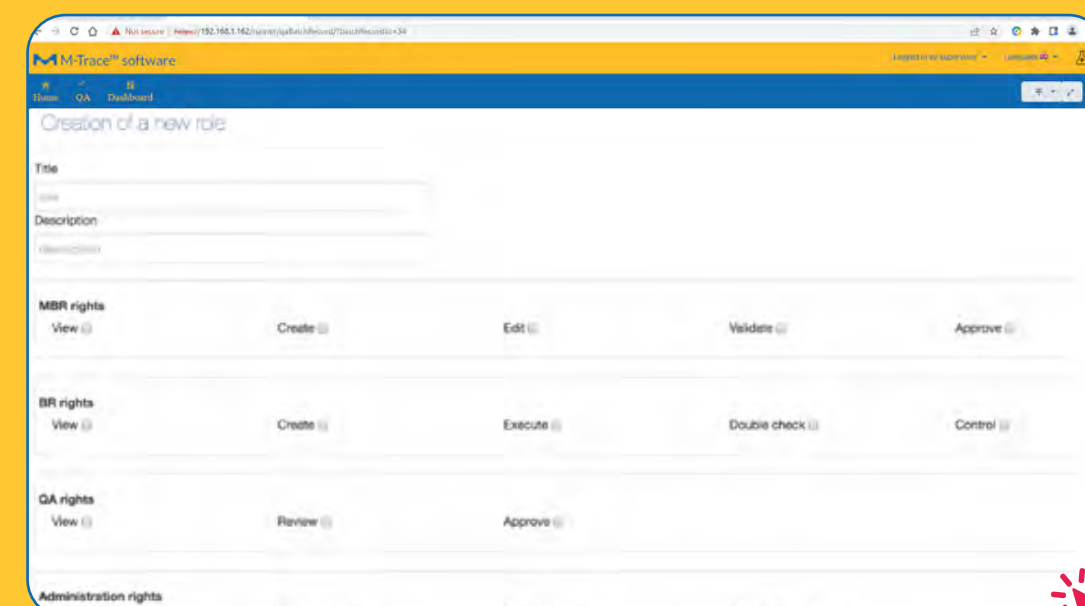
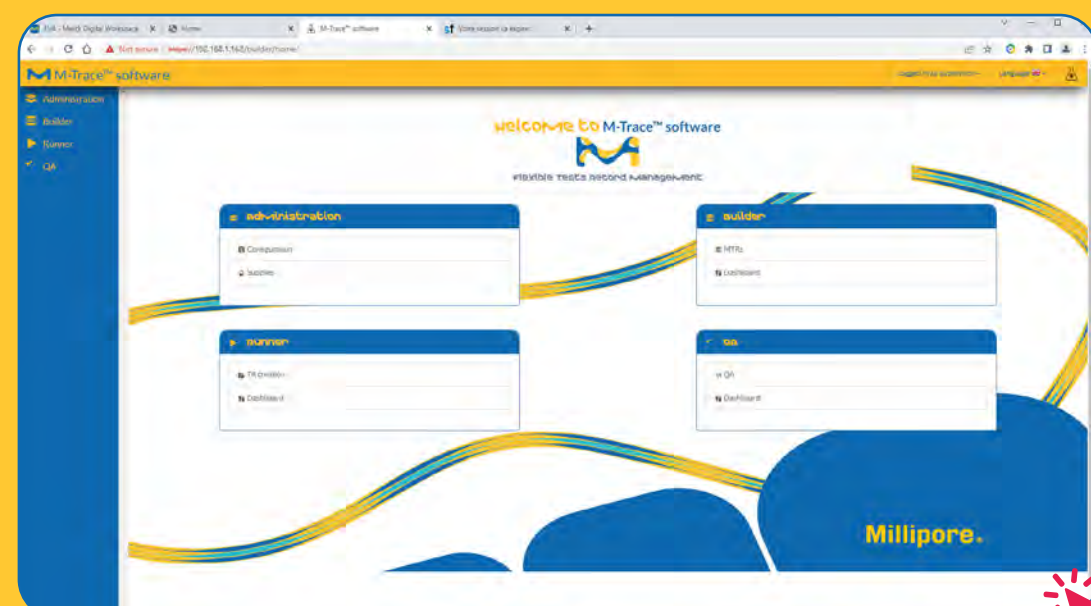
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# Boost Productivity, Ensure Compliance

with the M-Trace® solution



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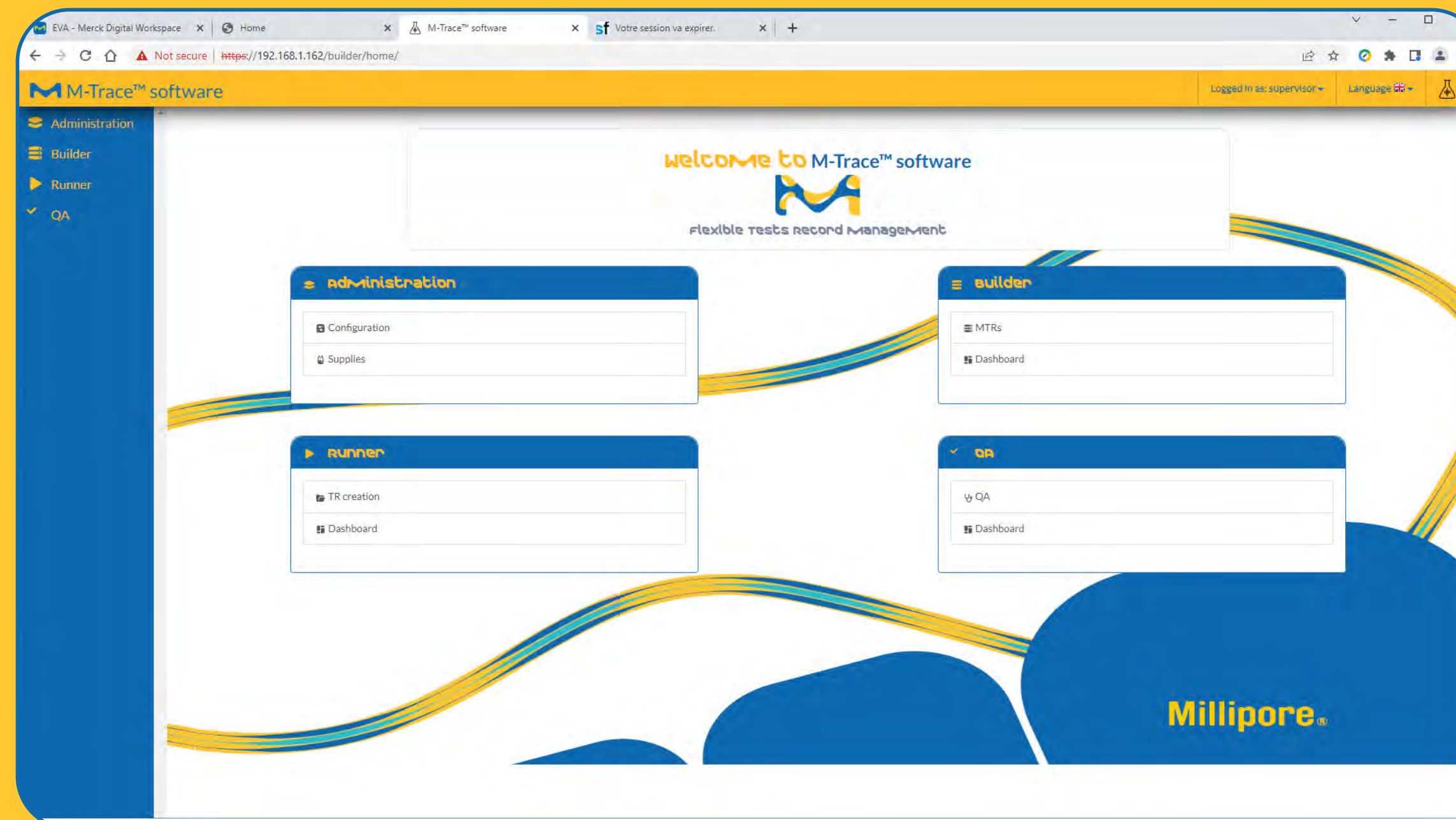
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## Boost Productivity, Ensure Compliance

with the M-Trace® solution



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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## Boost Productivity, Ensure Compliance

with the M-Trace® solution



M-Trace™ software

Home QA Dashboard

Creation of a new role

Title

Description

|                       |      |        |         |              |         |
|-----------------------|------|--------|---------|--------------|---------|
| MBR rights            | View | Create | Edit    | Validate     | Approve |
| BR rights             | View | Create | Execute | Double check | Control |
| QA rights             | View | Review | Approve |              |         |
| Administration rights |      |        |         |              |         |

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

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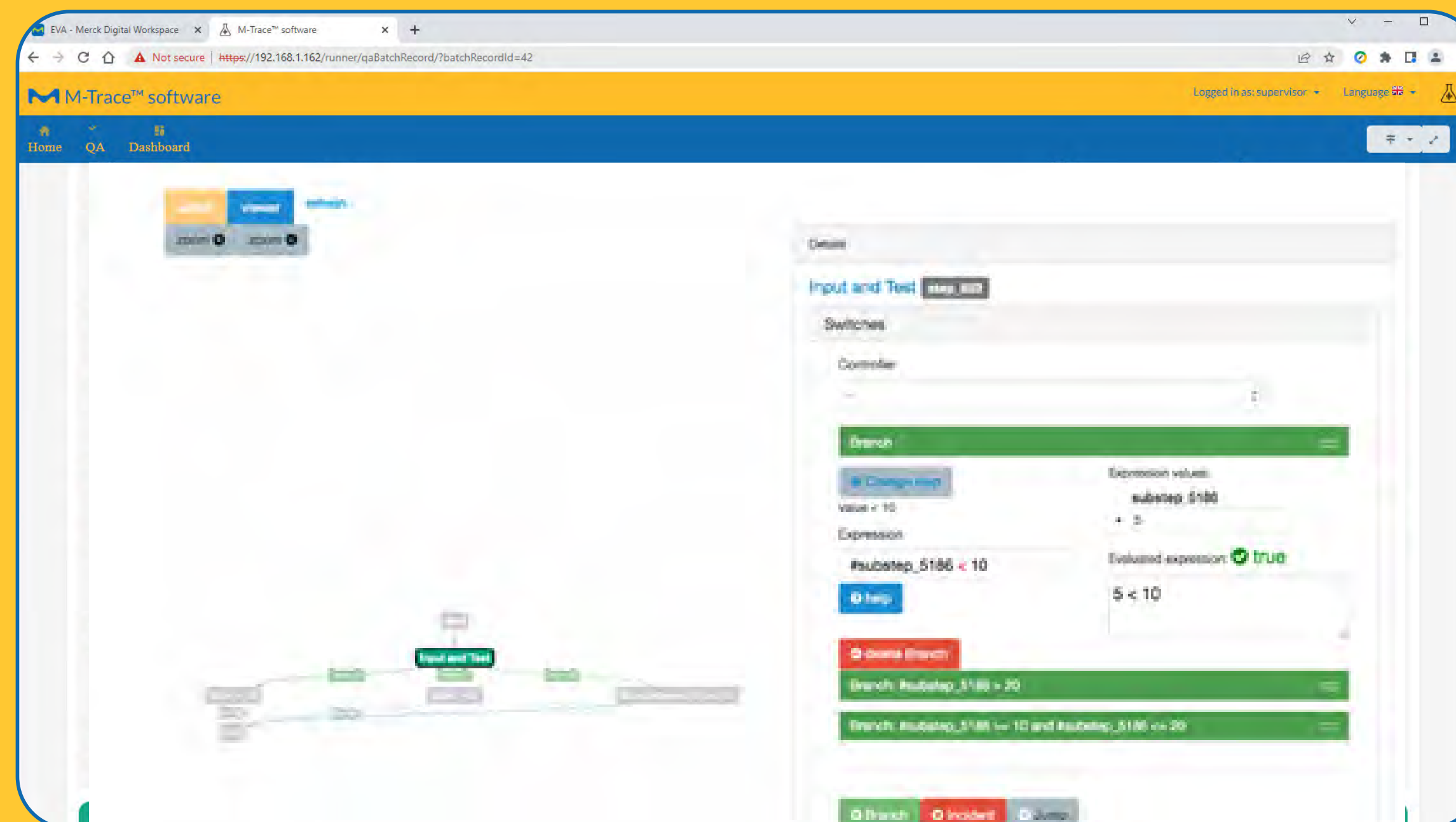
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## Boost Productivity, Ensure Compliance

with the M-Trace® solution



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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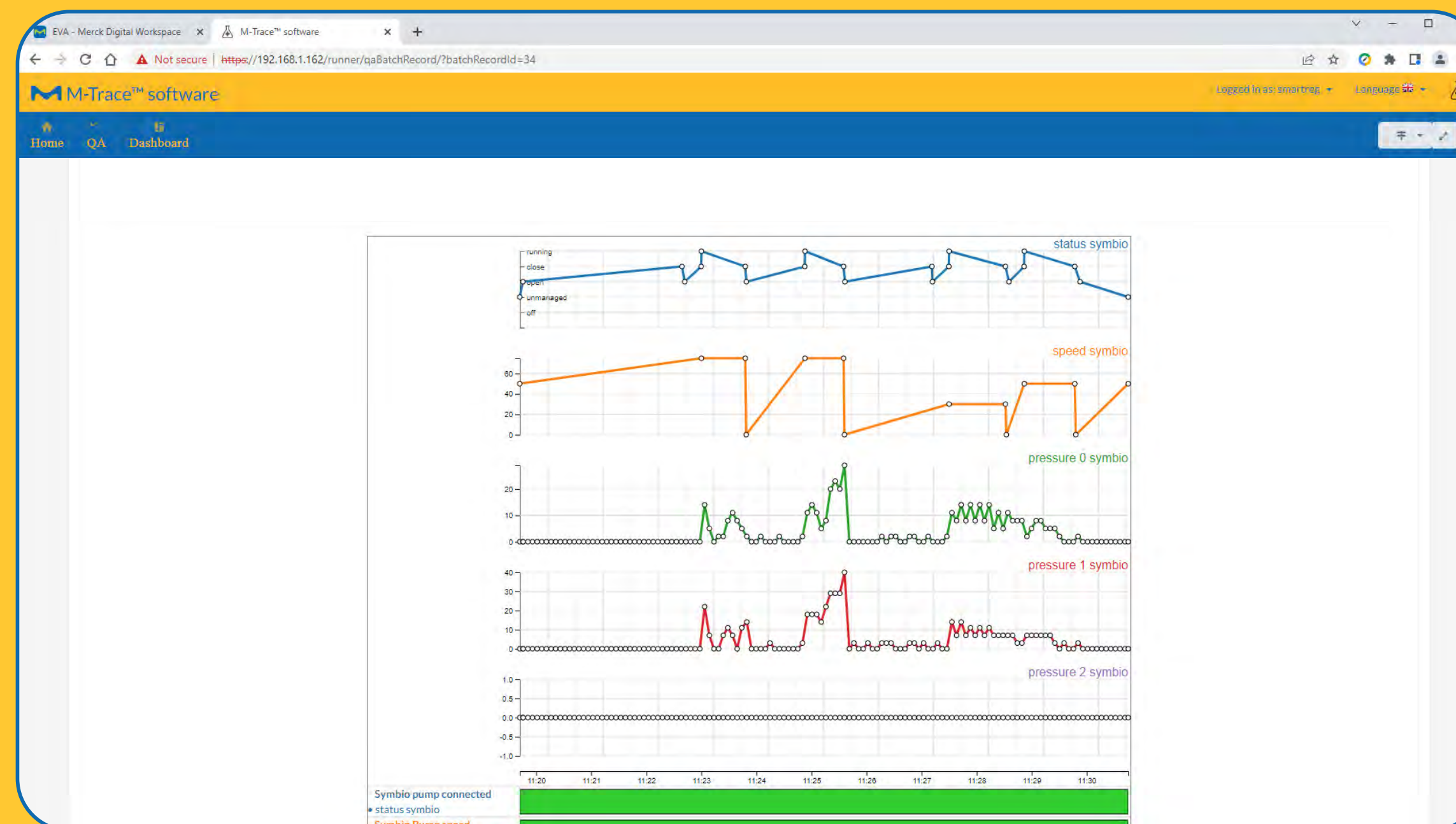
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## Boost Productivity, Ensure Compliance

with the M-Trace® solution



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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## Boost Productivity, Ensure Compliance

with the M-Trace<sup>®</sup> solution



The screenshot displays the M-Trace software interface within a web browser. The browser's address bar shows a URL: `https://192.168.1.162/runner/qaBatchRecord/7batchRecordId=42`. The page title is "M-Trace™ software". The interface includes a navigation bar with "Home", "QA", and "Dashboard" links. A message "unit to the mobile plugin." is visible. The main content area contains several sections for data entry:

- How many batches to test?**: Input field with value "1".
- Number of samples to test**: Input field with value "1".
- REQUESTING DETAILS PER BATCH**: Section with a "ST-1 VAL-3 : 1" label.
- Number of bottle per sample**: Input field with value "1".
- Enter Batch 1 ID**: Input field with value "53-04/11/22".
- FILLING ISOLATOR FTM BOTTLE**: Section with a "ST-1 VAL-3 : 1" label.
- Scan FTM Bottle 1**: Input field with value "22405TBMFTM12210F2PB50010217241".
- FILLING ISOLATOR TSB BOTTLE**: Section with a "ST-1 VAL-3 : 1" label.
- Scan TSB Bottle 1**: Input field with value "22405TBMTSB12210F0PB526892172209".
- FILLING ISOLATOR FULD A BOTTLE**: Section with a "ST-1 VAL-3 : 1" label.

An error message "Out of Range: expired(gs1\_expiry(a))" is displayed in a black box above the "Scan TSB Bottle 1" input field.

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

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**How Does it Work?**

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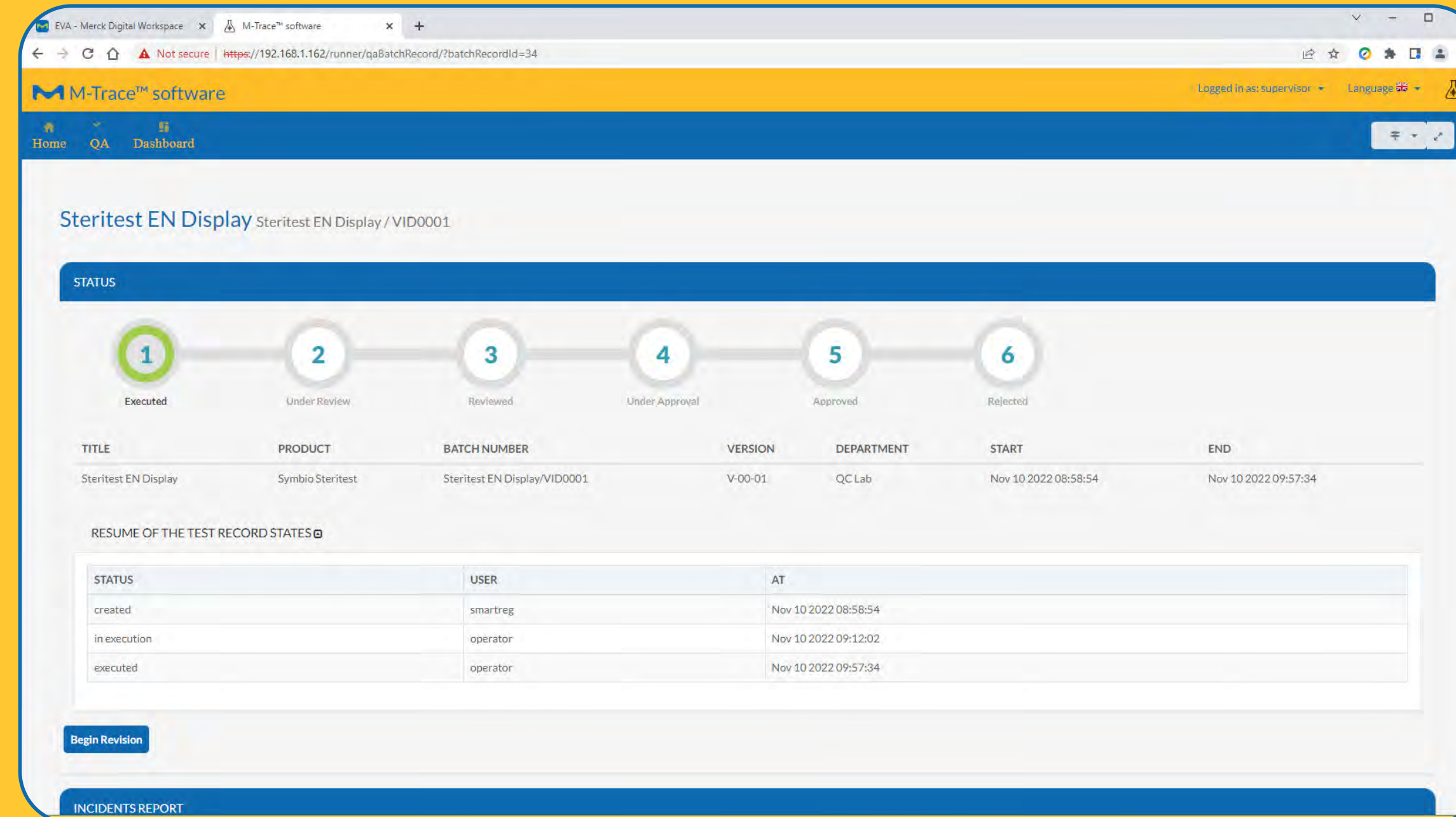
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## Boost Productivity, Ensure Compliance

with the M-Trace® solution



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

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**Rapid Sterility  
Testing System**

**Method**

**Benefits**

**Specifications**

**Software**

**Video**

**Ordering Information**

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## Milliflex® Rapid System 2.0



The Milliflex® Rapid System 2.0 is an automated solution based on ATP Bioluminescence for the rapid detection, imaging, and quantification of viable microbial contaminants in filterable samples throughout the manufacturing process and final sterility testing.

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## Method

Based on highly sensitive adenosine triphosphate (ATP) bioluminescence technology, the Milliflex® Rapid System 2.0 delivers faster test results than traditional microbial contamination detection methods. Using Milliflex Oasis® sample preparation and filtration devices, the Milliflex® Rapid System 2.0 ensures consistent and reliable results. It can clearly distinguish between mixed microbial growth of slow-growing and fast-growing microorganisms, and cope with variances in colony size and ATP content.

**SAMPLE**

Sample ID  
Sample\_21\_LOD\_CS

Operator ID  
LuckyCat

Date and time  
jeudi 28 juillet 2022 09:25:15

System  
SP2H21013B

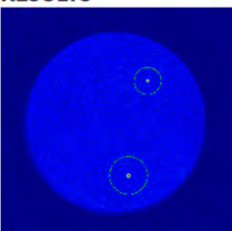
Settings  
Merck001

Sample size  
100

Sample unit  
mL

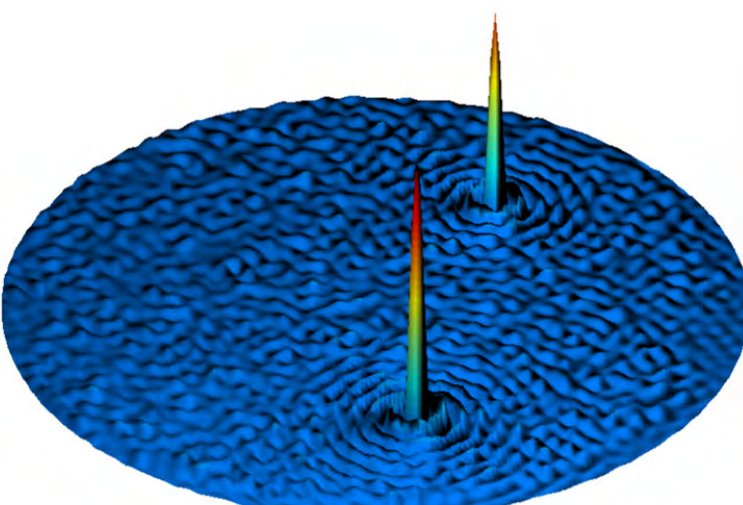
Comments

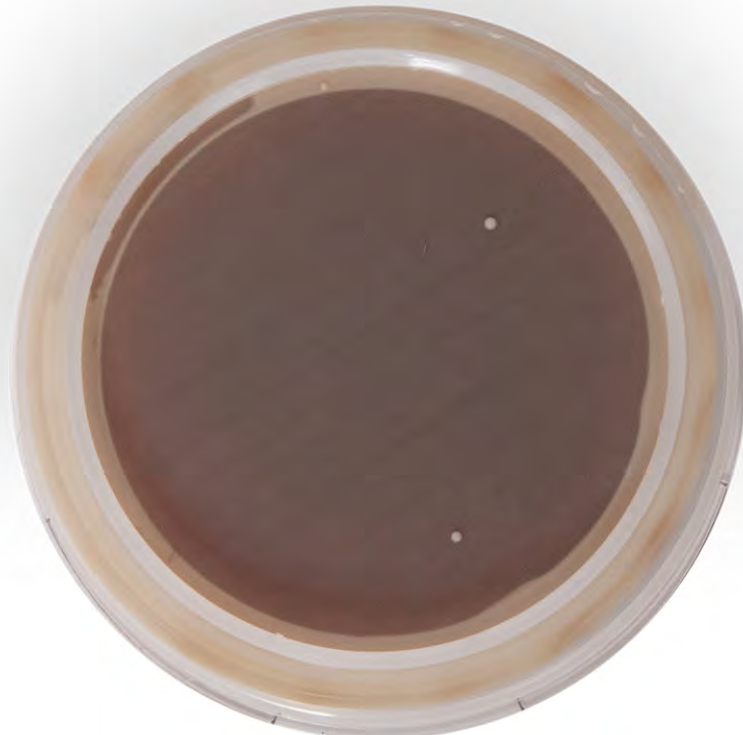
**RESULTS**



COUNT 2  
Count per unit 0.02

Warning Background  
80





RETURN

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**Rapid Sterility  
Testing System**

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## Benefits

The system's results will help to improve process control, product yield, and the timely release of final products. In case of contamination, corrective action can be taken earlier, avoiding loss of time, money, and production capacity.

The Milliflex® Rapid System 2.0 offers significant benefits for microbial contamination testing:

- Consistently fast and reproducible results
- Up to four times faster results than membrane filtration or pour plate methods
- Correlation of CFU counts with those of traditional methods
- Data integrity thanks to 21 CFR Part 11 compliant software
- Easy handling and validation



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# Specifications



AutoSpray Station



Detection Tower

|            |   |              |
|------------|---|--------------|
| Width      | 21 cm (8")  | 30 cm (12")  |
| Depth      | 40 cm (16")   | 13 cm (5")   |
| Height     | 31 cm (12")   | 35 cm (14")  |
| Weight     | 10 kg (22 lb)   | 5 kg (11 lb) |
| Electrical | Power supply: 230 V, 50 Hz, and 110 V, 60 Hz<br>Consumption: 30 W |              |

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**Rapid Sterility  
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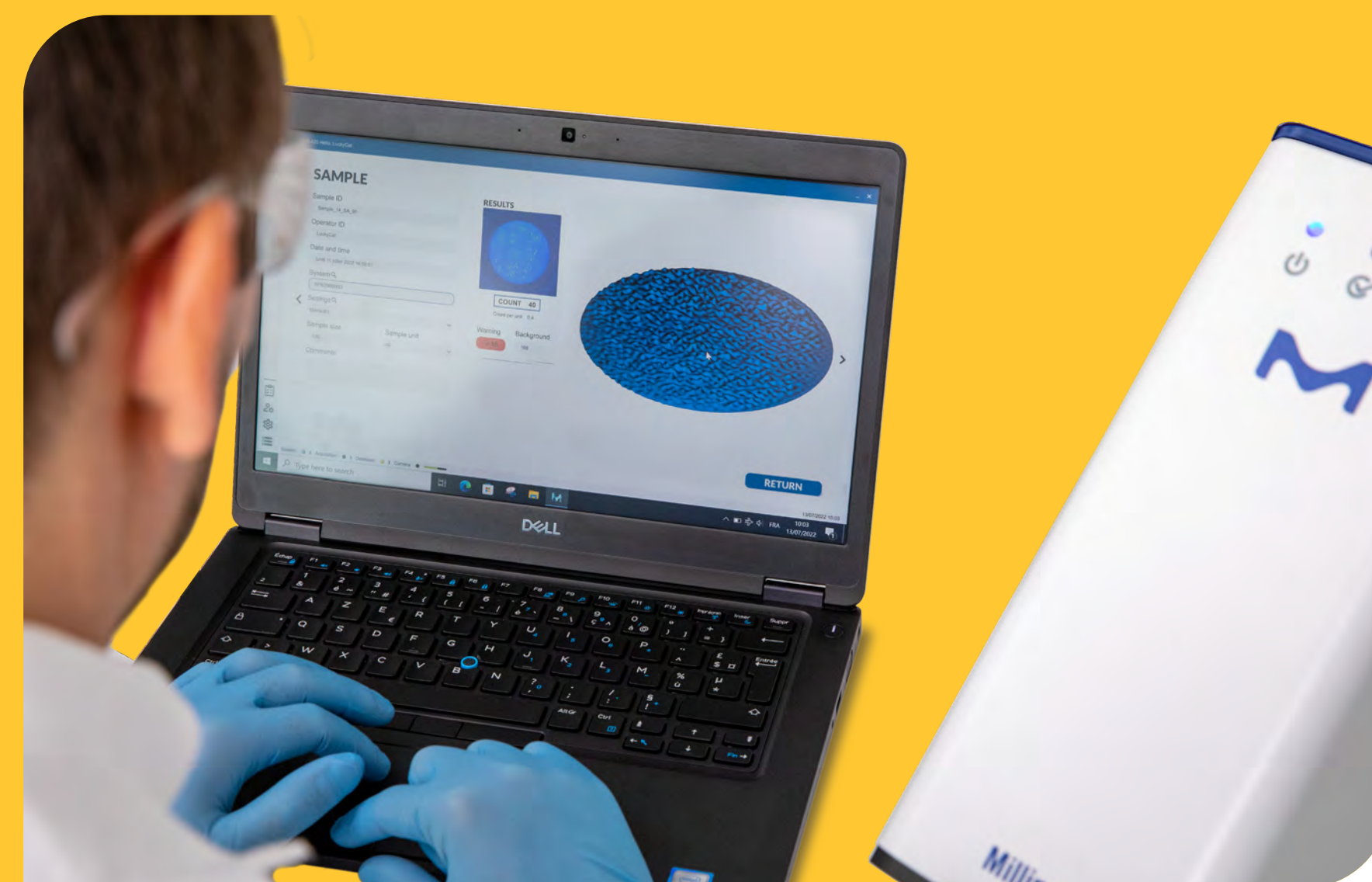
## Software

The Milliflex® Rapid System 2.0 software meets the requirements of FDA Regulation 21 CFR Part 11 for Electronic Records. The software's powerful batch reporting feature includes capabilities for electronic signing, performing audit trails, and preventing the alteration of data files. Access and editorial privileges are controlled via the software administrator module, ensuring secure data acquisition and audit trails conforming to 21 CFR Part 11.

### PC configuration

- Operating system: Windows 10
- RAM: 8 GB
- Disk: 500 GB
- USB 3.0 interface
- Ethernet connection

**Download  
the software**



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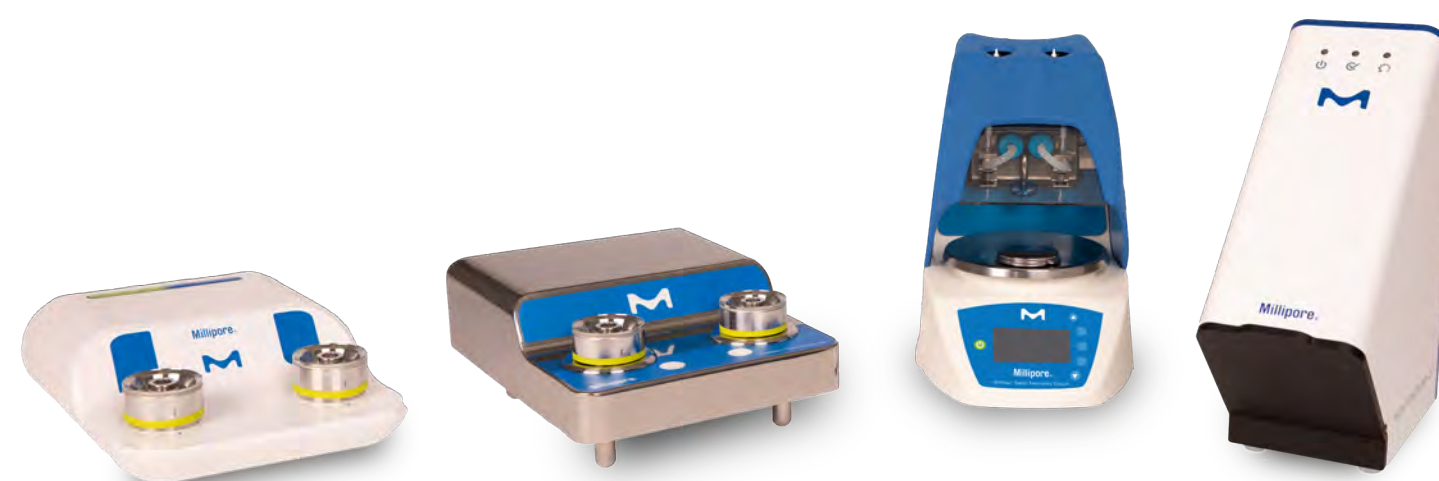
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## Ordering Information

### Hardware



**Material Table**

### Accessories



**Material Table**

### Consumables



**Material Table**

**Request information**



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## Ordering Information



### Hardware

| Product name   | Product #  | Request a Demo | Add to Cart |
|--|------------|----------------|-------------|
| Milliflex® Rapid System 2.0 Kit - Power supply sold separately <ul style="list-style-type: none"><li>Detection tower - MXRDP2DT00</li><li>AutoSpray station - MXRP2SPRKT</li></ul> | MXRDP2KT01 |                |             |
| Milliflex Oasis® VHP resistant filtration pump, kit - Power supply sold separately   | MMVHPKIT01 |                |             |
| Milliflex® Rapid System 2.0 detection tower - Power supply sold separately   | MXRDP2DT00 |                |             |
| Milliflex® Rapid System 2.0 AutoSpray station - Power supply sold separately   | MXRP2SPRKT |                |             |
| Milliflex Oasis® VHP resistant filtration pump for use in isolator - Power supply sold separately  | MMPPLUVHP  |                |             |

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## Ordering Information



### Accessories

| Product name  | Qty/Pk | Product #   | Add to Cart |
|---|--------|-------------|-------------|
| Power supply for Milliflex® Rapid System 2.0, needed for the AutoSpray Station or the detection tower | 1      | MXRPWRSP--  |             |
| Milliflex® Rapid System 2.0 USB connection cable for connecting the detection tower to PC             | 1      | MXRP2USBC   |             |
| Power supply for Milliflex Oasis® VHP resistant filtration pump                                       | 1      | VHPPWRSP--  |             |
| Milliflex® Oasis electrical cable for connecting two Oasis VHP pumps                                  | 1      | MMCABLEVHP  |             |
| Stainless steel plug for Milliflex Oasis® VHP pump outlet   | 1      | MMVHPPLUG   |             |
| Sanitization kit for Milliflex Oasis® VHP resistant filtration pump                                   | 1      | MMSANKITVHP |             |
| Stainless steel cover for Sanitization kit of Milliflex Oasis® VHP pump                               | 1      | MMSANKITCVR |             |
| Positive Control Tool for fast and reliable Milliflex® Rapid System efficiency verification           | 1      | POSICONT1   |             |
| Milliflex Oasis® T connectors for tubings for connecting two pumps                                    | 1      | MMTCNNECT   |             |

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## Ordering Information



### Consumables

| Product name   | Qty/Pk | Product #  | Add to Cart |
|--|--------|------------|-------------|
| Milliflex® Rapid Reagent Kit (100 tests)   | 1      | MXRPBLRST  |             |
| Milliflex® Rapid Cleaning/Decontamination Kit (20 cleanings)                               | 1      | MXRPCLKT1  |             |
| Milliflex® Oasis Rapid Funnel, 0.45 µm pore size PVDF membrane                             | 24     | MMHVMFX24  |             |
| Rapid Sterility Test Medium Cassettes, double packed                                       | 20     | 1460530020 |             |
| Milliflex Oasis® R2A low nutrient media plates for detection of waterborne microorganisms  | 48     | MMSMCRA48  |             |
| Milliflex Oasis® Tryptic Soy Media Plate for detection of aerobic and anaerobic microflora | 48     | MMSMCTS48  |             |
| Milliflex Oasis® Sabouraud Dextrose Media Plate for detection of yeasts and molds          | 48     | MMSMCSD48  |             |
| Milliflex Oasis® flow sanitization consumable for filtration pumps                         | 24     | MMSANSYFU  |             |

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## Shape Your Future

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.

[Learn More](#)



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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](https://SigmaAldrich.com/sterility-testing)**

To discuss with our Experts:

**[SigmaAldrich.com/info-sterility-testing](https://SigmaAldrich.com/info-sterility-testing)**

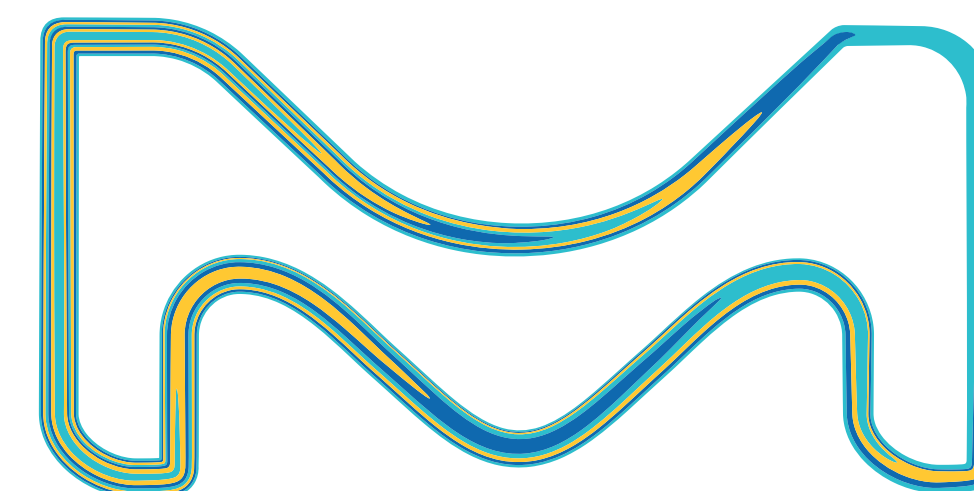
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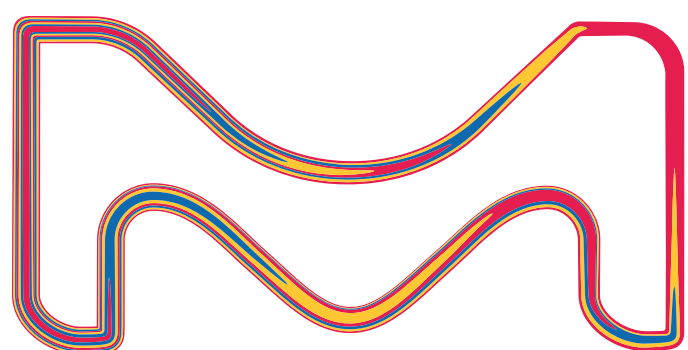
MilliporeSigma  
400 Summit Drive  
Burlington, MA 01803

**[SigmaAldrich.com](https://SigmaAldrich.com)**



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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

**Steritest® NEO  
Filtration Device**

**NEW Velax® cutting clamp**

**NEW Sampling Solutions**

**Culture Media  
& Rinsing Fluids**

**Services & Training**

### Story of the Steritest® system invention

**NEW M-Trace® Software**

**Peristaltic Steritest®  
Symbio Pump**

**NEW Rapid Sterility  
Testing System**

**Smart Accessories**

