

# SARTORIUS

## Sterisart® Universal | Gen 4

Where Convenience Meets Compliance

Sterility is paramount in pharmaceuticals and biotechnology, where products intended for patient care must meet rigorous quality and safety standards. Barrier technologies, such as isolators and cleanrooms, are essential for contamination prevention, necessitating solutions that not only enhance usability, but also ensure compliance and facilitate seamless integration with existing systems.

The Sterisart® Universal | Gen 4 pump, designed for barrier environments, enables precise, sterile sample transfers and features advanced software for compliant, paperless documentation, catering to modern lab needs.



Simplifying Progress

# Your Key Benefits



## A Legacy of Success Continues

- Universal pump for benchtop use in a cleanroom, biosafety cabinet or for integration in an advanced aseptic processing system
- Low profile and compact footprint
- 316L stainless steel with a mirror finish
- Designed with smooth contours and quick disassembly for easy cleaning
- Compatible with various sterilants, including vaporized hydrogen peroxide
- State-of-the-art rotor head ensures consistent liquid splitting at all speeds
- Effortless tube placement featuring a fail-safe locking mechanism
- Grip-optimized tactile knob with haptic feedback for precise user interface control
- Adjustable support rod, multi-functional bottle holder, drain container, and display
- Open design provides maximum freedom of choice

## Cutting-Edge Features

- Flexible Modular Design: Choose what fits you best and upgrade as your needs evolve
- Real-Time pressure detection in the sterility testing canisters – minimize stress on microbial contaminants & enhance process security
- High-Performance Display: 7-inch digital touchscreen offering vivid visuals, an intuitive user interface, and glove-friendly operation for use in isolators
- Automatic Data Capture: Integrated next-generation barcode scanner compatible with multiple formats for efficient material tracking
- Compliance Support: Advanced sterility testing software, designed to meet 21 CFR Part 11 and EU GMP Annex 11 requirements, with user access control, audit trails, secure data management, electronic reporting, and electronic signatures
- Effortless Method Validation: Automatically capture every user interaction and do away with manual documentation
- Automation-Friendly: Remote configuration and operation of a large library of customized SOPs
- Choice of multiple languages: English, French, German, Portuguese, Spanish, Italian, Russian, Chinese, Japanese and Korean












# Sterisart® Universal | Gen 4 Highlights



Sterisart® Universal   Gen 4	Basic	Essential	Advanced
Ordering Code	16421-B	16421-E	16421-A
<b>Hardware</b>			
Sterility Testing Pump	●	●	●
Display & Integrated Barcode Scanner	○	●	●
Pressure Sensor	~ (Restricted functionality)	●	●
Connectivity -USB-A/C & Ethernet Port	~ (Connectors present but restricted functionality)	●	●
<b>Software</b>			
Workflow Configuration	○	○	●
Simple Report	○	●	●
Extended Report	○	○	●
Remote Operation	○	○	●
21 CFR Part 11 Conformity	○	○	●

Select the perfect fit for your needs and seamlessly upgrade to more advanced versions as your requirements evolve. This adaptability ensures your investment matures in line with your ambitions, reducing the need for costly equipment replacements.

## Sterisart® Sterility Testing Canisters

Sample Type								
Product Container	Closed	Closed	Open	Closed	Closed with bow-fill seals	Syringes	Male luer locks or female slip	Male luer locks
								
<b>Regenerated Cellulose</b>								
Standard	16466-----GBD	16476-----GBD	16467-----GBD	16475-----GBD	16477-----GBD	16469-----GBD	16468-----GBD	16478-----GBD
Septum	16466-----GSD	16476-----GSD	16467-----GSD	16475-----GSD		16469-----GSD		
<b>Cellulose Acetate</b>								
	16466-----CA-GSD		16467-----CA-GSD					



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