

GETINGE

**GETINGE GEW cGMP WASHER/DRYERS
SECURING CRITICAL CLEANING
IN THE MANUFACTURING ENVIRONMENT**



EXPERIENCE TO RELY ON

Getinge is uniquely capable of offering you complete sterile systems. The earlier we are involved in the planning process for your new or replacement system, the more cost-effective the solution we can offer you.

Our knowledge and application expertise are drawn from over 100 years of dedication to washing and sterilization equipment within healthcare and life sciences.

From concept to compliance

We can support you with initial advice, system design, steam generation and water distillation equipment, extensive ranges of washer-dryers and sterilizers, closure processing systems, accessories, installation design, validation, support and maintenance. Dealing with just one competent company saves you a lot of time, effort and money. Getinge can satisfy virtually all your sterile processing needs – from “concept to compliance”.



Optimal lifecycle economy

Our systems are based on compatible modular units that can quickly be integrated and installed to form complete customized solutions based solely on your needs. The high quality and performance that have made Getinge the world leader in washing and sterilization systems ensure optimal lifecycle economy.

Because Getinge is a worldwide company, we have the resources to meet your service, maintenance and other support needs wherever you are. And our Getinge Academy offers thorough training to assure the proper and efficient handling of equipment for sterile processing.

You're in safe hands with Getinge.



PURPOSE DESIGNED FOR THE APPLICATION

Getinge develops, manufactures and supplies complete, integrated washing and sterilization systems for use within the life sciences.

Getinge GEW cGMP washer-dryers have been designed “from the ground up” to meet the needs of the pharmaceutical industry. Working in cooperation with users and engineers, our equipment has been developed to satisfy the unique demands and stringent regulations of the industry. Our current range of washer-dryers constitutes the most comprehensive range on the market today.

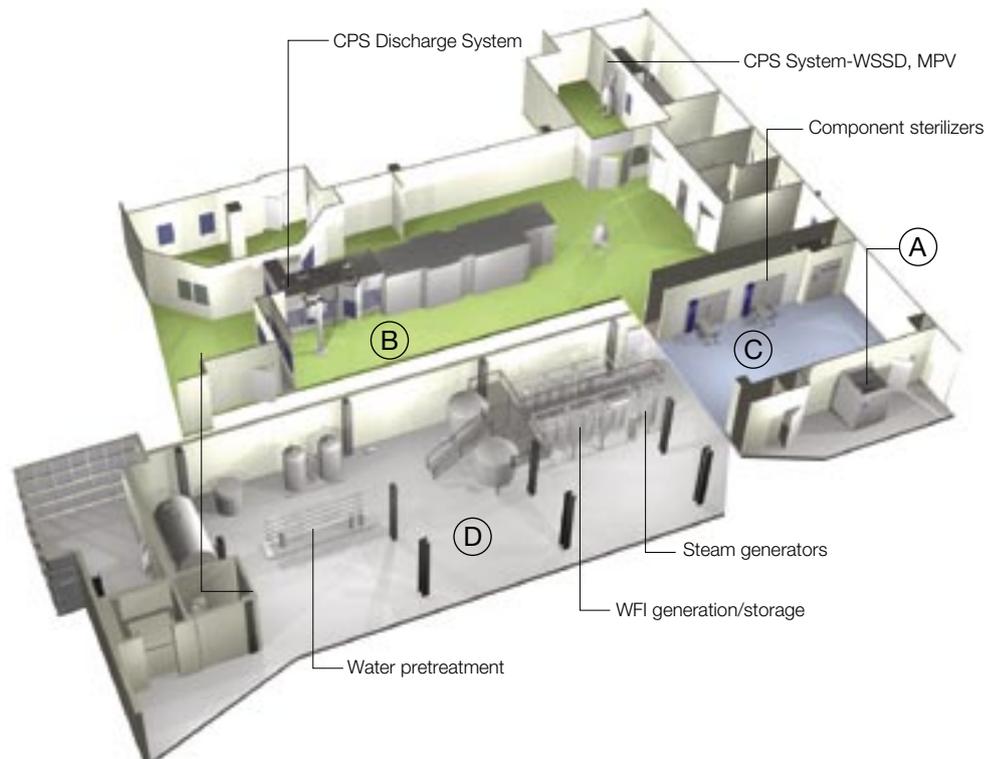


A: GEW Series
cGMP Washer / Dryers.
Single or double door, pass through models.
Fold-down doors for simple and ergonomic operation.
4 Standard chamber capacities:
0.3 to 0.9 m³.

B: Aseptic suite/manufacturing area
C: Equipment/component preparation
D: Utility area

QA Laboratory (not shown)

- Laboratory sterilizers
- Glassware washers
- Integral clean steam generator



SAFEGUARDING YOUR INVESTMENT

A production system represents a major capital investment. That's why Getinge works hard to ensure that our GEW cGMP washer-dryers provide true value in terms of design, performance and lifecycle economy.

State-of-the-art production

Getinge continually invests in state-of-the-art factories, production equipment and process development for one reason – to ensure that we can continue to provide our clients with the best equipment available. We believe we offer true value for money. This is reflected in our impressive client base – the world's leading pharmaceutical companies rely on Getinge.

Satisfying your needs

GEW Series washer-dryers, the products of many years of practical experience, are designed to handle the toughest applications. We recognize that most applications are unique, so we offer made-to-order racks and handling systems, as well as an extensive choice of standard accessories for common applications. Single-door and double-door pass-through models are available to suit your building layout and workflow.

Ergonomy

Our load handling systems are developed for user-friendliness. Fold-down doors provide easy and safe



access during loading and unloading, while a range of trolleys and other accessories enable easy transport of racks and articles to and from the work area.

Wide range of chamber sizes

The Getinge GEW Series comprises a range of chamber sizes that give optimum handling in all ordinary applications. Four standard models meet the requirements of most applications.

Custom size chambers are also available on request.

Regulatory issues

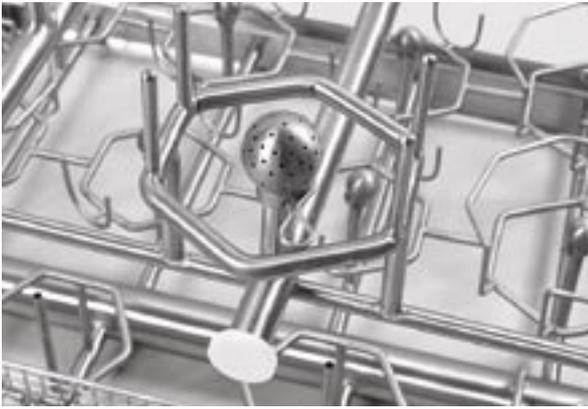
Getinge closely follows industry trends, practices, guidelines and regulatory requirements. We also actively participate in groups and committees that work to refine these requirements.

GAMP | cGMP | BPE2002 | MCA | ISPE BASELINE GUIDES FDA | EN46002 | ISO9000 | 21CFR Part 11

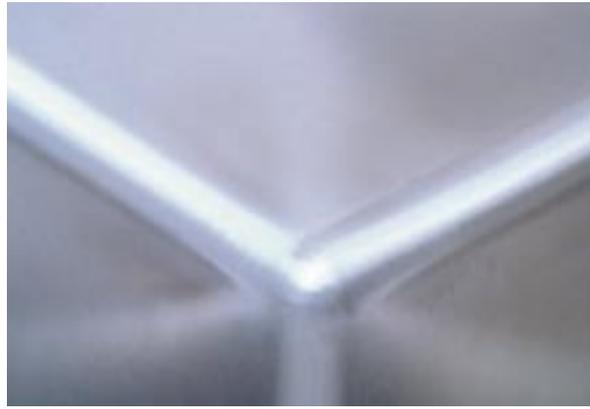
All of our washer-dryers are manufactured in accordance with the guidelines or standards relating to the intended applications and the country of installation.

Protecting the environment

All processes are optimized to minimize the use of energy and chemicals. Options are also available to reduce cooling-water consumption by up to 75%.



Sanitary spray arms in the chamber, in combination with injection points on racks ensure complete, uniform coverage of both chamber and load.



Chambers are fully welded (no seams) and feature rounded corners and a sloping base to ensure complete drainage.



A sanitary steam heating coil in the sump rapidly heats circulating water and accurately controls the temperature. If steam is not available, electrical heaters may be provided in the same location.



CAD is used extensively in the design phase. Our customization and 3D modeling service, for example, is normally used to help design inventory systems for specialized components to be processed.



Smaller models incorporate a convenient under-chamber storage cabinet for chemical containers. Larger models require bulk tanks stored externally.



Doors fold down to provide convenient and ergonomic loading. The operation is assisted by gas-dampened supports that reduce the effort required by the user. On larger models, legs fold out to support the open door, while on smaller models, the supports are anchored to the machine frame, as shown here.



GEW Series	666	787	8108	1388
Chamber volume m ³	0.25	0.42	0.74	0.94
Chamber width, mm	625	705	850	1300
Chamber height*, mm	640	855	1030	850
Chamber depth, mm	625	705	850	850

* Standard options to increase chamber height by 150 / 250 mm

FEATURES THAT SATISFY YOUR PROCESSING NEEDS

The GEW Series consists of four standard models in a variety of chamber capacities to suit most common applications. Non-standard variants of these models are also available on request*.

1. Efficient drying

Two separate drying systems: one for the chamber and one for the process path and racks. Ceramic heating elements allow variable drying temperature control for different materials. All components are upstream of the final HEPA filters. Air is exhausted to a vent connection.

The washer-dryer may be used to control the extractor system, and an optional isolation valve is available.

2. Filter monitoring

DOP ports and differential pressure transmitters are standard features, providing essential routine monitoring capability. Magnehelic® differential pressure gauges are available as an option for visual verification of filter loading.

3. Fully automated

The Getinge GEW washer-dryer is equipped with a GAMP-compliant, 21CFR Part 11-capable, state-of-the-art modular PLC system. Getinge's own PACS 3000 system is standard equipment and offers a selection of HMI panels. Allen Bradley or Siemens platforms are available as alternatives (see "Control Systems", page 13).

4. Robust and sanitary construction

Sloping design and smooth, crevice-free construction of chamber, piping, components and racks eliminates water retention and sites for biofilm or corrosion. Type 316L stainless steel is used throughout, with EPDM, PTFE or other FDA-approved gaskets and elastomers. Globally available components, e.g. Gemu process valves, are



standard. Orbital welding is used wherever possible and weld documentation is available on request.

5. Washing configurations

There are two rack-water inlets, providing washing on one or two levels, depending on the model. Multi-level washing is also possible via a multi-level washing rack, configured according to the load requirements.

Water is heated using a steam-water heat exchanger in the sump of the chamber (electrical heating if steam is not available).

6. Installation

All models are provided with 316L stainless steel fascia panels for recessed installation, or with additional side panels to form a cabinet that encloses the unit.

7. Chemical addition

On smaller models, chemicals are stored and dispensed from a cabinet beneath the door. Larger models require remote bulk chemical storage. Level sensors inhibit operation when there is insufficient chemical for the required process, and sensors monitor and document usage. During rinsing, the chemical dispensing circuits are flushed.

8. Final rinse with WFI

There are two options for the final rinse. The recommended method is to charge the sump with WFI and recirculate throughout the process path. Conductivity is checked (conductivity meter optional), and the process continues until it is within acceptable parameters. This process minimizes WFI consumption and provides a validatable, repeatable result.

The alternative method is to use direct injection to the wash chamber via the water inlets from the WFI loop system. This method requires a significant WFI flow rate and sustained pressure from the WFI loop. A drain cooler system is available to limit the drain outlet temperature, typically to 60°C.

9. Custom designed inventory systems

Racks and frames are evaluated and designed to solve specific cleaning and drying challenges. A wide range of standard accessories are also available.

10. Ergonomic loading platform

Doors hinge down to open, assisted by gas-dampened supports. The open door provides a convenient and ergonomic platform for the loading rack.

11. Door configurations

Each model is available in single-door or double-door pass-through configurations. Doors on the pass-through models interlock to prevent simultaneous opening (and all doors remain locked while the chamber is above 60°C).

12. Printer

A 40-column panel-mounted printer logs critical process parameters during each cycle. An 80-column color printer is available as an alternative.

INVENTORY SYSTEMS: EFFICIENCY, ERGONOMY & EFFICACY

Smooth, uninterrupted production requires that the right tools and equipment are available and ready for use when you need them. It must also be possible to move heavy or awkward articles to where they're needed, safely and efficiently.

Getinge's inventory management and handling accessories are specifically designed to meet these needs. Working in cooperation with our customers – and, where necessary, manufacturers of production equipment – we optimize washer-dryer accessories to assure a safe, ergonomic system that keeps you up and running.

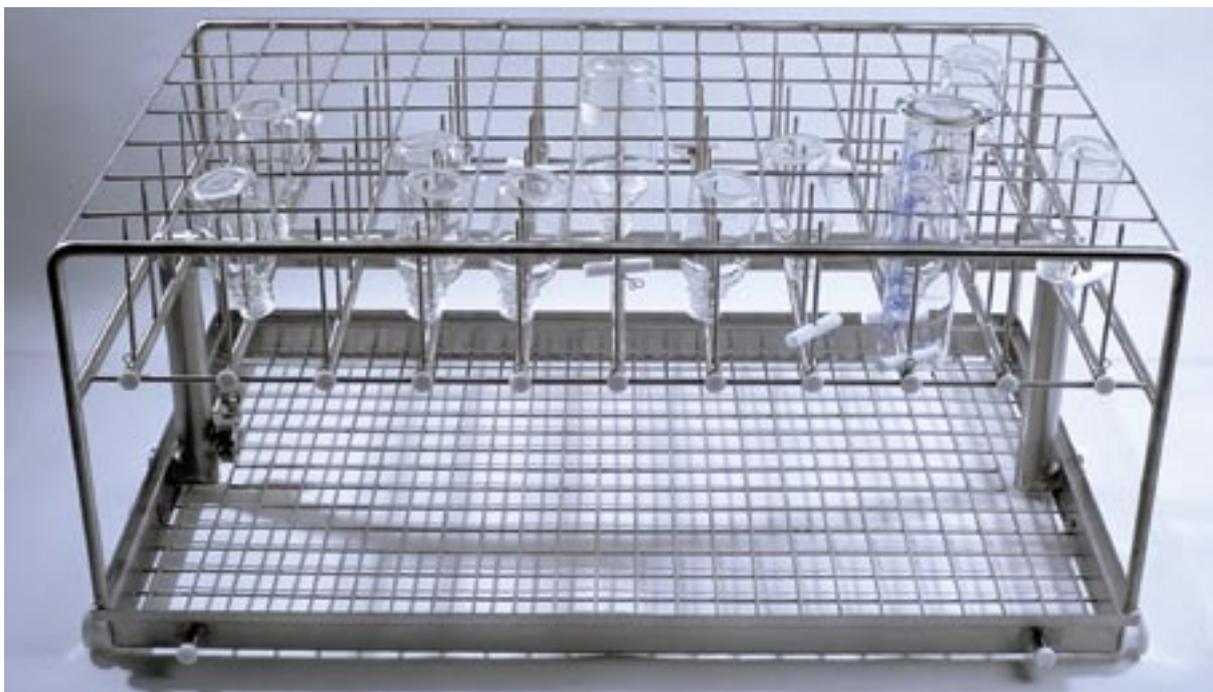
Equally important to production efficiency is cleanliness – elimination of the possibility of cross-contamination with residues or dirt from previous use. Getinge

uses CAD systems with 3D modeling to ensure that every corner and cavity of the article being processed is thoroughly washed. After washing, the same injection porting is used to convey hot sterile filtered air inside for drying.

The pictures on this page show examples of the many customized systems Getinge has supplied. A wide variety of standard racks are available for the most common applications.



Valve bodies, mount the exterior surfaces.



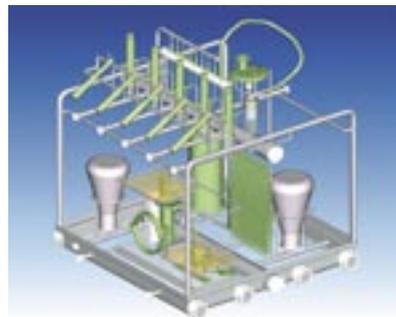
Glassware racks can be provided with a variety of holders and nozzles to ensure optimal cleaning without risk of damage.



Injection rack; designed and fabricated using a wealth of experience.



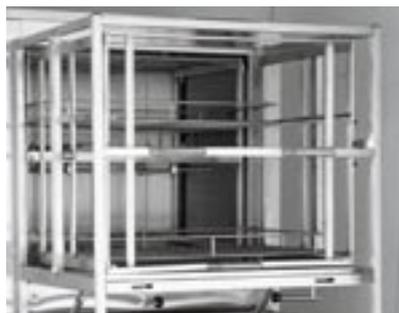
Machine parts are frequently sent to Getinge for modelling / rack design.



3D CAD modeling is used to design tailor-made racks for different applications, usually in cooperation with the user or equipment supplier.



Injection nozzles, designed for effective cleaning and drying may themselves be disassembled for cleaning and maintenance.



Loading trollies can be provided to efficiently move materials to and from the washer-dryers.



Special rack / basket for cleaning and drying silicon and metal tubing together with their tri-clamp fittings.

A rack designed for washing tubing – internally and externally. The tubing winds around the frame to avoid kinking while cleaning agents and water flush the inner surfaces.



VALIDATION SUPPORT DOCUMENTATION

Comprehensive documentation supports our customers' validation process. All documentation follows GAMP4 Guidelines.

During the manufacturing process, in-process checking is performed to ensure compliance with specifications, and documentation is maintained as confirmation. After manufacture, every unit undergoes comprehensive and rigorous Factory Acceptance Testing (FAT), again accompanied by detailed documentation. After installation, Site Acceptance Testing (SAT) services can be provided to confirm / reproduce the results obtained in

FAT, once again, with comprehensive documentation following pre-agreed procedures.

A complete package comprising these, together with installation, user and technical manuals, is provided with the equipment. These documents are intended to support your subsequent process validation procedures, thus saving considerable time, effort and expense.

OTHER WASHER/DRYERS FROM GETINGE

In addition to the GEW Series cGMP washer-dryers, Getinge supplies a wide range of other washers and washer-dryers. For example, the Getinge 9900 Series washer-dryers are designed for larger loads. With capacities from 1.75 - 2.48 m³, these washers are ideal for carboys, tanks, bulk containers or large shelf racks.

Additionally, a wide range of glassware washer-dryers is available for applications in quality assurance, research and microbiology laboratories. These washer-dryers are available in a range of capacities with a vast assortment of accessories. For some models, automated loading and unloading systems are also available.

In the research area, cage-and-rack washers quickly and efficiently process soiled animal cages, racks and drinking-water bottles. Tunnel and indexing washer systems are available for high capacity throughput applications.

◀ Typical small Getinge laboratory glassware washer-dryer.



Whatever the application in the life sciences, Getinge has the solution for all your washing and sterilization applications. Consult Getinge for further information. www.getingeproducts.com / info@getinge.com



The Getinge GEW Series Rack washers are ideal for larger items such as animal cages, cage racks, carboys, trolleys, tanks. May be pit mounted (as shown) for easy loading and unloading.

CONTROL SYSTEMS

Reproducibility of process control is crucial in life science applications, particularly in the manufacture of pharmaceuticals. To achieve this and minimize human error, Getinge supplies the PACS 3000 Control Systems.

Versatile features

The major features included in PACS 3000 are:

- Extensive documentation
- Automatic sensor calibration
- Comprehensive alarms/alerts
- Process and alarm logging
- Multilevel password protection
- Multilanguage display

Regulatory compliance

The entire PACS 3000 system is developed in accordance with the stringent GAMP guidelines of the pharmaceutical industry, and is FDA 21 CFR part 11-capable. Every system is supported with comprehensive system documentation.

Standard PLC Systems

The PACS 3000 system is specifically designed to control process equipment for applications in the life sciences. Many thousands of PACS systems are in operation around the world in validated production facilities. However, if a customer prefers, standard PLC systems are available based on Allen-Bradley or Siemens hardware platforms.

These PLCs are provided as standard options with similar functionality and documentation to the Getinge PACS 3000.



ALTERNATIVE CONTROL PANELS



OP30 user interface

- Door open/close buttons. Status LEDs.
- 5.7" color screen for process info:
 - Remaining time, cycle & phase, temperature(s)
- Graphical process presentation:
 - Plot graph, bar graph
- Parameter settings.
- Maintenance & service menus.
- System configuration.



T-DOC and OPTRAIL
Documentation tool & 21CFR Part 11 solutions



Process Documentation



Network solutions
Ethernet
Industry standard protocols
Remote support facility
CS 1000



Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

GETINGE

Getinge Infection Control
PO Box 69, SE-310 44 Getinge, Sweden
Phone: +46 35 15 55 00
Fax: +46 35 549 52
info@getinge.com www.getingeproducts.com

GETINGE

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