



# Steritest™ EZ Sterility Testing Devices

## *Easy, fast, and safe sterility testing devices*

- ▶ *Ergonomically designed needle adapter fits the majority of test containers while maintaining a closed concept system*
- ▶ *Pre-installed clamps simplify handling and save time*
- ▶ *Canister design reduces foaming enabling faster filtration*
- ▶ *Engraved information on each canister improves traceability*

Sterility testing is one of the most crucial steps in pharmaceutical product release. Millipore's Steritest EZ devices simplify every aspect of testing, from handling to traceability, all within a closed concept 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 Equinox pump, the Steritest sterility test system delivers unmatched sterility testing consistency.

For more than two decades, Millipore has been the market leader in sterility testing. With the introduction of Steritest EZ devices, we continue to set the standard for excellence, while maintaining all the advantageous components of the traditional Steritest canisters including the same membrane and membrane-base sealing technique.

### **Antibiotics and Products Containing Antimicrobial Agents**

Ideally suited for antibiotic sample testing, the "Red Base" Steritest EZ devices incorporate Millipore's Durapore® membrane, offering broad chemical compatibility and low binding properties. The chemical composition of the extremely thin 0.45 µm Durapore membrane provides low antibiotic binding, which improves rinsing efficiency and reduces the risk of false negatives. The canister design ensures efficient rinsing of residual antimicrobial agents and the needle adapter and connections minimize the risk of antibiotic residuals.

### **Large Volume Parenterals and Synthetic Drugs without Antimicrobial Activity**

The "Blue Base" Steritest EZ devices offer the ultimate in flexibility. Perfect for use with the majority of pharmaceutical drugs that do not have antimicrobial activity, Millipore's mixed esters of cellulose HA membrane allows fast flow rates for optimum throughput performance, and reduced testing time.

A range of ergonomic needle adapters is available to meet specific drug packaging requirements as well as simplify handling by gloved operators.

## Pre-installed Clamps and Increased Tubing Length for Easy Handling

Steritest EZ canister tubing includes pre-installed clamps, simplifying and reducing testing time. Closing and re-opening the clamps during testing is as simple as pressing down or



releasing as necessary. The longer 850 mm tubing length offers easier set-up with ample room to perform the manipulations involved in sterility testing.

## Canister Inlet Reduces Foaming and Speeds Filtration

In the past, analysts needed to reduce pump speed in order to minimize foaming when filtering protein solutions or adding media. The innovative Steritest EZ canister inlet design



reduces foaming enabling faster filtration. This feature, coupled with our high-flow mixed esters of cellulose membrane, improves reliability while allowing you to maintain high pump speeds and reduce testing time.

## Needle Adapters Increase Efficiency and Security

Innovative needle adapters enable fast and easy manipulation of liquid drugs.

- Fits the majority of drug containers; reducing the risk of blockage when testing drugs in vials with thick septa
- Ergonomic, non-skid design provides a firm grip for gloved operations, especially in isolators



## Closed Environment for Complete Testing Confidence

Using Steritest EZ devices ensures that pharmaceutical products are never exposed to the environment during the testing process. Sampling, filtering, rinsing, media transfer and incubating are all conducted within the Steritest EZ closed system. There is no need to open the containers or manipulate the membrane at any time — greatly reducing the risk of adventitious contamination.

## Convert to Steritest EZ Canisters

Steritest EZ canisters offer equivalent performance as the previous generation Steritest canisters and both canister fluid paths are constructed of the same material. Millipore has compiled a comprehensive Steritest Qualification Report that confirms Steritest and Steritest EZ test performance equivalency.

## Consistent Performance

From the people who know sterility testing, we still take nothing for granted. We rigorously test each device during and after manufacturing.

- 100% integrity testing on every canister
- Strict physical and microbiological tests at every step of the assembly of the Steritest EZ 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



## Specifications

### Steritest EZ “Red Base” Devices

For Antibiotics and Products Containing Antimicrobial Agents

	<b>Steritest EZ</b>	<b>Steritest</b>
<b>Canister Base Color</b>	Red	Red
<b>Canister Base Membrane</b>	Low adsorption Durapore membrane, 0.45 µm hydrophilic PVDF	Low adsorption Durapore membrane, 0.45 µm hydrophilic PVDF
<b>Materials of Construction</b>		
<i>Filtration Chamber (Canister):</i>	Styrene acrylonitrile	Styrene acrylonitrile
<i>Double Lumen Tubing:</i>	PVC, 850 mm length	PVC, 750 mm length
<i>Needle Adapter:</i>	Stainless steel and polyamide 6-6	Stainless steel and polyamide 6-6
<b>Sample Container Capacity</b>	120 mL (graduation marks at 50, 75 and 100 mL)	120 mL (graduation marks at 50, 75 and 100 mL)
<b>Minimum Flow Rate (for water)</b>	300 mL/min at 690 mbar (10 psi)	300 mL/min at 690 mbar (10 psi)
<b>Maximum Temperature</b>	45 °C	45 °C
<b>Maximum Operating Pressure</b>	3.15 bar at 25 °C (45 psi at 77 °F)	3.15 bar at 25 °C (45 psi at 77 °F)
<b>Sterilization</b>	ETO (ethylene oxide gas)	ETO (ethylene oxide gas)

### Steritest EZ “Blue Base” Devices

For Large Volume Parenterals and Synthetic Drugs without Antimicrobial Activity

	<b>Steritest EZ</b>	<b>Steritest</b>
<b>Canister Base Color</b>	Blue	Blue
<b>Canister Base Membrane</b>	Mixed Esters of Cellulose (HA) membrane, 0.45 µm	Mixed Esters of Cellulose (HA) membrane, 0.45 µm
<b>Materials of Construction</b>		
<i>Filtration Chamber (Canister):</i>	Styrene acrylonitrile	Styrene acrylonitrile
<i>Double Lumen Tubing:</i>	PVC, 850 mm length	PVC, 750 mm length
<i>Needle Adapter:</i>	Stainless steel and polyamide 6-6	Stainless steel and polyamide 6-6
<b>Minimum Flow Rate (for water)</b>	300 mL/min at 690 mbar (10 psi)	300 mL/min at 690 mbar (10 psi)
<b>Sample Container Capacity</b>	120 mL (graduation marks at 50, 75 and 100 mL)	120 mL (graduation marks at 50, 75 and 100 mL)
<b>Maximum Temperature</b>	45 °C	45 °C
<b>Maximum Operating Pressure</b>	3.15 bar at 25 °C (45 psi at 77 °F)	3.15 bar at 25 °C (45 psi at 77 °F)
<b>Sterilization</b>	Gamma irradiation	ETO (ethylene oxide gas)

## Ordering Information

Description	Base Color	Qty/Pk	Catalogue No.
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### Steritest EZ "Red Base" Devices

For Antibiotics and Products Containing Antimicrobial Agents

Steritest EZ Device for Antibiotics	Red	10	TZHV AB 210
Steritest EZ Device for Liquids in Vials (HV membrane)	Red	10	TZHV LV 210

### Steritest EZ "Blue Base" Devices

For Large Volume Parenterals and Synthetic Drugs without Antimicrobial Activity

Steritest EZ Device for Liquids in Ampoules and Collapsible Bags	Blue	10	TZHA LA 210
Steritest EZ Device for Liquids in Vials	Blue	10	TZHA LV 210

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In every application, every step and every scale, count on Millipore to be everywhere for you—from monoclonals to vaccines, from clinical through pilot to full-scale manufacturing. Our technologies are used by most of the world's major biopharmaceutical companies. But we deliver more than advanced separation, purification, sterilization and quality control products. With Millipore, you get services to optimize and validate your processes, comprehensive resources to streamline and enhance your operation, unmatched know how forged from 50 years' experience—and solutions that integrate it all. For higher yields, improved process economics and faster speed to market, discover the more in Millipore.

### To Place an Order or Receive Technical Assistance

For additional information call your nearest Millipore office:

In the U.S. and Canada, call toll-free **1-800-MILLIPORE (1-800-645-5476)**

In the U.S., Canada and Puerto Rico, fax orders to **1-800-MILLIFX (1-800-645-5439)**

Outside of North America contact your local office.

To find the office nearest you visit [www.millipore.com/offices](http://www.millipore.com/offices).

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Lit. No. DS1035EN00 Rev. – 09/04 04-217 Printed in U.S.A.

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