

Cleaning and sterilization solutions

serving the biopharmaceutical industry worldwide



Exceed expectations through innovation.



Solutions for the global bio-pharmaceutical industry

Located in modern factories near Venice in Italy, Steelco Group is a major global supplier for cleaning and sterilization solutions for the global pharmaceutical industry as well as healthcare and laboratory. Steelco's success is demonstrated by its strong growth, becoming the partner of choice for many of the world's leading pharmaceutical companies who appreciate the company's:

Experience and knowledge

- Strong track record of establishing long term global partnerships.
- Integrated in-house operations in more than 52.000 sq.mt. manufacturing sites. Equipment totally manufactured in Italy.
- Fully certified quality systems with knowledge of pharmaceutical manufacturing standards.

Global footprint

- Global HQ in Italy with regional customer support centres in the Americas and Asia.
- Network of factory trained agencies in over 100 countries worldwide with after service capabilities.

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.

Extensive product range

- Over 3000 installations worldwide.
- Innovative washing equipment with customized loading racks.
- Diversified sterilization equipment.
- Fully automated closure processing equipment.
- Drying and depyrogenation ovens.
- Automation systems to maximize productivity and safety.



Flexible solutions

- Ability to meet the most challenging processing needs.
- Only proven, non-proprietary, globally available components and automation systems.



Quality system certification

We constantly strive to improve on our high standards to enable us to deliver optimal solutions for our partners in the biopharmaceutical industry: Process certifications (ISO 9001, ISO 14001), Product certifications.

Compliance and guidelines

The planning and the production of our washing, drying and sterilization systems is based on globally recognised standards as well as applicable regulations in the final installation country.

Validation documents

Equipment is developed and validated according to the latest GAMP and cGMP standards. Steelco “know-how” 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.

Extensive customer support services

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



Integrated architecture

Steelco can install new equipment into an existing automation system through the adoption of a simple (HMI) or more sophisticated (SCADA) man-machine interface.

User friendly control systems developed according to the latest GAMP and design for 21 CFR Part 11 available, sourced from the best available suppliers avoiding customized electronics.

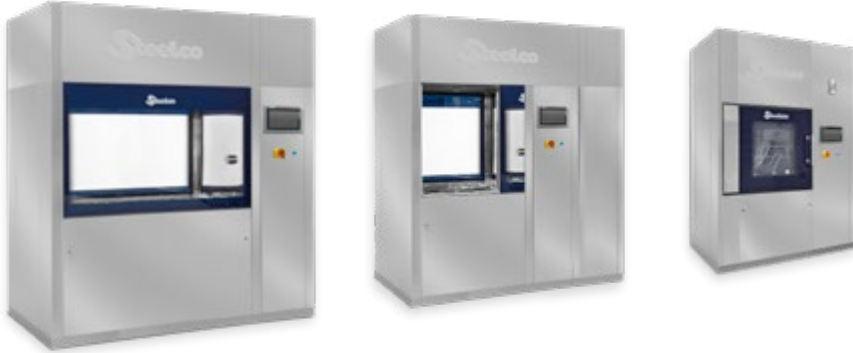


Cleaning systems

DS PH range

Pharma Grade Parts Washers

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Main features

- Highest cleaning performance
- Protection of processed items
- Low water consumption
- Efficient drying system
- Repeatable and validatable process
- Globally available components and technical support

Chamber volume

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

Available in different dimensions and configurations.

Steelco understands the particular critical cleaning and drying requirements of equipment and components used in pharmaceutical production including: Glassware, filling line

components and tools, tubing, TC fittings, valve and pump bodies, filter housings, punches and dies, reactor vessels and diverse equipment, bulk containers, tanks and carboys.

LC PH Series

Pharma Grade Cabinet Washer

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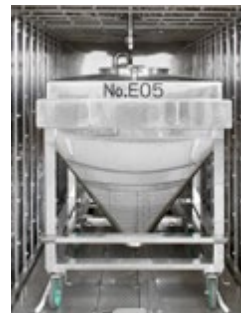
LC PH is a versatile system to treat large volume of items such as wash containers, large components, ultracentrifuges, bulk chemicals.

Easily adjustable floor guides for different carts with access to filter. Spray nozzles on oscillating arms for perfect washing results. High performance efficiency with steam heater versions available.

Chamber volume

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

Available in different dimensions and configurations.



Main features

- Easy cart connections
- Continuous moving spray arms and 360° constant internal bin cleaning for bulk loads
- Double drying unit
- Rotating washing arms to assure an adequate cleaning of loaded items
- Repeatable and validatable cycle
- Automatic loading and unloading system available upon request

Pharma carts and trolleys

Standard and Customized Solutions

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Using sophisticated 3D tools, Steelco's engineering department optimizes cart design in order to reduce process time and water consumption whilst maximizing process effectiveness.



Sterilization solutions

AV Series

Saturated Steam Sterilizers



Versatile cGMP Steam Sterilizers, available in single or pass-through versions, with hinged or sliding doors.

Built to a high standard, each unit is tailored to the customer's individual specifications. Cart guides are welded into chamber floor for easy loading. Components from the market.

Chamber volume
from 195 litres / 7 cu.ft
to 10.000 litres / 353 cu.ft

Main features

- Only Stainless Steel material: AISI 316L chamber, door, jacket, piping.
- AISI 304: control board and frame.
- "Unique" design of door gasket with standard warranty three years without replacement.
- PLC with copy of source code.
- Open architecture Siemens or Allen Bradley.

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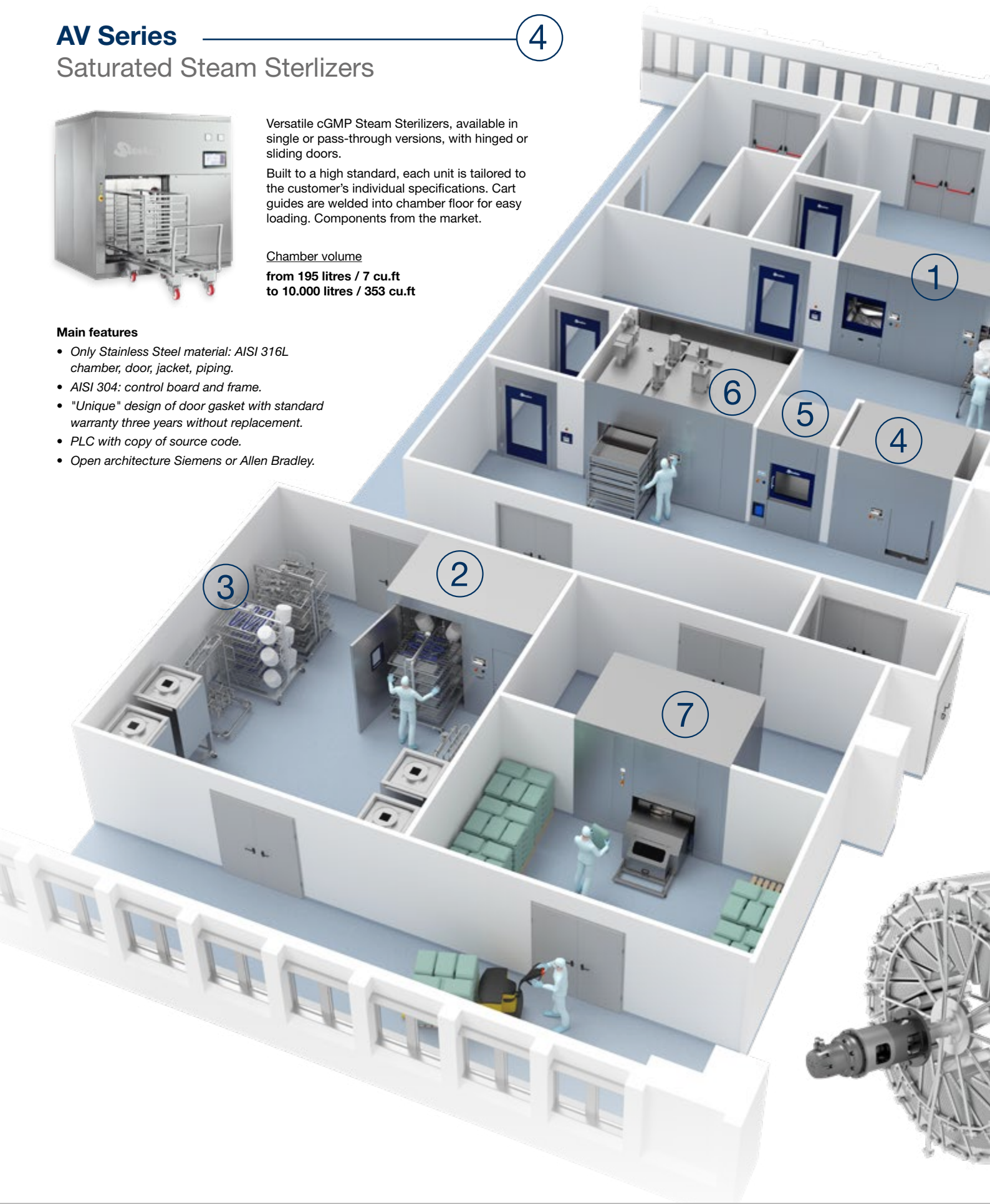
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DHP Series

Decontamination Lock

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DHP 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.

This device is available both in **hinged stainless steel door version** or with an **hinged full glass door**. It can be provided with an integrated or standalone hydrogen peroxide or nitrogen dioxide vapour generator.

Chamber volume

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

SD or EG Series

Depyrogenation Oven & Hot Air Drying

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The SD series is used to sterilize and depyrogenate of heat resistant materials including **bottles, vials, glass containers, metal trays and production equipment, laboratory glassware and instruments**, materials sensitive to humidity, **thermostable basic pharmaceutical products, chemical compounds** and non aqueous liquid materials such as **oils, glycerines**, etc.

Chamber volume

**from 330 litres / 12 cu.ft
to 10.000 litres / 353 cu.ft**



The EG series is used for drying by hot air of materials such as **granulates, powders and porous loads**.

For the treatment of granules with the presence of solvents, the dryer can be equipped to monitor flammability hazard by controlling LEL.

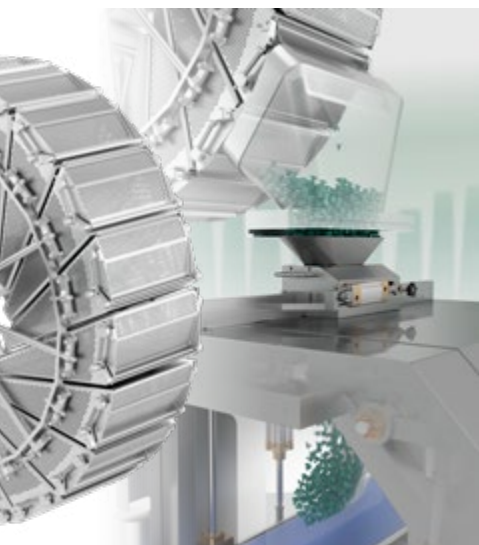
Chamber volume

**from 330 litres / 12 cu.ft
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SPE Series

Stopper Processing Equipment

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Innovative customized stopper processor solutions for highly cost-effective projects. Process validated with major suppliers of stoppers and multinational pharma companies. Simultaneous processing of different types of stoppers.

Complete treatment of closure devices such as: rubber stoppers, plastic stoppers, syringes plungers, aluminium cap and other similar components.

Where **continuous sterility has to be maintained**, the SPE Series offers **washing, rinsing, siliconizing, sterilizing, drying and cooling** all in one solution.

Chamber volume

**from 40 litres / 1.4 cu.ft
to 480 litres / 17 cu.ft**

Main features

- *Elimination of excessive accumulation of material during treatment phases*
- *Enhanced surface exposure to process fluids*
- *Optimized washing process, with effective endotoxin and particle reduction*
- *Uniform silicone distribution on individual stoppers and the entire batch*
- *Optimization of the CIP phase*
- *High productivity and efficiency*
- *Compatible with different loading/unloading systems, with the option of interfacing with vaporized hydrogen peroxide isolators.*
- *Automatic unloading into Sartorius Stedim Biotech clean & pre-sterilized Biosafe® Bags through the Biosafe® Biosteam S Port*

Terminal sterilization

AMS & ASW Series

Steam Air Mixture sterilizer & Superheated-Water Sterilizer

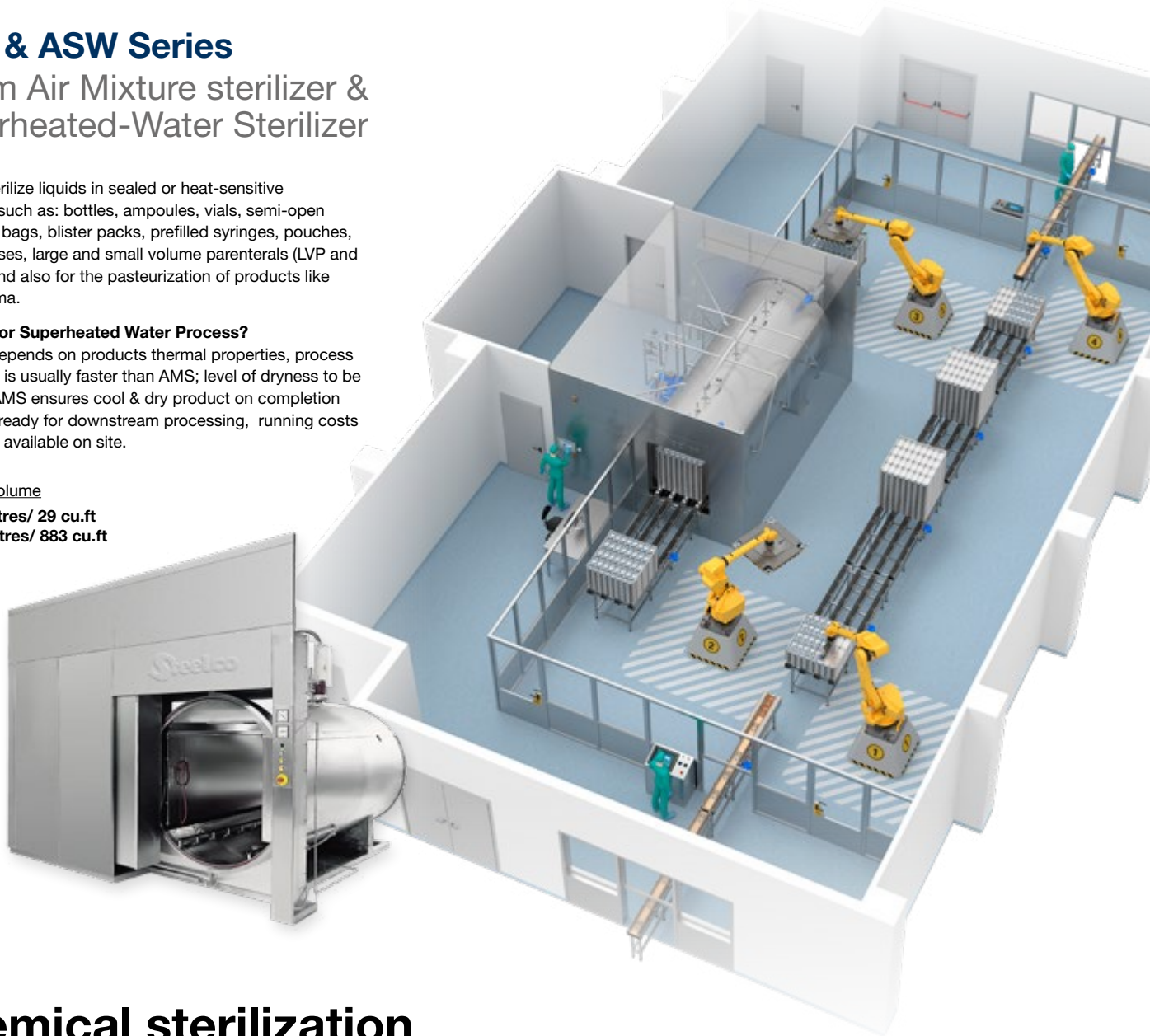
Used to sterilize liquids in sealed or heat-sensitive containers such as: bottles, ampoules, vials, semi-open containers, bags, blister packs, prefilled syringes, pouches, contact lenses, large and small volume parenterals (LVP and SVP) etc, and also for the pasteurization of products like blood plasma.

Air-Steam or Superheated Water Process?

Selection depends on products thermal properties, process time - ASW is usually faster than AMS; level of dryness to be reached - AMS ensures cool & dry product on completion of process ready for downstream processing, running costs and utilities available on site.

Chamber volume

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



Chemical sterilization

AGS & AGS-E Series

Ethylene Oxide Sterilizer

AGS and AGS-E series are used for a low temperature sterilization of heat-sensitive products such as: plastic syringes, perfusion sets, dialysis cartridges, heat-sensitive rubber products and special surgical instruments.

AGS series

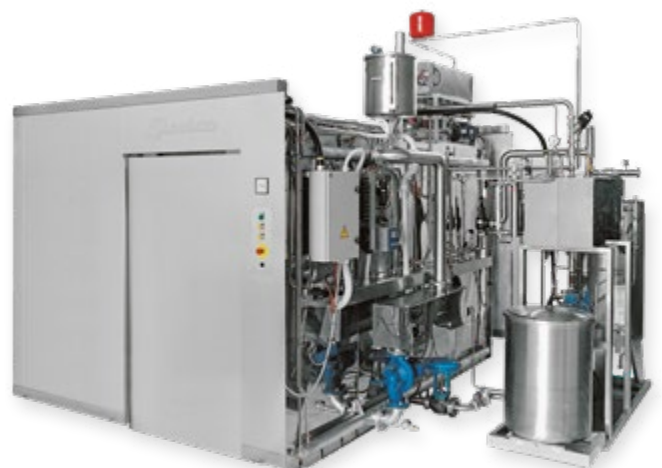
Pressure sterilization program up to 10% of Ethylene Oxide, with the remaining 90% made of inert gas.

AGS-E series

Vacuum sterilization program up to 90% or 100% of Ethylene Oxide, with the residual 10% made of inert gas.

Chamber volume

from 1 to 32 pallets





Miele Group Member



Headquarters and Center of washing system production

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Products offered for sale may differ from those described or illustrated in this brochure due to later production changes or/and optional configurations. The products and technical specifications are subjected to change without prior notice. Please consult your Steelco dealer for the latest information.