



Cleaning and sterilization solutions for the biopharmaceutical industry

Miele

Group
Member

Global supplier for cleaning and sterilization solutions for the pharma and biopharma industry

Located in modern factories near Venice in Italy, Steelco Group is a major global supplier of infection/contamination control equipment and solutions for the healthcare, laboratory, biomedical and pharmaceutical sectors. Steelco's success is demonstrated by its strong growth, becoming the partner of choice for many of the world's leading companies who appreciate the company's:

Experience and knowledge

- Strong track record of establishing long term global partnerships.
- Network of factory trained agencies in over 100 countries worldwide.
- Integrated in-house operations from incoming raw materials to installation, validation and technical support.
- Fully certified quality systems with deep knowledge of manufacturing standards.

Extensive product range

- Over 3000 installations worldwide.
- Innovative washing equipment, customizing loading racks.
- Diversified sterilization range.
- Fully automated closure processing equipment.
- Drying and depyrogenation ovens.
- Automation systems to maximize productivity and safety.
- Environmental control systems.

Quality engineering process

- Technical consulting, design, engineering, project management, as well as commissioning and qualification services of our equipment is offered, with customers appreciating the cost effective high performance solutions offered to resolve complex washing and sterilization challenges.
- Customers are always welcome to visit Steelco factories to see design and manufacturing methods and audit our processes.

Flexible solutions

- Ability to meet the most challenging processing needs.
- Only using the best proven and ready available "Non-Proprietary" components such as control systems and valves to reduce running costs and down time.



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The most comprehensive range to meet diverse customer needs



cGMP Washing Systems

- Parts and Glassware Washers
- Rack/Bin/Large Parts Washer
- Standard and Customized Loading Solutions

cGMP Sterilization & Decontamination Solutions

- Saturated Steam Sterilizers
- Steam-Air Mixture Sterilizers
- Superheated Water Sterilizers
- Closure Processing Equipment
- Depyrogenization Ovens
- Hot Air Drying Oven
- Ethylene Oxide Sterilizer
- Decontamination Air Locks with VH_2O_2

DS PH Series

Pharma grade parts and glassware washers



Single or double door version, full glass vertical/horizontal sliding doors or hinged door also in stainless steel

Chamber volume*

from 230 litres / 8 cu ft
to 2.400 litres / 85 cu ft

*Custom dimensions available upon request

Overall dimensions may vary according to machine configuration and customer requirements

Field application:

- + Glassware, pipettes and glass bottles
- + Filling line components and tools
- + Tubing, TC fittings
- + Valve and pump bodies, filter housings
- + Punches and Dies
- + Reactor vessels and equipment
- + Bulk containers, tanks and carboys

Pharma Grade Parts Washers are engineered and utilized for throughput, efficiency and validatable cleaning and drying of various materials and components used in the biotechnology and pharmaceutical manufacturing processes.

DS Series can be configured with different layout: single door or passthrough double version, with automatic motorized opening in vertical or horizontal sliding doors. Available also in hinged door version, full glass or stainless steel.

The electrical cabinet can be integrated within the skid of the unit or remotely installed. Technical area can be on right or left side, alternatively can be shared in case of "in line" installation.

Key Features:

- + More than 400 options available
- + Steam or electrical heated
- + Unrivalled cleaning and drying
- + Integrated automation architectures
- + Non-proprietary parts
- + Modular or custom rack configuration
- + Cycle development support
- + Remote assistance



Complete layout versatility

Safety and ergonomics is our priority. DS Series can be configured with different layouts: single door or double door pass-through version, offering sliding and hinged door models in various configurations. Possibility of interfacing unloading door with various models isolators.



Reliable and hygienic construction

All wetted surfaces are crevice-free construction, with orbital welding for piping to eliminate water retention and stagnation points where biofilm could accumulate.



Effective sampling solutions

Steelco offers a wide range of sampling systems to meet the most rigorous requirements. For each sampling solution a T/C port, a manual or automatic valve can be installed in the technical service area or in an alcove on the machine fascia panel, according to client requirements.



Innovative (COP) for mobile tanks

Cleaning of mobile tanks usually requires a large washer with high capital cost, utility consumption and GMP floorspace. Steelco has developed an innovative Cleaning Out of Place (COP) system, combining a medium-sized GMP parts washer with a cleaning station for the mobile tanks



DS Optima PH

Pre-configured, cost-effective,
full GMP washer

**3 months ready
for FAT!**



Single or passthrough double door
version with hinged full glass door

Chamber Dimensions WxDxH

1000 x 1000 x 1200 mm
40" x 40" x 48"

Chamber Volume

1200 liters / 43 cu ft

Overall Dimensions WxDxH

2200 x 1150 x 2500 mm
87" x 45" x 98"

Field application:

- + Glassware, pipettes and glass bottles
- + Filling line components and tools
- + Tubing, TC fittings
- + Valve pump bodies, filter housings
- + Punches and Dies
- + Reactor vessels and diverse equipment
- + Bulk containers, tanks and carboys

A fast-track development of a pre-configured fully GMP compliant washing machine for the pharmaceutical manufacturing industry. A compact-size, cost-effective GMP washer with standard features and available options to enable minimal lead time from order to delivery.

The design ensures self-cleaning of the chamber and pipework at each process stage, to prevent cross contamination risk. It can be configured in different layout: single or passthrough double door version with hinged full glass door. The technical area can be on right or left side.

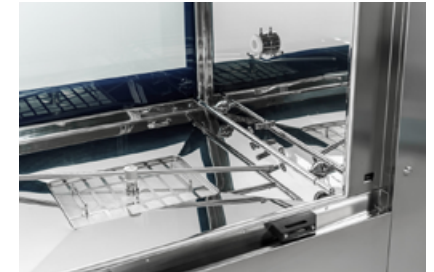
The electrical drying unit assures complete drying of the chamber and items loaded both on the internal or external surfaces.

Key Features:

- + Compact-Size
- + Cost-effective
- + Steam or electrical heated
- + Unrivalled cleaning and drying
- + Non-proprietary parts
- + Modular or custom rack configuration
- + Cycle development support
- + Remote assistance

Reliable and hygienic construction

The chamber features angled surfaces and rounded corners to ensure complete drainage. Detailed engineering on the sump reduces water consumption and assures high performance in terms of both cleaning and consumption.



Easy access to sampling and dosing system

Different sampling systems are available: from sump, from final rinse, and from point of use for each water. Easy access to sampling system and detergents from technical area below the chamber from loading side.



Easy maintenance

The machine is developed considering technicians' access to the maintenance and service area. Easy access to all components from the loading side. The electric cabinet is installed on sliding rails for easy maintenance.



Modular or customized carts

Steelco designs, develops, manufactures, and tests all its own wash racks in-house, ensuring that the quality of this critical process is carefully monitored. All racks are provided with standard validation package.



LC PH Series

Rack/bin/large parts trolley washer



Single door or double door versions, floor mounted or pit mounted, with automatic horizontal sliding doors or hinged doors, in full glass or stainless steel

Chamber volume*

from 4.250 litres / 150 cu ft
to 10.500 litres / 370 cu ft

*Custom dimensions available upon request.

Overall dimensions may vary according to machine configuration and customer requirements

Field application:

- + Bulk Containers (IBC)
- + Large components and drums
- + Ultracentrifuges
- + Glassware, tanks and carboys
- + Filling line components and tools
- + Tubing, TC fittings
- + Valve and pump bodies, filter housings
- + Reactor vessels Bulk containers

The LC PH Series of pharmaceutical grade washers is a range of cabinet washers developed for all applications where it is necessary to wash and dry large volumes of items or large diameter / bulk components.

The chamber floor, manufactured with easily removable floor grating, allows the operator to walk with safety on it. The top and lateral oscillating washing arms guarantee perfect washing and drying results.

The inline heating elements, located in the hydraulic circuit, are pharma industry compliant, sanitary, and dead-leg free, fabricated from AISI 316L (1.4404) stainless steel and electro-polished. They may be connected to plant steam in the steam heat exchanger version or directly to plant power in the electrical heat exchanger version.

Key Features:

- + More than 400 options available
- + Steam or electrical heated
- + Unrivalled cleaning and drying
- + Integrated automation architectures
- + Non-proprietary parts
- + Modular or custom rack configuration
- + Cycle development support
- + Remote assistance

Complete layout versatility

Offering hinged or sliding door models in various configurations. Furthermore, the electrical cabinet and the drying system can be integrated within the skid of the unit or remotely installed. The technical area can be on the right or left side; alternatively, it can be shared in the case of “inline” installation.



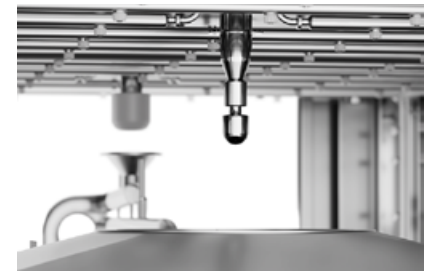
Reliable and hygienic construction

The chamber features angled surfaces and rounded corners to ensure complete drainage. Detailed engineering on the sump reduces water consumption and assures high performance in terms of both cleaning and consumption.



Automatic manifold for bin washing

Cleaning and drying of Intermediate Bulk Containers (IBC) and drums. Custom made for individual customer needs, these units feature the possibility to rotate both the container being cleaned and/or the spray nozzle arm 360° inside the load ensuring exceptional cleaning of all surfaces.



Effective sampling solutions

Steelco offers a wide range of sampling systems to meet the most rigorous requirements. For each sampling solution a T/C port, a manual or automatic valve can be installed in the technical service area or in an alcove on the machine fascia panel, according to client requirements.



Pharma carts and trolleys

Standard and customized loading solutions

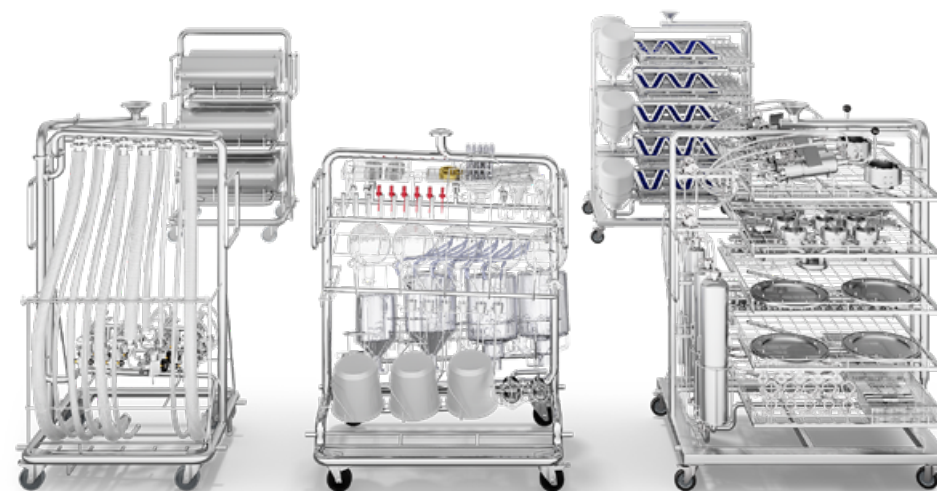
With most of the industry's largest Pharma companies as its customers, Steelco has an in-depth understanding of the rigorous critical cleaning requirements of equipment used in pharmaceutical production.

Steelco designs, develops, manufactures, and tests its own racks and trolleys in-house, ensuring that this critical process' quality attribute is assured and providing a single point of responsibility for the design and function of the entire cleaning process.

Steelco's engineering experience and sophisticated 3D CAD programs provide that every point, corner, and cavity of an item to be processed is deeply and efficiently cleaned, thus avoiding the possibility of cross-contamination and eliminating all soil and contaminant residues from the previous process.

The same injection porting is used to also convey hot sterile filtered air inside each cavity for effective drying.

- + **3D Modelling**
- + **Ergonomics**
- + **Quality and safety**
- + **Process effectiveness**
- + **Documentation and testing**
- + **Automatic loading systems**





AV Series

Saturated Steam Sterilizers



Single or double door version, stainless steel hinged door or vertical/horizontal sliding doors

Chamber volume*

from 195 litres / 7 cu ft
to 10.000 litres / 353 cu ft

*Custom dimensions available upon request

Overall dimensions may vary according to machine configuration and customer requirements

Field application:

- + Vials, bottles and glass items,
- + Fabric materials,
- + Sealed or vented containers,
- + Rubber parts,
- + Machine part and filters
- + Other similar components

Steelco AV Series Pharmaceutical Grade Saturated Steam Sterilizers are a fundamental part of the process used to render an object free from viable infectious agents, including viruses and bacterial spores. Built to a very high standard, each unit is tailored to the customer's specifications. AV series is used to sterilize with clean/pure saturated steam materials such as vials, bottles, glass items, fabric materials, sealed or vented containers, rubber parts, machine parts, filters, etc.

The AV Series of steam sterilizers are high-performing, reliable, and easy to use. Its sterilization cycle has been specifically designed to minimize time and energy consumption while maximizing efficiency and throughput.

Key Features:

- + Door seal guaranteed for 4 years
- + Energy saving and low wastage
- + Drain cooling system available as option
- + Air detector following EN 285
- + Easy validation testing
- + Cycle development support
- + Non-proprietary parts
- + Remote assistance



Complete Layout Versatility

AV series can be configured as standard with different layout configurations: floor mounted or pit mounted version; electrical cabinet integrated within the skid of the equipment or remotely installed; technical area: right/left or shared in case of "inline" installation.



Reliable and hygienic construction

The chamber is self-draining with a cylindrical or rectangular cross section and covered by a full jacketed system of dimple welded type for fast and uniform heat transfer and optimization of chamber temperature distribution.



Sterilization cycle development

The sterilization cycle has been specifically designed to reduce time and energy consumption, improving efficiency and throughput. Complete flexibility to customize each phase and its parameters. All standard or custom cycle recipes are analysed and identified during design phase.



AVD Series

The AVD Series combines all the features of a saturated steam sterilizer with the capability of performing bio-decontamination cycles using VH₂O₂. Sharing the same chamber, utilities, and control system, this multipurpose device requires less space and operating cost compared with two independent and dedicated unit. Using VH₂O₂ technology provides a complete turnkey solution for the bio-decontamination of heat-sensitive equipment to be transferred from one classified area to another.



AMS Series

Steam-air mixture sterilizers



Horizontal sliding single or double doors, designed for terminal sterilization of parenteral drugs

Chamber volume*

from 830 litres / 29 cu ft
to 25.000 litres / 883 cu ft

*Custom dimensions available upon request

The overall dimensions may vary according to machine configuration and customer requirements

Field application:

- + Liquids in sealed, semi-open or heat-sensitive containers
- + Bottles, ampoules and vials
- + Bags, blister packing
- + Pre-filled syringes
- + Pouches
- + Contact lenses and LPV's
- + Pasteurization of blood plasma

Steelco's range autoclaves using air + steam is for the terminal sterilization of injectable solutions. This sterilization method avoids any damage of the processed liquid material and their containers, including heat sensitive materials.

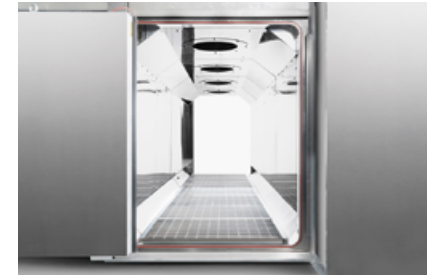
The homogeneous air + steam and temperature distribution is performed by the action of the recirculation fans on top side of the chamber. Rapid cooling of the product is performed through the jacket or heat exchangers installed inside the chamber, running with cold soft water, available as option. Sterile compressed air for counter-pressure maintain the proper pressure inside the chamber.

Key Features:

- + Load completely dry at the end of the cycle
- + Optimal temperature distribution
- + Rapid Cooling
- + Flexible and versatile loading and unloading solutions
- + Easy maintenance
- + Non-proprietary parts
- + Remote assistance

Doors and gasket

The chamber is equipped with horizontal sliding double doors and the movement is controlled by an electromechanical device. The door tightness is guaranteed by gasket in Silicon FDA compliant swallowtail pneumatically pressurized by compressed air.



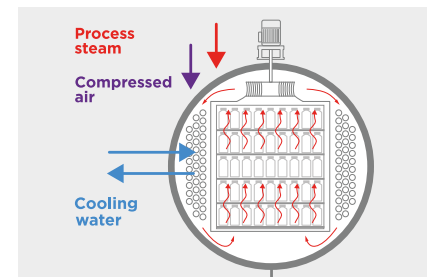
Reliable and hygienic construction

A high-quality AISI 316 L stainless steel chamber guarantee long-term reliability and steam cleanliness. Sterilization chamber of round cross section provided with jacket for a fast and uniform heating and cooling of the load, or by heat exchanger inside the chamber.



Sterilization process

Pure steam is used in the chamber for heating liquids. Over-pressure filtered air is injected into the chamber to compensate for the rising temperature and pressure inside the products. Internal fans ensure a uniform temperature distribution, between 110°C to 135°C, to avoid cold spots across the chamber.



Workflow optimization and load handling

Semiautomatic or fully automated conveyor systems for loading and unloading racks and integration with robots are available to optimize workflow and maximize productivity. In addition, loading racks made of AISI 316L stainless-steel equipped with a guide for shelves positioning can be provided with automatic push and pull device guides to be installed inside the chamber.



ASW Series

Superheated water sterilizers



Horizontal sliding single or double doors, designed for terminal sterilization of parenteral drugs

Chamber volume*

from 830 litres / 29 cu ft
to 25.000 litres / 883 cu ft

*Custom dimensions available upon request

Overall dimensions may vary according to machine configuration and customer requirements

Field application:

- + Liquids in sealed, semi-open or heat-sensitive containers
- + Bottles, ampoules and vials
- + Bags, blister packing
- + Pre-filled syringes
- + Pouches
- + Contact lenses and LPV's
- + Pasteurization of blood plasma

Steelco's range autoclaves using superheated water are for the terminal sterilization of injectable solutions. This sterilization method avoids any damage of the processed liquid material and their containers, including heat sensitive materials.

Water is continuously circulated through the system and cascades over the load using spray nozzles, high capacity pump and large diameter piping to ensure high water flow rates. The recirculating water is heated and cooled by external heat exchangers. The process includes the application of counterpressure to avoid permanent deformation of containers.

Key Features:

- + Energy saving & low wastage with recirculation water cooling system.
- + Optimal temperature distribution
- + Rapid Cooling
- + Flexible loading/unloading solutions
- + Easy maintenance
- + Non-proprietary parts
- + Remote assistance

Doors and gasket

The chamber is equipped with horizontal sliding double doors and the movement is controlled by an electromechanical device. The door tightness is guaranteed by gasket in Silicon FDA compliant swallowtail pneumatically pressurized by compressed air.



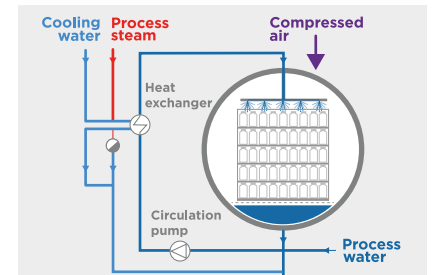
Reliable and hygienic construction

Sterilization chamber of round cross-section, containing all the accessories for its use with superheated water. The design of the lower part of the chamber allows complete drainage, and it is fitted with guides for moving the product holding carts.



Sterilization process

Sterilization by superheated water spray system supplied by a water-recirculation pump. Cooling of the product through direct water shower. Sterile compressed air for counter-pressure or air exhaust are able to maintain the proper pressure inside the chamber.



Workflow optimization and load handling

Semiautomatic or fully automated conveyor systems for loading and unloading of racks and integration with robots are available to optimize workflow and maximize productivity. Loading racks completely made of AISI 316L stainless-steel equipped with guide for shelves positioning can be provided of automatic push and pull device guides to be installed inside the chamber.



SPE Series

Closure Processing Equipment



Five models with five different chamber capacities. Chamber volume: from 40 litres / 1.4 cu ft to 240 litres / 20 cu ft

Model	Useful volume	Volume per basket	No. of baskets
SPE-40	40 Lt / 1.4 cu ft	10 Lt / 0.35 cu ft	4
SPE-80	80 Lt / 2.8 cu ft	10 Lt / 0.35 cu ft	8
SPE-120	120 Lt / 4.2 cu ft	10 Lt / 0.35 cu ft	12
SPE-180	180 Lt / 6.4 cu ft	10 Lt / 0.35 cu ft	18
SPE-240	240 Lt / 8.5 cu ft	12 Lt / 0.42 cu ft	20

Field application:

- + Rubber and plastic stoppers
- + Plungers
- + Tip caps
- + Aluminum caps and seals
- + Other similar components

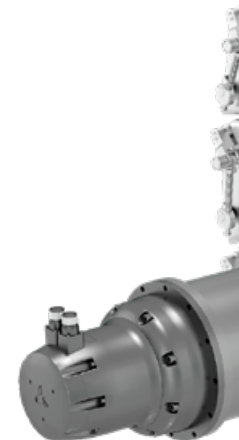
The SPE Series is ideal for treating closures for containers normally used in the pharmaceutical industry, where continuous sterility has to be maintained between different phases. The pharma grade closure processing system fully integrates all the phases of the treatment in an all in one solution:

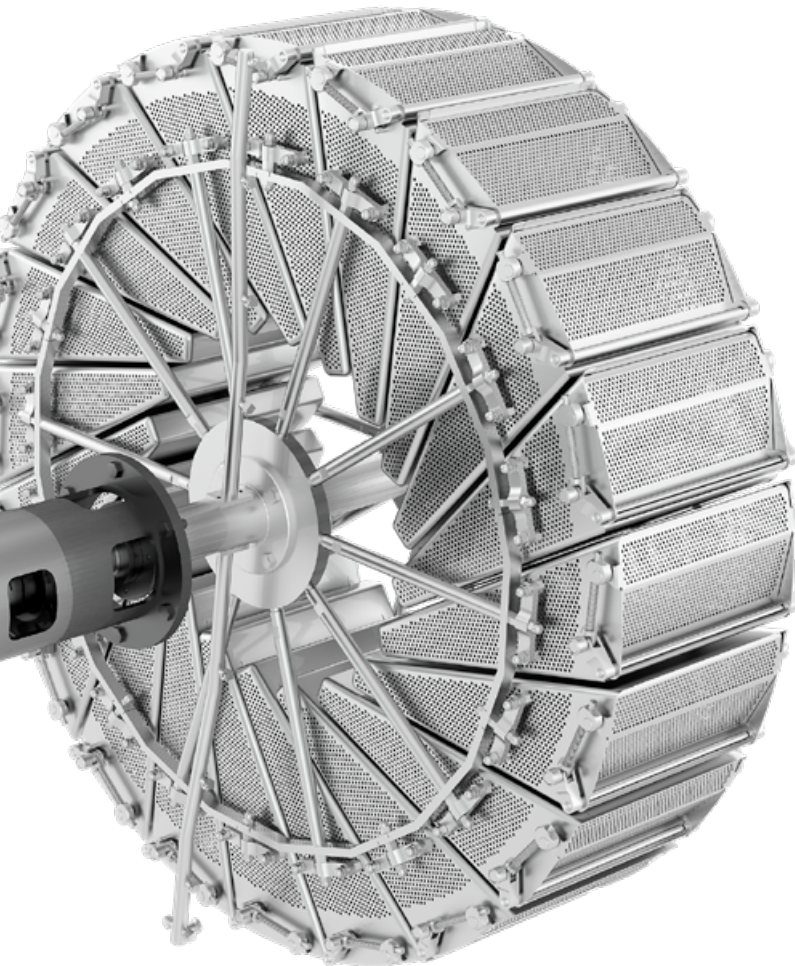
Pre-treatment handling - Washing, rinsing & siliconizing - Sterilization, drying and cooling - Sterile delivery

The high-quality AISI 316 L chamber with a round cross-section and two torispherical heads ensures an even distribution of load in separate baskets for optimized final results. In addition, Steelco produces a “Closure washer” version (SPE-W series) that only provides washing, rinsing, siliconizing, drying, and cooling phases.

Key Features:

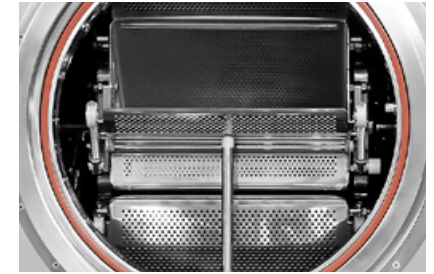
- + All in one solution
- + Reduce the number of manipulations during the process steps
- + Endotoxin and particle reduction
- + Effective and fast drying
- + High flexibility for loading and unloading.
- + Easy maintenance
- + Remote assistance





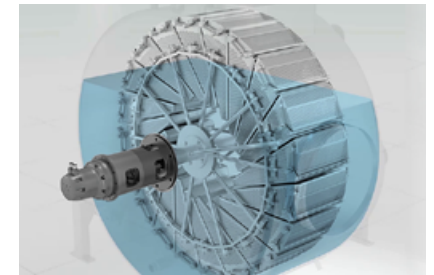
State-of-the-art chamber design

Chamber and jacket made of high-quality AISI 316L stainless steel with no sharp edges to prevent injuries to equipment operators or damage to the closures. The even distribution of load in separate baskets avoids excessive accumulation of material during the treatment phases.



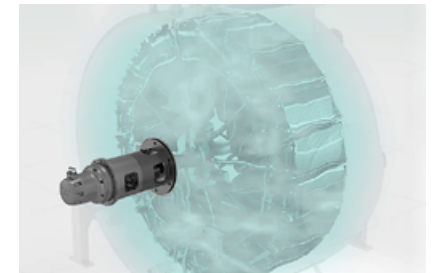
Double washing action.

While the baskets rotate through the water to distribute the washing action evenly over the entire load, a centrifugal pump takes water from the bottom of the chamber and circulate it again back through the spreader placed in the bottom of the chamber to create a fluidized bed.



Sterilization & drying

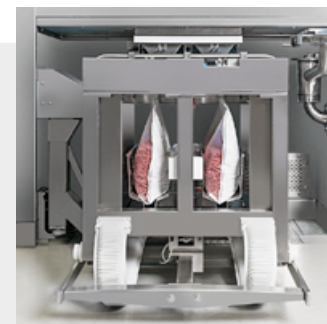
At the end of the washing/rinsing or siliconization phase, the closures may be sterilized using pure steam: the vessel is treated as an autoclave. Unparalleled drying efficacy, residual humidity <0.03%. Over 60% process time reduction compared to traditional systems.



Flexible sterile delivery solutions

Answering the needs both of smaller-scale production and more extensive processing facilities, various options for automatic unloading are available:

- Into a thermosealer unit with single or double bag
- Into RTP ported bags
- Into Sterile transfer container
- Direct unloading into filling line bowl within isolator.



SD Series

Depyrogenization Ovens



Single or double door pass-through
hinged door version

Chamber volume*

from 330 litres / 11.7 cu ft
to 10.000 litres / 353 cu ftw

*Custom dimensions available upon request

Overall dimensions may vary according to machine
configuration and customer requirements

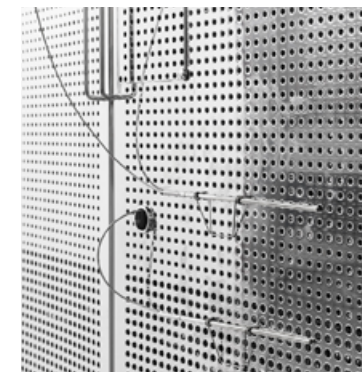
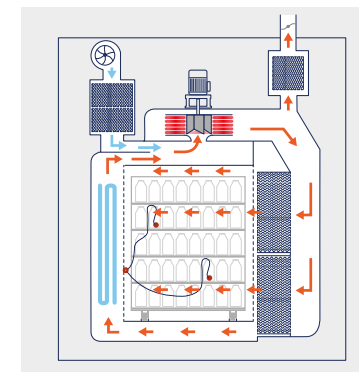
Field application:

- + Bottles, vials, laboratory glassware
- + Metal trays and instruments,
- + Materials sensitive to humidity,
- + Thermostable basic products
- + Chemical compounds
- + Non-aqueous liquid materials such as oils, glycerine, etc.

Steelco designs and manufactures a wide range of Class 100 static depyrogenation sterilizers (ISO 14644-1 class 5) to meet the most challenging pharmaceutical requirements.

The depyrogenation process aims to reduce the level of pyrogens, with the use of hot air in temperature which ranges from 220°C up to 280°C for a controlled period of time. The high-performance Class 100 oven solution ensures an even distribution of hot air for the entire cycle, including large loads, with the installed HEPA filters preventing cross-contamination.

Steelco's GMP depyrogenation ovens and dry heat sterilizers are designed, manufactured, validated, and documented according to the latest global practices and standards to facilitate customer compliance with current Good Manufacturing Practices (cGMPs).



EG Series

Hot Air Drying Oven



Single or double door pass-through
hinged door version

Chamber volume*

from 330 litres / 11.7 cu ft
to 10.000 litres / 353 cu ftw

*Custom dimensions available upon request

Overall dimensions may vary according to machine
configuration and customer requirements

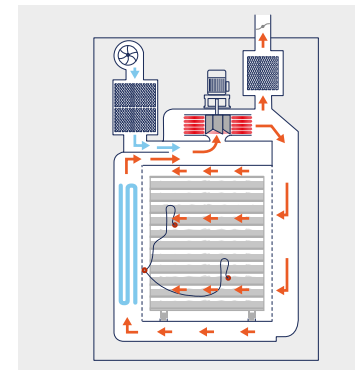
Field application:

- + Granulates,
- + Pellets,
- + Powders
- + Porous load used in
pharmaceutical processes

The EG Series is designed for optimizing process parameters for effective, uniform, and gentle drying by hot air of materials such as granulates, pellets, powders, porous load, and equipment used in pharmaceutical industry processes.

Its cycle has been specifically designed to minimize time and energy consumption while maximizing efficiency and throughput-drying process temperature ranges from 50 to 160°C. In addition, upon request, the unit can be supplied with a self-washing system for performing CIP (Clean-In-Place) of the chamber and air ducts.

The EG Series is designed, manufactured, validated, and documented according to the latest global practices and standards to facilitate customers' compliance with current Good Manufacturing Practices (cGMPs).



AGS Series

Ethylene Oxide Sterilizer



Horizontal sliding single or double doors, designed for chemical sterilization

Chamber volume*
from 1 to 32 pallets

*Custom dimensions available upon request

Overall dimensions may vary according to machine configuration and customer requirements

Field application:

- + Plastic syringes
- + Perfusion sets
- + Dialysis cartridges
- + Heat-sensitive rubber products
- + Special surgical instruments
- + Medical devices

The AGS Series of sterilizers using Ethylene Oxide represents the best relationship between engineering and quality price, operating running costs, and, most important, the safety of the system and operators.

AGS Series has been designed for low-temperature sterilization of heat-sensitive products according to the EN 1422 Standards for the medical processing industry. Following customer requests, dedicated chambers for separate processes can be supplied: Pre-conditioning, Sterilization, and Degassing chambers.

In the case of separate load cells, automatic loading/unloading systems are required allowing the operators to save time and avoid exposure to a potentially contaminated environment.

Key Features:

- + Flexible solutions
- + Safe door closure
- + Environment and safety
- + Automated load handling solutions
- + Remote assistance
- + Non-proprietary parts



High productivity, low consumption

The new range of sterilizers has been designed for best-in-class energy recovery to optimize consumption. The vacuum system is provided with a water ring pump, supplied with water drawn from the separator by creating a closed circuit. The temperature is maintained at optimum levels by a heat exchanger.



Highest industrial standards

A high-efficiency heating jacket surrounds the sterilization chamber for rapid and even heating of loads. The machine body is AISI 304 stainless steel, insulated with high-density ceramic material. The chamber and the hydraulic system are entirely built and clad stainless steel. Process piping is made of tri-clamps and flange connections.



Complete environment protection

Effective and safe abatement of Ethylene Oxide at the completion of sterilization process by thermal combustion: increasingly stringent parameters make it necessary to offer safe accepted abatement systems on every Ethylene Oxide sterilizer. Steelco Group follows the ATEX, UL, OSHA, NFPA, and FDA regulations and complies with ISO 11135, EN 1422.



Ethylene Oxide sterilizers are available in two versions:

AGS series - Pressure sterilization program - Up to 10% of Ethylene Oxide, with the remaining 90% made of inert gas (normally Nitrogen)

AGS-E series - Vacuum sterilization program - Up to 90% of Ethylene Oxide, with the residual 10% made of inert gas (normally Nitrogen)

DHP Series

Decontamination air lock with VH_2O_2



Single or double doors versions with hinged door(s) in stainless steel with glass windows.

Chamber volume*

from 436 litres / 15 cu ft
to 7.875 litres / 278 cu ft

*Custom dimensions available upon request

Overall dimensions may vary according to machine configuration and customer requirements.

Field application:

- + Packaged single-use materials
- + Packaged drug delivery devices
- + Packaged stainless steel instruments
- + Machine parts, small stainless steel containers
- + Electronic devices
- + Various laboratory materials made of glass or plastic

The Steelco Decontamination air Lock is manufactured to provide a validated turnkey solution for the biodecontamination of heat and moisture sensitive equipment to be introduced into a facility or to be processed through a permanent barrier.

The vaporization process of the liquid hydrogen peroxide is performed through an onboard generator fully integrated into the technical area. A ventilation system guarantees a uniform VH_2O_2 distribution in the chamber and on the load assuring a fast aeration phase and higher throughput.

Following this low-temperature treatment, the decontamination reaches the sterility assurance level (SAL) values up to 10^{-6} .

Key Features:

- + Floor or pit mounted
- + Door interlocking system
- + On-board generator
- + Smart load cell
- + Aeration Efficiency
- + Easy maintenance and remote assistance
- + Integrated automation architectures



Fast and safe aeration phase

Fast aeration phase is performed by injection of fresh filtered air into the chamber, piping, and on board generator. The vapor is decomposed into water and oxygen by an in-line catalyzer installed on the exhaust line.



Precise H₂O₂ dosing system

The on-board generator prepares the correct dose of H₂O₂ and delivers it to the vapouriser system. The Liquid H₂O₂ is delivered from a canister easy accessible via an alcove in the fascia panel and a precise load cell verifies the consumption of H₂O₂ for each cycle.



Double inflatable door gaskets

The double inflatable gaskets are separately controlled to give total tightness safety even in the event of failure of one of the seals. An air reservoir provides additional protection by maintaining the gasket pressure in power failure or loss of compressed air pressure.



Maximum Safety

Fully designed with operators' and instruments' safety in mind. Two test points ensure that no gas residues are still present and that the aeration has been adequately carried out. An interlocking system assures the separation of environments at different contamination levels, allowing installation in a barrier.



4 Integrated automation architectures to satisfy the most diverse requirements

Steelco can install new equipment into an existing automation system by adopting a simple (HMI) or more sophisticated (SCADA) man-machine interface. User-friendly control systems developed according to the latest ISPE GAMP® Guidelines and designed for FDA 21 CFR Part 11, EU Annex 11 compliance. System platforms available include Siemens, Rockwell/Allen-Bradley, GE Digital iFix.

Level 1

Local

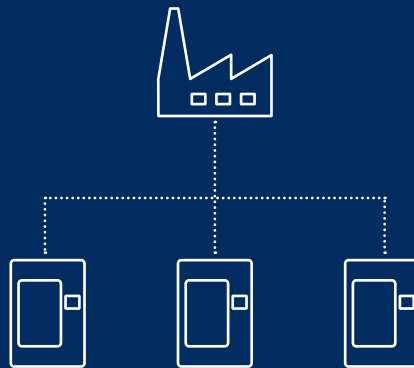
Standalone automation system intended for simple operation of a machine with no connection to client network.



Level 2

Network

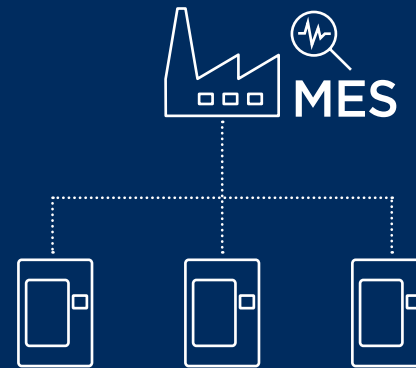
Standalone automation system intended for simple operation of a machine with connection to client network for limited network services.



Level 3

Enterprise

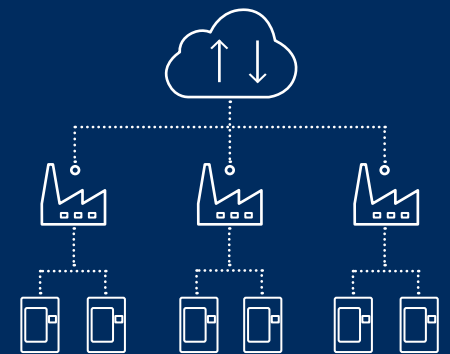
Customized automation system, connection to client network and comprehensive network services, such as integration with MES.



Level 4

Virtualise

Customized automation system, completely integrated with client IS/IT system. SCADA hosted on virtual server platform with thin client / terminal HMI.



Maximized performance with Steelco's experts

Comprehensive project management

A comprehensive range of services to ensure the success of projects at each important step including:

- Process and workflow design
- Process equipment design and manufacture
- Automation systems
- Installation and commissioning
- Integration with corporate IT systems
- Validation and documentation
- Periodic validation and re-qualification as required

Validation Documents

Steelco “knowhow” allows the client's to benefit from optimal solutions for their individual requirements, in order to perform effectively and reproducibility cleaning, sterilization and validation of pharma production components.

Design qualification (DQ), Installation qualification (IQ), Operational qualification (OQ), and Performance qualification (PQ) are provided in standard version or customized according to the final scope of supply.

Steelco Group is available anytime to support customers during all acceptance on site including process development and mapping, qualification as required

Remote FAT Service

FAT is an activity that our client usually has to perform at the Steelco production site. During a factory visit, customers verify that the equipment is manufactured according to URS and meets the relevant Good Manufacturing and Engineering Practices. It is also usually a contractual milestone. Today, thanks to advanced information technologies, all the procedures and testing, together with the related documentation can be executed remotely. Remote FAT is a smart alternative that simplifies the process, reducing the time required for staff to be away from the office and the associated costs including: travel, accommodation, visa application etc.

Service and preventative maintenance

Preventing equipment failure can help users avoid unnecessary production losses as well as health and safety violations. Steelco's Preventive Maintenance services provide greater operational control to users and help prevent known problems in the future:

- Fully comprehensive and preventative maintenance contracts
- Spare parts supply and first line service training

Customer service excellence is Steelco Group's commitment to our clients and a cornerstone of our success with emergency service support available, if needed, 24 hours, 7 days a week.



Customization. Innovation. Excellence.

STEELCO - Miele Group Member

Headquarters:
Via Balegante, 27 - 31039
Riese Pio X (TV) - Italy
Ph. +39 0423 7561
Fax +39 0423 755528
info@steelcogroup.com
www.steelcogroup.com

Branches:

STEELCO AUSTRIA
Wals-Siezenheim, Austria
info-at@steelcogroup.com

STEELCO BELGIUM
Mollem, Belgium
info-be@steelcogroup.com

STEELCO BENELUX
Vianen, Netherlands
info-benelux@steelcogroup.com

STEELCO CHINA
Shanghai, China
info-cn@steelcogroup.com

STEELCO FRANCE
Paris, France
info-fr@steelcogroup.com

STEELCO GERMANY
Gütersloh, Germany
info-de@steelcogroup.com

STEELCO HUNGARY
Budapest, Hungary
info-hu@steelcogroup.com

STEELCO MEA
Dubai, UAE
info-mea@steelcogroup.com

STEELCO MEXICO
CDMX, Mexico
info-mx@steelcogroup.com

STEELCO NORDIC
Glostrup, Denmark
info-nordic@steelcogroup.com

STEELCO NORGE
Nesbru, Norway
info-no@steelcogroup.com

STEELCO SPAIN
Madrid, Spain
info-es@steelcogroup.com

STEELCO SWITZERLAND
Spreitenbach, Switzerland
info-ch@steelcogroup.com

STEELCO USA
West Palm Beach, USA
info-usa@steelcogroup.com

