



# GEW cGMP washer/dryer

Cleaning for Biopharmaceutical Production

# Complete sterile processing systems

– meeting strict biopharmaceutical requirements

Our GEW cGMP washer/dryers have been developed in cooperation with users and engineers to maximize efficiency, reliability, and traceability. They are configured to meet the most demanding requirements for pharmaceutical manufacturing. Together with purpose-designed inventory systems, they provide critical cleaning of equipment, parts and components.

Full traceability (ASME BPE) and documentation packages are included to meet your regulatory requirements, allowing you to track design, construction, and processes. The GEW cGMP range is easy to maintain, which minimizes downtime to keep your facility running smoothly.

## **Versatility for production and QA/QC**

GEW Series washer/dryers are suitable for many common applications within biopharma production. They are equipped with appropriate features and options for demanding processes within production and QA/QC laboratory environments.

## **Environmental efficiency**

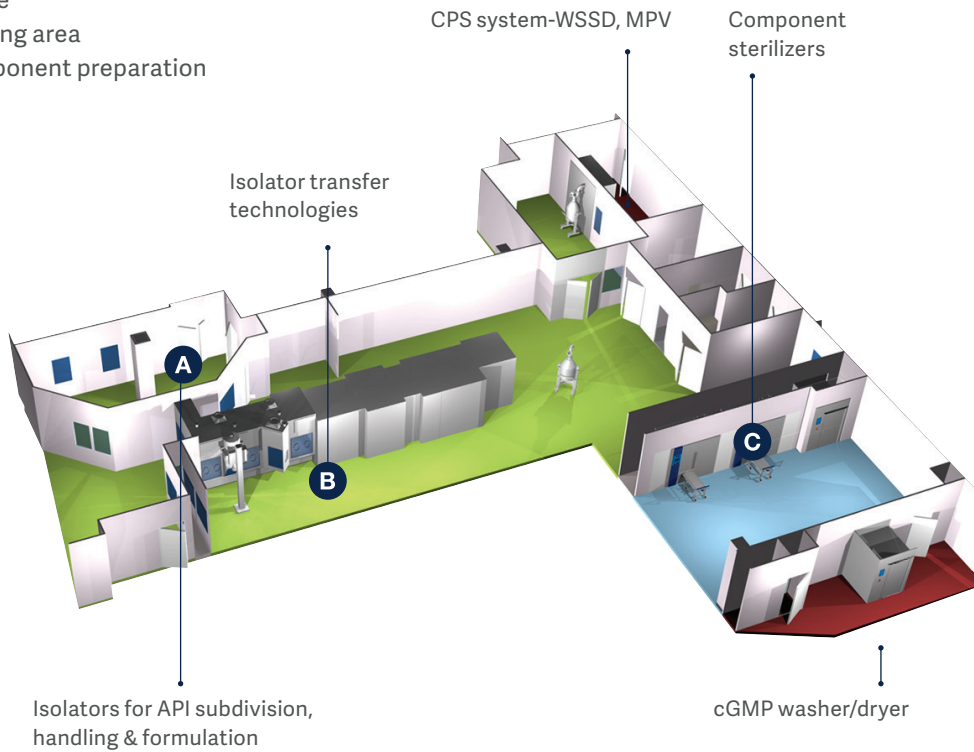
The GEW cGMP Series washer/dryers have the lowest utility and water consumption on the market, reducing your environmental footprint and total cost of ownership.

Getinge GEW washer/dryers are completely integrated cleaning systems. They have been designed to meet the specific needs and stringent regulations for cleaning glassware, components, and production equipment in biopharmaceutical production and quality assurance laboratories.



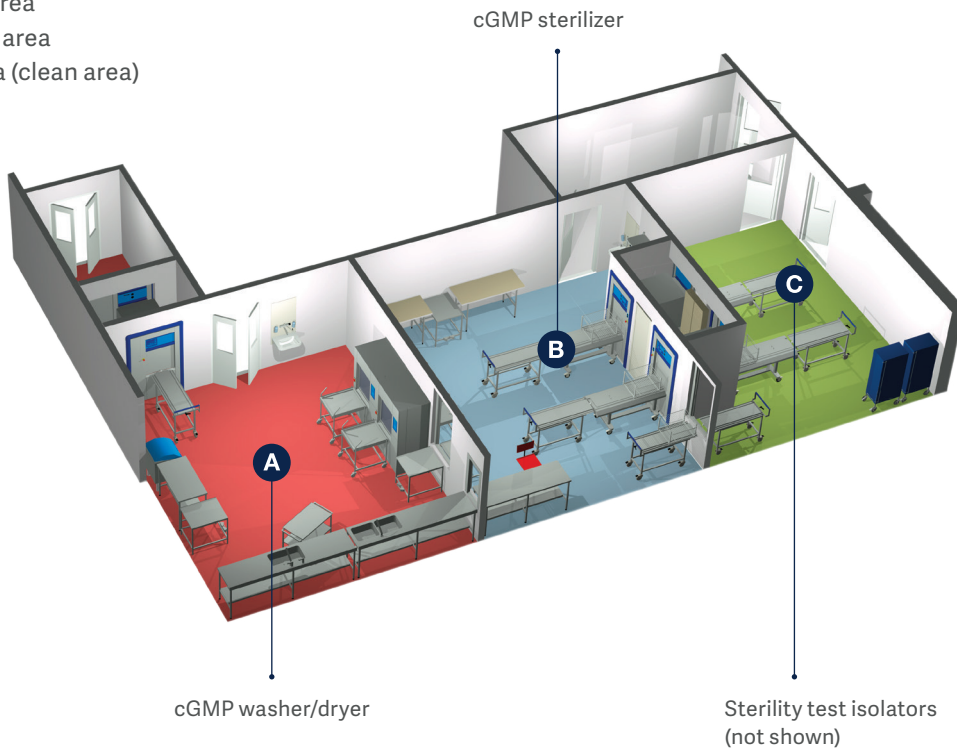
## Pharmaceutical Production

- A:** Formulation suite
- B:** Aseptic suite/filling area
- C:** Equipment/component preparation



## QA/QC Laboratory

- A:** Reception area
- B:** Preparation area
- C:** QA test area (clean area)



# A comprehensive range

## – critical cleaning for your unique processing needs

The Getinge GEW Series of washer/dryers includes a variety of sizes to fit your needs. All models include a full traceability and validation package.



### **GEW 888 neo\***

#### **A compact washer for small premises**

[For biotech/biopharmaceutical manufacturing and QA/QC applications](#)

The compact GEW 888 washer/dryer with an automatic vertical sliding door that does not require additional height above the washer is the ideal solution for space constraints. Service access is from the front and the large washing chamber can accommodate a broad range of different production components and various sizes of glassware.

- Single- or double-door models are available for single-side or pass-through operation
- Compact with very small footprint of 1,3 m<sup>2</sup> (14 sq.ft)
- Sustainable performance with low utility and energy consumption
- Chamber capacity: 482 L (17,0 cu. ft)
- Internal dimensions, W x H x D: 805 x 770 x 778 mm (31.7" x 30.3" x 30.6")
- Cross contamination barrier (CCB) on unloading side available as option
- The patented single-pass rinse uses minimal water, and can be used multiple times in final or pre-rinse phase. No additional footprint needed.



### **GEW 9109**

#### **Ideal for multipurpose applications**

[For biopharmaceutical manufacturing and QA/QC applications](#)

The larger GEW 9109 washer/dryer is a multipurpose washer for cleaning glassware, filling line modules and equipment parts. Horizontal sliding doors minimize floor space needed for operation.

- Single- or double-door models are available for single-side or pass-through operation
- A two-port wash system allows for use of two level accessory racks thereby increasing productivity and reducing cycle costs
- Chamber capacity: 810 L (211.3 gal)
- Internal dimensions, W x H x D: 900 x 1000 x 900 mm (35.5" x 39.4" x 35.5")
- Cross contamination barrier (CCB) available as option

\*More information can be found on the dedicated GEW 888 neo brochure



### GEW 101210 and GEW 131313

#### Designed for manufacturing

For biopharmaceutical manufacturing and bulk chemical/API production

These medium-sized washer/dryers include many standard features necessary for GMP compliance in cleaning of IBCs, carboys and equipment. A wide range of optional features are also available to make the models adaptable to a variety of applications. A variety of standard racks and an ergonomic transport trolley are available for common applications. Custom racks can also be designed and provided.

- Single- or double-door models are available for single-side or pass-through operation
- Glass doors are vertically hinged to save space
- Loading height: 710 mm (28")
- Chamber capacity:
  - GEW 101210: 1212 L (43 ft<sup>3</sup>) / GEW 131313: 2146 L (76 ft<sup>3</sup>)
- Internal dimensions, W x H x D:
  - GEW 101210: 1005 x 1200 x 1005 mm (39.6" x 47.2" x 39.5")
  - GEW 131313: 1300 x 1285 x 1285 mm (51" x 50.5" x 50.5")
- Cross contamination barrier (CCB) available as option



### GEW 131820

#### The largest, pit-mounted washer

For biopharmaceutical manufacturing and bulk chemical/API production

The GEW 131820 is the largest washer in the series. It is designed for pit mounting in a 500 mm (19.7") deep pit, allowing direct floor loading of large, heavy or bulky items. Where pit mounting is not possible, the machine may be floor mounted with a loading height of 500 mm (19.7"). Use for cleaning IBCs, bulk chemical containers, vessels, machine parts.

- Racks are application-specific to maximize throughput
- Single- or double-door models are available for single-side or pass-through operation
- Sliding doors save space and optimize ergonomics
- Chamber capacity: 4680 L (165 ft<sup>3</sup>)
- Internal dimensions, W x H x D: 1300 x 1800 x 2000 mm (51" x 70.9" x 78.7")
- Cross contamination barrier (CCB) available as option

Model	Configuration doors	Overall dimensions* W x H x D
GEW 888-1 neo	Single (with or without SPRF option)	1450 x 2300 x 895 mm (57.1" x 90.6" x 35.2")
GEW 888-2 neo	Double (with or without SPRF option)	1450 x 2300 x 895 mm (57.1" x 90.6" x 35.2")
GEW 9109-1	Single	2350 x 2243 x 1185 mm (92.5" x 88.3" x 46.6")
GEW 9109-2	Double	2350 x 2243 x 1320 mm (92.5" x 88.3" x 52")
GEW 9109-1	Single (with SPRF option)	2593 x 2243 x 1260 mm (102.1" x 88.3" x 49.6")
GEW 9109-2	Double (with SPRF option)	2593 x 2243 x 1320 mm (102.1" x 88.3" x 52")
GEW 101210-1	Single	2190 x 2485 x 1266 mm (86.2" x 97.8" x 49.8")
GEW 101210-2	Double	2190 x 2485 x 1345 mm (86.2" x 97.8" x 53")
GEW 101210-1	Single (with SPFR option)	2350 x 2485 x 1266 mm (92.5" x 97.8" x 49.8")
GEW 101210-2	Double (with SPFR option)	2350 x 2485 x 1345 mm (92.5" x 97.8" x 53")
GEW 131313-1	Single	2439 x 2604 x 1716 mm (96" x 102.5" x 67.6")
GEW 131313-2	Double	2439 x 2604 x 1947 mm (96" x 102.5" x 76.6")
GEW 131313-1	Single (with SPFR option)	2678 x 2604 x 1716 mm (105.4" x 102.5" x 67.6")
GEW 131313-2	Double (with SPFR option)	2678 x 2604 x 1947 mm (105.4" x 102.5" x 76.6")
GEW 131820-1	Single	3053 x 2850 x 2300 mm (120.2" x 112.2" x 90.6")
GEW 131820-2	Double	3053 x 2850 x 2600 mm (120.2" x 112.5" x 102.4")

\*Subject to modifications due to technical development

# Form follows function

– experience the benefits of intelligent design



### 1. Efficient drying

Two separate drying systems (one for the chamber and one for the process path and racks) provide once-through HEPA filtered air for maximum drying efficiency. Ceramic heating elements enable variable drying temperature control for different materials (steam heating is an option). All components are upstream of the final HEPA filters. Air is exhausted to a vent connection on the washer.

### 2. Filter monitoring for safety

DOP ports and differential pressure switch are standard features, providing essential routine monitoring capability of the HEPA filters. Magnhelics® differential pressure gauges are available for visual verification of filter loading.

### 3. Fully automated for efficiency

The Getinge GEW washer/dryer is equipped with a GAMP 5 compliant, 21 CFR Part 11 capable, state-of-the-art modular PLC system. Getinge offers a selection of Allen Bradley or Siemens platforms, all with equal functionality and documentation.



Siemens interface

### 4. Robust and sanitary construction

A sloped (min 2%) design, and smooth (Ra < 0.6 mm/25 mm), crevice-free construction of chamber, piping, and racks eliminates water retention and sites for biofilm or corrosion. 316L stainless steel is used throughout, with EPDM, PTFE, or other FDA (21 CFR part 177) and USP class VI approved gaskets. Globally available components, e.g. GEMU process valves, are standard. Orbital welding is used wherever possible and extensive documentation is provided.

### 5. Washing configurations improve throughput

An integral chamber spray system with wash rack interface provides multi-level washing that optimizes load configuration and minimizes processing time. Water is heated using an efficient and effective sanitary steam-water heat exchanger in the sump of the chamber (electrical heating is optional).

### 6. Recessed installation

All models are provided with brush finish stainless steel fascia panels for recessed installation, with additional side panels to form a cabinet as an option. On larger models, single or dual cross-contamination barriers are available to maintain clean area classification and facilitate room air balancing (optional).

### 7. Confirmed proper chemical addition

The washer can be fitted with up to three peristaltic dosing pumps (according to application) for cleaning and neutralization agents to aid the mechanical cleaning process. Sanitary dosing valves are welded directly to the chamber wall to ensure proper rinsing. Pump pressure is continuously monitored, and a conductivity sensor (optional) is available to confirm proper additive dosing.

### 8. Final rinse with high-quality WFI

The sump is filled with water for injection (WFI) and recirculated throughout the hydraulic circuit; this provides a single fluid path design to ensure complete rinsing of the entire system. This process continues for the time interval specified during process development studies and is followed by a conductivity check of rinse water. Optimal total organic carbon check may also be included as part of final rinse.

Conductivity and/or online TOC monitors are available to confirm that all cleaning agents and soil have been removed. This process minimizes WFI consumption and provides a validated, repeatable result.

### 9. Single pass final rinse

To meet specific process requirements, Getinge offers a Single Pass Final Rinse (SPFR) system which can be programmed as a part of the total validated cycle. During SPFR, components are not exposed to recirculated water.

The SPFR step can be user-programmed and repeated in accordance with process requirements. Rinse water conductivity is monitored by the control system. If the conductivity goes out of range, a fault code is activated.

### 10. Air exhaust system for API containment

Active Pharmaceutical Ingredients (APIs) and Highly Potent Active Pharmaceutical Ingredients (HPAPIs) may be highly toxic substances contained in today's drugs.

The Getinge GEW cGMP washers model 101210 and 131313 can be equipped with an Air Exhaust Unit that uses a highly effective HEPA filtration system to capture the residual APIs during the equipment cleaning process.

Multiple system parameters are consistently monitored to ensure reliable system performance, protecting your employees and your environment from the potential dangers of API exposure.

### 11. Safe, lockable door configurations

Each model is available in single door or double door configuration. Doors are equipped with interlocks to prevent opening during washer operation and simultaneous opening of the dual door units.

### 12. Loading rack identification and AutoStart system

A loading rack identification system through camera/reader and data matrix code will ensure that the correct validated wash cycle is executed for the intended load. The wash cycle is either preselected for manual confirmation or through AutoStart function for models with automated door. The sequence made is logged on the batch report and audit trail for full traceability. *(feature not applicable for the GEW 131820)*

# Inventory systems

– have equipment ready when you need it

Smooth, uninterrupted production requires that the right tools and equipment are available and ready for use when you need them. Getinge inventory management and handling accessories allow you to move heavy or awkward articles where they are needed, safely and efficiently.

We work in cooperation with our customers to optimize and customize washer/dryer accessories, ensuring a safe, ergonomic system that keeps you up and running.

When designing custom accessories, Getinge uses CAD systems with 3D modeling to ensure that every corner and every cavity is being thoroughly washed and dried with hot, sterile and filtered air.

This technology helps you to eliminate the possibility of cross-contamination from lingering residue.

Getinge has designed specialized racks and trolleys to accommodate both large and small parts. These custom creations complement the wide variety of standard racks that are available for more common applications.

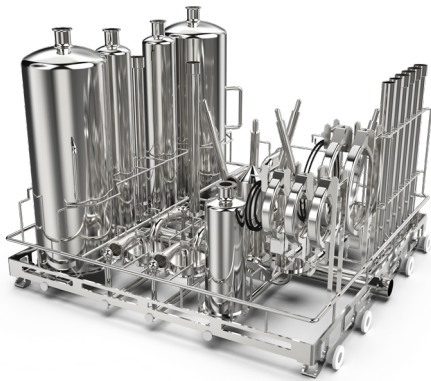






Loading trolleys can be provided to efficiently and ergonomically move materials to and from washer/dryers.

### Customized racks based on your needs



Valve bodies, mounted on a customized manifold fitted to an otherwise standard rack, ensure 100 % coverage of all product contact parts, as well as the exterior surfaces.

### Innovative standardized modular rack solution



Getinge has developed modular rack solutions to better satisfy your needs. Read more about our Modular Rack Solutions for GEW cGMP Washers in the rack catalogue.

# Inspection, testing and documentation

## – comprehensive manufacturing validation

Every GEW washer/dryer undergoes rigorous testing. Getinge follows ISPE's Baseline® and GAMP 5 Guides to support our clients' qualification of sterile process equipment.

Quality is inherent to the design, development, and manufacture of every Getinge product. The design and construction are sanitary and traceable at every step of the process.

From the design specification, through component selection, fabrication, assembly and factory testing, we examine and document every aspect of the manufacturing process in accordance with Good Engineering Practice. You can be confident that the product you receive has been designed, built and tested according to your specifications and performance requirements.

### **Comprehensive validation support documentation**

During the manufacturing process, in-process checking is performed to ensure compliance with specifications; documentation is maintained as confirmation. After manufacturing, every unit undergoes comprehensive and rigorous Factory Acceptance Testing (FAT), again accompanied by detailed documentation. A complete package of testing documentation, installation guides,

and user and technical manuals, is provided with the equipment. These documents support your on-site qualification procedures, saving you considerable time, effort, and expense.

We can also provide a "pre-qualification" of the system upon request, carrying out the same test procedures defined in the IQ/OQ protocols as will later be performed on site as part of the validation exercise. This exhaustive procedure identifies any minor issues with equipment and documentation and ensures a trouble-free startup and site acceptance testing later on.

Deliverable documentation packages include:

- Submittals (design documentation)
- Construction
- Automation
- Testing and qualification
- Installation manual
- User manual
- Technical manual



# Reliability and reproducibility

## – the cornerstone of life science applications

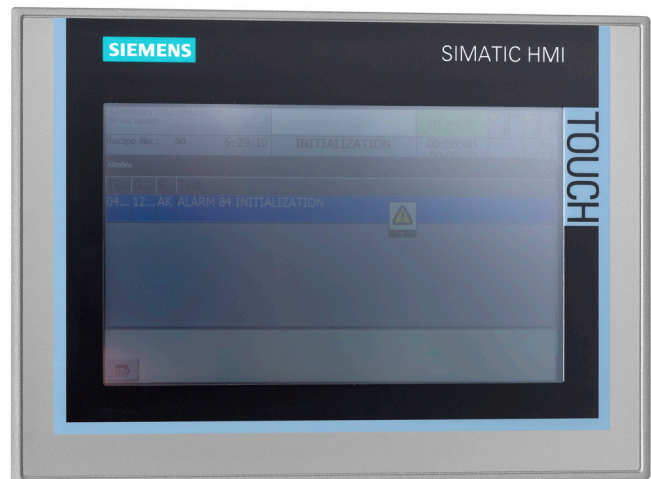
To minimize human error, Getinge supplies PLC-based automation systems designed for the challenging environments typically found in life science applications.

Getinge offers a choice of hardware platforms for wash process traceability, each with the same fundamental equipment functionality and programming methodology.

- Rockwell – Allen Bradley (Logix platform)
- Siemens – Simatic (S7 Based platform)

All systems accurately handle tasks such as parameter setting, recipe handling, sequence control, and data processing, presentation and storage.

A TOC monitoring option is also available on every Getinge GMP washer/dryer. With this option, you will be able to self-run controls on level of endotoxins and microbes at the end of your cycle — a key element to track the efficiency of your cleaning process. The TOC option saves time and money by providing direct results of your cleaning process, without the need to wait for external results.



The Siemens - Simatic (S7 Based platform) control system incorporates an intuitive touchscreen interface that provides reports, control options and real-time system monitoring.

### Included benefits

- User-friendly interface
- Extensive documentation
- Remaining cycle-time indicator
- Automatic sensor calibration
- Comprehensive alarms/alerts
- Process and alarm logging
- Multi-level password protection
- Highly customized control system available

### Regulatory compliance

Getinge's automation systems are developed according to stringent GAMP 5 (Good Automated Manufacturing Practice) guidelines of the pharmaceutical industry and are FDA 21 CFR part 11 capable. Every system is supported with comprehensive documentation.

# Important features

– supporting production efficiency in the biopharma industry

Getinge GEW cGMP Series washer/dryers are designed for optimized layout and easy maintenance. Innovative door designs maximize chamber volume while minimizing the external footprint.



## Key features

- Hinged and sliding glass door(s) to optimize installation footprint
- Heat and noise insulated glass allows for visual monitoring of cleaning process
- Single- or double-door models for optimized workflows
- Cross-contamination barrier (CCB) to prevent excessive air transfer and contamination of clean areas
- Fully drainable, sanitary design
- ASME BPE compliant design
- HEPA filtered dual path drying system with independent channels for chamber and load
- Sustainable performance with low utility and energy consumption
- Powerful recirculation pumps for cleaning efficacy
- Selection of automation systems
  - Rockwell – Allen Bradley (Compact Logix as standard)
  - Siemens – (Simatic S7 platform)
- GAMP 5 compliant documentation and programming
- Highest level of parametrically controlled cleaning to meet the demands of the biopharmaceutical industry

Chamber	
316L stainless steel construction/FDA (USP class VI) approved elastomeric seals / Ra < 0.6 µm (< 24 µin) surface finish or better. Radius-corner chamber (>12 mm (½")) and fully drainable hydraulic circuit	■
Chamber welds ground flushed	■
Chamber welds polished	■
Chamber light for load viewing/verification of water distribution	■
Door	
Glass door for load viewing, double pane insulated safety glass for verification of water distribution	■
Process Piping and Valves	
Fully drainable hydraulic circuit	■
Orbitally welded, chamber piping slope > 2%	■
Forged sanitary diaphragm valves	■
ASME BPE compliant	■
Pump	
Sanitary recirculation pump	■
Recirculation pump pressure monitoring with vertical pump outlet	■
Water Inlets	
Quantity of water inlets *If the SPFR option is chosen, one additional water inlet will be required.	1
Additional water inlets (up to 3 total)*	<input type="checkbox"/>
Water distribution loop piloting	<input type="checkbox"/>
Chemical Dosing Systems	
Quantity of dosing pump	1
Additional dosing pump (up to 3 total)	<input type="checkbox"/>
Chemical pump pressure monitoring	■
Conductivity monitoring-final rinse phase	■
Conductivity monitoring-final rinse phase and wash phase	<input type="checkbox"/>

\* dependent on model

Automation system	
Allen Bradley/Siemens PLC	<input type="checkbox"/>
A4 printer (for Siemens)	<input type="checkbox"/>
Installation	
Side access for easy maintenance	■
Single (GEW 888 neo and GEW 9109) or dual cross contamination barrier (GEW 101210, GEW 131313 and GEW 131820)	<input type="checkbox"/>
Flush brush finish stainless steel front panels/easy cleaning/washdown capable	■
Documentation	
GAMP 5 compliant validation support for documentation package and comprehensive manuals	■
Weld numbering, weld mapping and weld boroscopic inspection	■
Full material traceability (3.1 certificates)	■
Testing and qualification	
Prequalification in factory	■
Accessories	
Range of customized and standard modular racks (basic rack, jet rack)	<input type="checkbox"/>
Custom made racks - e.g. glassware, filling line, hoses, IBCs, carboys	<input type="checkbox"/>
Transfer trolleys for racks	<input type="checkbox"/>
Rinse	
Single Pass Final Rinse System	<input type="checkbox"/>
Air exhaust system for API containment	
Air exhaust unit	<input type="checkbox"/>

■ Standard /  Optional features

# Protecting your investment

## – value in performance and reliability

A production system represents a major capital investment in your future revenue stream. That's why Getinge works hard to ensure that our GEW washer/dryers provide true value in design, performance and reliability. Our commitment to excellence is why the world's leading biopharmaceutical companies rely on Getinge.

### State-of-the-art value

Getinge continually invests in state-of-the-art factories, production equipment and process development for one important reason: to ensure that we can continue to provide our clients with the best equipment available. We offer true value for your money.

### Protecting the environment

The Getinge GEW washer/dryers operate on remarkably low water volumes without compromising cleaning efficiency. This reduces the consumption of detergents and energy to minimize the total cost of ownership.

### Easy maintenance access

The washer/dryers require only one side for maintenance access – either the front or side panel. Units can be placed along a wall, if needed. With front access, the electrical cabinet is mounted on runners and fully extendable. The cabinet can rotate on a vertical axis for side access.

### Wide selection of chamber configurations

The Getinge GEW Series consists of a range of chamber sizes that offer optimal handling of common loads. Combining our five standard models with a wide variety of options allows us to provide a custom washer/dryer configuration to meet your specific needs.

### Meeting regulatory requirements

Getinge actively participates in the groups that establish and update industry best practices, operational guidelines, and regulatory requirements. All of our washer/dryers are manufactured in accordance with application specific guidelines.

### Designed for the toughest applications

Getinge GEW Series washer/dryers are built on a foundation of practical experience and are designed to handle the toughest applications. To complement our standard models, we also offer an extensive choice of standardized accessories for common applications. Single-door and double-door models are available to suit your building layout and workflow.

### Ergonomic design for user-friendly handling

Our user-friendly systems protect the safety of your operators. Load handling systems and hinged and sliding doors provide easy and safe access during loading and unloading. A range of trolleys and other accessories enable easy transportation of racks and articles to and from the work area.



# Experience to rely on

## – from concept to compliance

Getinge brings more than 100 years of cleaning and sterilization experience to each project. We are uniquely prepared to provide you with all aspects of a complete sterile process system – saving you time, effort and money. Let Getinge help you satisfy all of your sterile processing needs.

### **Early involvement for best outcomes**

Our early involvement in the planning process can help you to achieve more cost-effective solutions. We offer support with initial advice and system design; we provide an extensive range of washer/dryers and sterilizers, closure processing systems, and barrier isolation technology; and we can guide your project through installation and validation.

### **Quality performance from custom systems**

Our systems are based on compatible modular units. These standardized, tested units can be integrated and installed quickly to form complete customized solutions that meet your unique needs. These systems offer the high quality and performance that have made Getinge the world leader in cleaning and sterilization systems.

### **Global support and training**

Wherever you are, we're here to support you. We have comprehensive resources for service, maintenance, and support on six continents.

Our Getinge Academy educational programs provide thorough training, both online and on-site, as needed. With Getinge, you can be certain that your operators are thoroughly trained in the proper and efficient handling of equipment for sterile processing.

**For more than a century, customers have been in safe hands with Getinge.**





With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries. This information is intended for a professional audience. The information herein is for informational purposes only and should not be relied upon as a replacement of the Instructions for Use or service manual. Getinge shall bear no responsibility or liability for any action or omission by any party based upon this material, and reliance is solely at the user's risk.

This document is intended to provide information to an international audience outside of the US.

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