Laboratory Steam Sterilizers

AS-666 WA

Business Case

In this document you will find the net dealer prices (in EUR and EXW, Góra Kalwaria – Poland) of our premium **AS-666 WA Series** Steam Sterilizers.

The units are manufactured in Poland (European Union) and have standard AISI 316 L chamber and door(s), a water saving system, drain cooling system, automatic blow down (steam generator) vertical sliding door(s) and a very sophisticated **remote control** function.

Obviously these units are **CE marked** and manufactured according the **EN285** (Sterilization - Steam sterilizers - Large sterilizers). Besides these standards, and feel assured, we follow all necessary European Standards & Directives (including the Pressure Equipment Directive – 2014/68/EU).

The units offered in this document are intended to use in the <u>Laboratory</u> market. Be informed that we can also offer Steam Sterilizers for the Health Care, Pharmaceutical or Industrial Markets. As these are tailor made projects I kindly advise you to contact us with the User Requirement Specifications for a quotation.

In a later stage of possible projects if would be advisable to receive a dwg file (AutoCAD). With this file our technical department can provide you the necessary drawing(s) with precise location of applicable utilities.

Company Profile

SMS is a global supplier of innovative cleaning, disinfection and sterilization solutions to the health care, life sciences, pharmaceutical and industrial market. It is headquartered in Góra Kalwaria – Poland, and is represented by a network of sales subsidiaries and authorized partners worldwide.

Increasing demands make it ever more important to operate at highest productivity and efficiency levels. With a combination of products SMS offers the best-possible solution to each client in any country: the machine from the standard product range or customized large-scale projects. Through excellent product support and customer services SMS delivers added value to its customers.

About us

SMS protects lives and health of millions people supplying high tech medical equipment at affordable prices that satisfy medical organizations' needs. We promote innovation in the infection control industry and provide healthcare workers with the information of the latest world healthcare achievements. SMS constantly works on meeting the satisfaction of customers, employees and shareholders.

Quality

SMS is focused on producing reliable and efficient solutions for sterilization and infection control. Our equipment is safe, highly productive, user-friendly and eco-friendly. SMS works to keep prices affordable both for the equipment and the further maintenance. SMS medical equipment has all certificates needed in accordance with international standards (CE and ISO).

Sustainability

SMS pays a lot of attention to the maintenance of our equipment based on energy efficiency and resource conservation. Our produce is constructed to use less water, energy, chemicals. That leads to reduce the consumption of resources used and helps our clients to decrease costs.

Company Highlights

- ✓ End-to-end solutions
- ✓ A wide range of equipment starting from a standard product range following to customized large-scale projects
- ✓ Development and innovation, continuous monitoring and implementation of new technologies in production, development of new models of equipment
- ✓ Manufacturing of equipment meets the needs of users and can be customized to special local characteristics

SMS supplies a wide range of equipment

- ✓ **Steam sterilizers**
- ✓ Low-temperature plasma and EtO sterilizers
- ✓ Washer disinfectors
- ✓ Drying and storage cabinets
- ✓ Ultrasonic cleaners
- ✓ Furniture and accessories
- ✓ Heat sealers
- ✓ Water treatment systems
- ✓ Steam Generators
- ✓ Consumables

Product description

Our line of sterilizers is designed for a wide range of applications. All sterilizers are equipped with reliable non-proprietary European components, maximizing "uptime" while providing an ultra-low total cost of ownership. Sterilizers continue to be the first line of defense against infection and SMS takes this responsibility seriously.

A Flexible Range of Models

SMS offers an unmatched range of models that are available in the AS Series.

The chamber sizes range from 100 to 900 liters. In addition, we accommodate your special requirements and design tailor made solutions and non-standard chamber sizes. Models are available in either single or double vertical sliding door(s) configuration.

The doors are constructed from a high grade stainless steel that provides maximum reliability and minimum maintenance. The doors closure is secured by means of a high-grade silicon profile that is forced against the door by compressed air.

- ✓ **The chamber** is sealed by a movable compressed air-driven silicon gasket. Steam on request.
- ✓ **Air removal** and drying are made possible by a very efficient system based upon using a water-ring vacuum pump and a condenser.
- ✓ **Valves** – Pneumatic control valves are used for precise control of steam flow in and out of the chamber and jacket.
- ✓ **Drain Tempering** – Condensate is cooled to below 60°C before being discharged
- ✓ **The microprocessor controller** assures a fully automatic and safe run of a selected sterilization program.

WATER RING VACUUM PUMP

The vacuum pump effectively removes air from the chamber. The pump is mounted on vibration absorbers to minimize vibration.
During vacuum action the flow path of the media is through the condenser (heat exchanger) and the vacuum pump to drain. This protects the vacuum system from excessive temperatures.

VALIDATIONS PORTS

The sterilizer chamber is equipped with two measurement connectors. The connector for a pressure measuring instrument: – pipe thread ISO 228-G½"A, and the connector for temperature sensors – pipe thread ISO 228-G1" A.

AIR FILTER

Programs, the sterilizing cycle of which is completed by a vacuum drying phase, require direct ambient air supply to the sterilizing chamber. For this purpose sterilizer is equipped with a filter (sterile air filter) able to capture not less than 99,998% of particles larger than 0,30 µm.

STEAM SUPPLY

The autoclave is supplied with either a steam generator or an option to connect to building steam supply. A combined option of steam generator and building steam supply is also available.

STEAM GENERATOR

Supplies steam for the sterilization process. The stainless steel steam generator is an electrically heated type generator equipped with immersion heaters, divided in three-phases. The electrical of the steam generator is located in separate electric box. Water to the steam generator is supplied by a three-phases pump, from a feed water reservoir, which is connected to a source of mineral-free water.

Control System

The work of the sterilizer and its steam generator is controlled by **Siemens** controller.

All the activities such as the following: supplying steam into the chamber, maintaining constant temperature during the exposure phase, course of the cycle, opening and closing the door etc.; and for the version with the built-in steam generator: automatic filling of the steam generator boiler with water, inspection of heating elements to ensure a constant steam pressure, are monitored on an on going basis by the monitoring system. The controller stores the following sterilization and test programs: Bowie-Dick test and chamber Leak test.

Cycle Performance Documentation

The SMS AS series sterilizer provides two standard means for cycle documentation:

- Paper printer
- USB flash memory drive

On the insertion side there is a printer that records the sterilization cycle parameters.

- all the standard parameters of the cycle are printed in a table.
- the printout includes the following data:
- temperature in the chamber;
- date and time of the cycle start;
- sterilization cycle number;
- operator number;
- serial number;
- set sterilization program parameters (duration, temperature);
- name and start time of the process stage;
- temperature and pressure in the chamber at the intervals set in the printing interval;
- duration and end time of the cycle;
- minimum and maximum sterilization temperature;
- process outcome (sterilization or a tightness test) (positive/negative).

For backup / informational purposes, the same cycle performance data is also automatically sent to a USB flash drive port.

Standards and Directives

We supply solutions for infections and sterilization control that provide consistent, high quality results. SMS global experience has earned a reputation as an expert on worldwide Standards and Quality considerations.

As experts in infection and sterilization control products and processes, we understand the market's varying needs and comply with the strictest international standards and directives.

Standards and codes

SMS products meet the following provisions and standards:

Europe:

• EN 285 for Large Autoclaves
• EN ISO 17665-1:2006

Directives & Guidelines:

• Medical Device Directive – MDD 93/42/EEC
• Pressure Equipment Directives – PED 2014/68/EU (previously 97/23 EEC)

Safety and EMC Standards:

• EN 61010-1:2010
• IEC/EN 61010-2-040:2005
• EN 61326-1:2013
• EN 60204-1:2006. EN 60204-1/A1:2009

Quality System Compliance:

• ISO 9001:2015 (Quality Systems)
• EN ISO 13485: 2016 Quality Management System

Safety

Safety is Our Top Priority

Standard safety features

✓ **Steam interlock door switch** – Prevents steam from entering the chamber when the door is not sealed.

✓ **Steam safety valves** – Ensure that the pressure in the chamber and/or jacket do not over-pressurize.

✓ **Door obstruction shut-off** – On the top part of the door is located security bar, which enable safety close the door. In contact with security bar all obstacles with a mass greater than 3 kg stops the closing the door.

✓ **Analog chamber gauges** – Needle-style gauges provide real-time pressure readings in the jacket and chamber even in the event of a micro-computer control system outage.

✓ **Thermal protection** - In case of sterilizers with an integral (built-in) steam generator an additional protection against overheating has been mounted. A temperature limiter, has been mounted on a boiler bottom. The limiter turns off the heater power in case when temperature on the surface of the boiler significantly exceeds permissible operating temperature.

✓ **Level sensors** – Steam generator is equipped with two level sensors. The first is to keep the constant level in the boiler. The second one is for disconnection.

Customer Service and After Sales Support

Project Management

SMS provide full project management services with all capital equipment contracts to ensure installations are completed to the highest level of satisfaction to the customer. Our project managers and/or engineers can co-ordinate between all parties involved and will continually communicate to the project team ensuring work is completed efficiently, effectively and with consideration to the facilities procedures and processes.

We have invested in a training regime to promote a proven methodology to our project managers. The program provides fully comprehensive Project Management capabilities specifically designed for installations within controlled environments. As a commitment to support and invest in this area of our business, all our project managers have received this training.

Training

SMS have a number of training packages to suit the needs of each specific customer. Our partners can use our telephone support for assistance after the training. Optionally the training can be repeated four (4) weeks later to ensure total user understanding is achieved.

In addition we also offer more detailed training packages for your onsite engineering group. These packages can be tailored to suit your people's specific skills and engineering proficiency levels and can provide you with the knowledge to avoid trivial/user faults which can often lead to unnecessary callouts therefore saving costs and improving site operating up times and efficiencies.

Customer Relations

As a commitment to continually improve our customer service levels, SMS invest and update customer related software. We also extend the opportunity for all office-based staff to develop themselves with customer service courses. SMS continually develop its Quality Management systems in line with new legislations and guidelines to further improvement the service we deliver.

In addition to the above the biggest area of importance is with the relations we create, SMS pride themselves on the attention to detail and the relations that exist with our customers. Perception surveys and periodic review meetings are all important areas to allow us to maintain a high level of customer's service and satisfaction.

Technical Support

SMS have a designated phone number, which connects directly to the service department and engineers team. Our software allow 24/7 contact and support to be provided.

Our staff is able to provide technical assistance from within the office and all engineers are contactable via mobile phones with email capability and internet access. SMS set Key Performance Indicators (KPI's) within our service agreements for each piece of equipment we maintain. We promise to provide technical assistance via telephone with the Service Level Agreement agreed. These KPI's are periodically reviewed in management meetings internally and in review meetings with the client.

As a leading manufacturer investment within technical support is of primary importance. Our management continually monitors existing accounts, new accounts and trends to ensure engineering staffing levels are of an optimal level to allow our response times and high service levels to be maintained minimizing downtime and compromise to our customer's processes.

Callout's and Emergency Response

Unlike other suppliers providing support and maintenance services to a dedicated market segment SMS engineers work within medical, laboratory and pharmaceutical establishments, therefore we have experienced engineers able to secure your processes. With this in mind it allows us to respond quickly to emergency callouts without compromising your security.

Availability of Spares

Critical proprietary and non-proprietary spare spares kept in stock and available for delivery to site the following day from our warehouses. This allows the engineer to source a limit downtime and reducing carriage costs. For any items that are not in stock with SMS we have an express service arrangement with our supply partners to provide back-up.

Maintenance engineers

SMS has a team engineers based in several countries providing fast and effective emergency support as well as planned and preventive services. Our engineers are trained and highly experienced with autoclaves and other relevant infection control products. All engineers have undergone and achieved training ensuring a high level of support and competency to the equipment proposed.

Availability of Spares for Life Time of Equipment

We guarantee availability of spares for the lifetime of the equipment proposed.

Concise and clear Service Reports

Callout and service reports are generated after each intervention.

Instructions Manuals

All offered equipment comes complete with an Operation and/or Maintenance manual.

Appendix I - Training and instruction Plan

User Training

- ✓ Basic principles cleaning and sterilization

- ✓ Functional principles of sterilization

- ✓ SMS Horizontal sterilizer:

  - o Functional description
  - o Test programs
  - o Sterilization programs
  - o Human Machine Interface (HMI)
  - o Cycles explanation
  - o Error explanation
  - o Sterilization preparation
  - o Maintenance
  - o Hand-on session

Technical Training

The first part of the training is identically to the User Training.

- ✓ Basic principles cleaning and sterilization

- ✓ Functional principles of sterilization
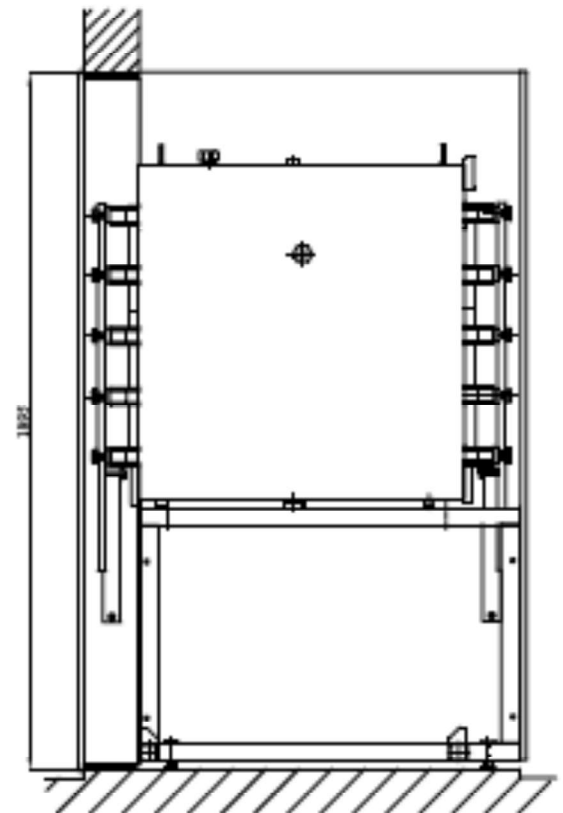
- ✓ SMS Horizontal Sterilizer:

Additional

  - o Theoretical explanation
  - o Practical explanation
  - o Diagrams (piping)
  - o Electrical drawing
  - o Software Management

Appendix II – Drawing & picture Bio Barrier / seal

Connection method of the sterilizer flange to the wall
(vertical section)

Connection method of the sterilizer flange to the wall
(horizontal section)

Seal around whole flange

Sterilizer flange

Steriliser chamber