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Технические характеристики на паровые стерилизаторы для лабораторных и биомедицинских исследований GSS L&R, GEB компании GETINGE

Lights on

– Getinge GEB series sterlizers

The Getinge GEB series is one example of the new breed of state-of-the art sterilizers from the world's leading brand in infection control and contamination prevention.

Sterilizers that further perfect the efficient performance and superior throughput you can always expect from Getinge. You recognize them by their clear, light and characteristic touch-screen panels, easily readable from a distance. As well as by their thought-through and user-friendly design, making them easier to operate than ever.

Ergonomic and user-friendly
The clear and intuitive interface of the new touch-screen panels is only one of many examples of how we ensure that Getinge sterilizers are easier to operate and more ergonomic.

Specially designed for the application
For more than 100 years, Getinge has developed equipment to help improve and save people's lives.

Getinge GEB Bioasafety Sterilizers

Safe, reliable decontamination in biocontainment facilities

A new sense of reality

In light of the biohazards we live with today, and may be faced with in the future, the bio-containment community is responding with a new sense of urgency to prepare for these emerging threats.

Purpose Built Bio-Safety Laboratories: New Challenges

Biocontainment laboratory facilities once considered state-of-the-art are being reconfigured and upgraded to reflect the new reality of pandemic research. There has been an absence of accepted standards governing sterilizers used in a biocontainment environment, despite the need for them.

That's why Getinge is collaborating with laboratory designers, architects and bio-containment specialists to determine industry wide guidelines for sterilizer design and installation. Getinge is dedicated to providing biocontainment sterilizer systems that minimize risks associated with existing bio-safety facilities, while establishing the benchmark of sterilization and containment for laboratories that have yet to be built.

Getinge GEB Steam Sterilizers offers:

- The independently validated Bioseal flange creates a hermetic seal between zones.
- Electrical signals to the hot zone pass through sealed conduits
- The doors of Getinge sterilizers are the cleanest, safest and simplest on the market.
- Top-quality piping and components are assembled to the highest standards.

A dedicated yet versatile range

Like all laboratories and research facilities, bio-containment suites need autoclaves for sterilization and decontamination. The pathogenic nature of the waste material from such facilities coupled with the use of the autoclave as a barrier between the facility and the outside world places special requirements on the autoclave design and processes used that standard autoclaves cannot fulfill.

The Getinge GEB Series is a standardized range of dedicated autoclaves, specifically designed for use in BSL 3 and 4 facilities.

A wide variety of chamber sizes are available, ranging from 0.3 to 17 m3 and all models are available with one or two doors as appropriate for use in the facility.

The GEB range is available with a variety of flexible program combinations to suit the type of facility, for example:
• Microbiology laboratory (including Biosafety facilities)
• Glassware, culture media, hazardous waste
• Animal care facility / vivarium
• Cages, racks, bedding, pathogenic waste
Please refer to individual product specifications for additional details.

Unique features of the GEB range includes but is not limited to:

- Validated biological sealing system (bioseal). Creates a hermetic seal between hot and cold zones. Notified body certified design.
- Hermetically sealed conduits (condulets) through the bioseal for all electrical cabling into the hot zone.
- Membrane filtration on all pneumatic signal lines passing through the bioseal.
- Isolating valves and chemical decontaminant injection ports in the process system – for decontamination of piping system prior to maintenance activities.
- Getinge's unique effluent sterilization process. Safe and effective air removal for sterilization efficacy as well as condensate retention and sterilization.
- Optional interface for Class III Safety Cabinets (isolators)
- Uniquely designed and validated incinerator. Equipped as standard with an independent redundant controller ("Supervisor").

GEB Series – typical models*	6610	6910	91422	102222	182222
Chamber volume, ft3 / m3	16/0.45	29/8.83	154/2871	170/4.8	308/8.70
Chamber width, in/mm	26/672	26/672	35/900	39/1000	71/1800
Chamber height, in/mm	26/627	36/920	57/1450	86/2200	86/2200
Chamber depth, in/mm	39/1000	53/1350	86/2200	86/2200	86/2200

* Only a selection of our available standard models. Specific sizes can be made upon request.

1. Small GEB Steam Sterilizers – 600 Series
Fully automatic high-pressure steam sterilizers with a single vertical sliding door, or two vertical sliding doors for passthrough operation.
Standard chamber volume: 10 to 26 ft3 (0.3 to 0.8 m3)

2. Medium-size GEB Steam Sterilizers – 900 Series
Fully automatic high-pressure steam sterilizers with a single vertical sliding door, or two vertical sliding doors for passthrough operation.
Standard chamber volume: 21 to 36 ft3 (0.6 to 1.1 m3).

3. Large / Bulk GEB Steam Sterilizers – 1400 and 2200 Series
Sterilizers with automatic horizontal sliding door(s) for largescale applications. They can be pit-mounted for convenient floor loading.
Standard chamber volume: 47 to 590 ft3 (1.4 to 17 m3)

Features that set the industry standards

The GEB Series Sterilizers set the industry standard for autoclaves designed specifically in response to the need for new, modern biocontainment facilities; to define a new 'state-of-the-art'.

Diaphragm isolated instrumentation

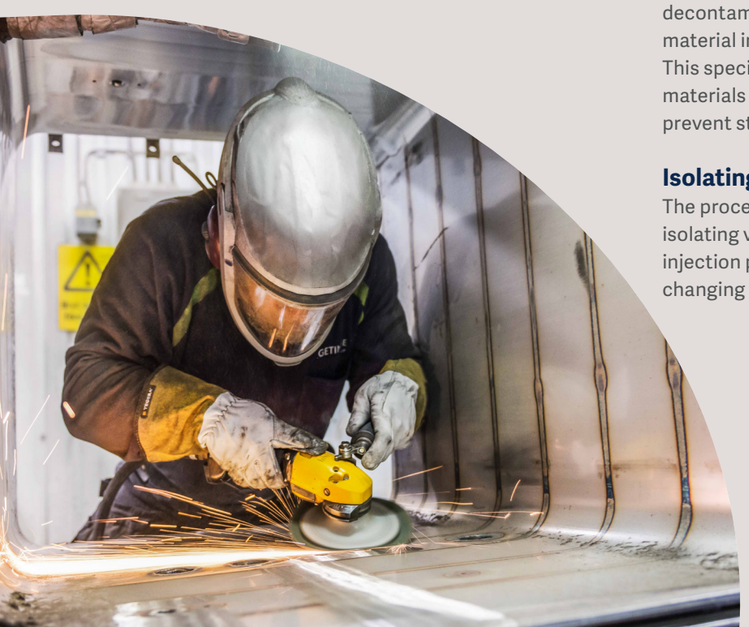
Pressure transducers and gauges are isolated from the chamber by sanitary diaphragms. This eliminates capillary piping which accumulates stagnant water in the process system (where microorganisms may multiply).

Door sealing mechanism

Choose from Getinge's traditional active door gasket or the revolutionary 'Slideloc'™ passive system. The active gasket is mechanically simple and inherently reliable while Getinge's Slideloc System does not rely on utilities to maintain the seal between chamber and door.

Bioseal connections

Sealed conduits are provided through the bioseal for electrical connections (with 100% redundancy). All pneumatic lines are provided with membrane filters.



Biological sealing flange (bioseal)

Typically a double door GEB autoclave is a part of the barrier between the hot and cold zone. As such, it should be treated with the care, attention and respect as any other part of the barrier, such as doors and windows. It must be designed to be hermetically sealed, and be guaranteed to remain so for it's design lifetime. The cross contamination seal of a standard double door autoclave cannot do this due to thermal stresses and sealing materials typically used. Getinge's Bioseal combines bolted stainless steel panels, arubber gasket and a wall flange that is installed in the building fabric. The design is independently validated and certified (see more details on page 9 picture 2).

Specialized waste processing

Processes are intentionally designed for effective decontamination, including treatment of plastic waste material in disposal bags and part sealed containers. This specialized process prevents fusion of the plastic materials and entrapment of air which would otherwise prevent steam penetration.

Isolating valves & injection ports

The process and drain piping system is provided with isolating valves and chemical (typically formaldehyde) injection ports to allow safe maintenance and filter changing

– Sterilization decontamination efficacy versus containment GEB series sterlizers

Containment presents several challenges to the sterilization system designer. An established principle of steam sterilization demands air removal prior to steam injection. Challenge: air in contact with materials in the chamber is contaminated and cannot be removed without treatment. A physical principle is that steam condenses when it comes in contact with cooler surfaces. Challenge: the condensate produced as steam heats the contaminated materials, prior to achieving sterilization decontamination conditions, is itself contaminated. It requires treatment prior to release to the building drain. Several options are available to treat the removed air and condensate, and should be applied based on a risk assessment of the facility design.

Option 1

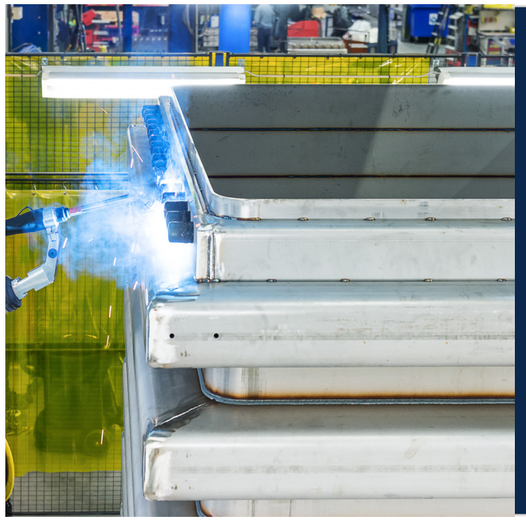
Filter the air evacuated from the chamber through a 0.22µm sterile membrane filter. This renders the air sterile and the filter is steam sterilized during the subsequent process. For added security, a second filter may be installed in the series. Additionally, an automatic in-place Water Intrusion Testing (WIT) integrity test may be performed on the filtration system. Condensate produced is collected in the chamber base and is heated by incoming steam and by the steam heated external jacket. Sterilization decontamination of the condensate is confirmed by temperature sensors.

Option 2

Pass the air through the unique Getinge incineration system. This validated ultra high temperature device provides a torturous pathway for the evacuated air. This destroys all viable organisms, rendering the exhaust air sterile and safe to discharge. Condensate is treated as described for Option 1.

Core features of the GEB series

Safeguarding your investment.



Sectional Jacket

The unique sectional jacket adds strength and rigidity to the chamber, and robotic welding eliminates defects. The resulting construction ensures a long product lifecycle to safeguard your facilityand investment.

Bioseal

The independently validated bioseal flange creates a hermetic seal between zones. Fabricated from a combination of bolted steel panels and a rubber gasket. The mating wall flange is provided during construction for installation in the building fabric.

Condulets

Electrical signals to the hot zone pass through sealed conduits (condulets). Similarly pneumatic signals pass through membrane filters.

Doors

The doors of Getinge sterilizers are the cleanest, safest and simplest on the market.

Passive door

Getinge's unique "Slidelock" passive door locking system, provides a compression seal of the door gasket when the door is in the closed position. Does not rely on utilities to maintain the seal.

Process system

Top-quality piping and components are assembled to the highest standards.

Taking reliability to the next level

GSS L & R Series Steam Sterilizers for biomedical laboratory rese

GSS L & R Series Steam Sterilizers help you achieve safety and scientific data integrity. We work together with you every step of the way to give you the solution you need and can trust.

Safe
Easy to use and safe to handle, the GSS L & R Series is designed to secure containment, process result and operator safety.

Reliable
The GSS L & R Series is optimized for the consistent process flow required to secure repeatability in research.

Flexible
Every biomedical facility and country has specific regulations and requirements. Together we customize the GSS L & R to meet your needs.

Technical data

MODEL	USABLE DIMENSIONS (mm) W x H x D	USABLE DIMENSIONS (INCH) W x H x D	CHAMBER VOLUME (Nominal) LITRES	 FEET^3
GSS 6710	660 x 700 x 1000 mm	26” x 26 ½” x 39 3/8”	470	16.0
GSS 6713	660 x 700 x 1300 mm	26” x 26 ½” x 51 1/4”	612	20.7
GSS 6910	660 x 920 x 1000 mm	26” x 36 ¼” x 39 3/8”	618	21.8
GSS 6913	660 x 920 x 1350 mm	26” x 36 ¼” x 53 1/8"	835	29.5
GSS 6915	660 x 920 x 1540 mm	26” x 36 ¼” x 60 5/8"	952	33.6
GSS 6917	660 x 920 x 1700 mm	26” x 36 ¼” x 66 7/8"	1051	37.1
GSS 71413	670 x 1450 x 1350 mm	26 3/8” x 57 1/8” x 53 1/8”	1370	48.4
GSS 91413	870 x 1450 x 1350 mm	34 ¼” x 57 1/8” x 53 1/8”	1762	62.2
GSS 91415	870 x 1450 x 1540 mm	34 ¼” x 57 1/8” x 60 5/8”	2010	71.0
GSS 91418	870 x 1450 x 1800 mm	34 ¼” x 57 1/8” x 70 7/8”	2349	83.0
GSS 91422	870 x 1450 x 2200 mm	34 ¼” x 57 1/8” x 7’ - 2 5/8”	2871	101.4
GSS 91815	920 x 1800 x 1540 mm	36 ¼” x 70 7/8” x 60 5/8”	2633	93.0

MODEL	USABLE DIMENSIONS (mm) W x H x D	USABLE DIMENSIONS (INCH) W x H x D	CHAMBER VOLUME (Nominal) LITRES	 FEET^3
GSS 91825	870 x	34 ¼" x 70 7/8" x 8' - 2 3/8"	4275	151
GSS 121422	1220 x 1450 x 2200 mm	48" x 57 1/8" x 7' - 2 5/8"	3988	141
GSS 92222	870 x	34 ¼" x 7' - 2 5/8" x 7' - 2 5/8"	4356	154
GSS 122222	1220 x 2200 x 2200 mm	48" x 7' - 2 5/8" x 7' - 2 5/8"	6050	214
GSS 182222	1800 x 2200 x 2200 mm	70 7/8" x 7' - 2 5/8" x 7' - 2 5/8"	8857	313

When safety and results come first

Securing integrity in research

Sterilization and biocontainment are vital components in biomedical research. To discover the cures of tomorrow you need reliable results every day. GSS L & R Series Steam Sterilizers help you achieve a high level of safety and scientific data integrity.

Biomedical facilities are specialized environments with high demands on predictability, containment and safety. Vivariums have to be clean and contamination-free, and researchers and staff protected from pathogens. You need equipment you can rely on to protect data integrity, achieve sterility and uphold critical biosafety levels. Only then can you focus on what is really important – your research.

In addition, your equipment must comply with local and global regulations and be consistent with best practices. At the same time as it satisfies growing demands for a more sustainable use of energy and natural resources.

With their built-in flexibility, GSS L & R Series Steam Sterilizers can be customized to meet your specific requirements and comply with worldwide regulations. Designed around a proven concept, they emphasize safe processes and easy handling, while reducing environmental impact.

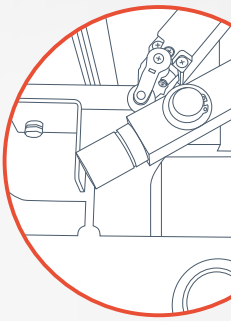
For more than 100 years, Getinge has developed equipment to help improve and save people's lives. We are confident that the GSS L & R Series raises the bar for reliable contamination prevention and biocontainment for biomedical research.

Applications

The sterilizer range is designed for general purpose steam sterilization in laboratory and biomedical research applications.

Application areas	Description	Products
Biopharma production	Component sterilization – Steam sterilizers used for sterlization of parts and components used within pharma production. Typical loads are filling machine parts, tools, containers and solutions. The sterilizer is used as a pass through sluice into the clean production area. Terminal sterilization – Sterilization of finished injectable pharmaceuticals in its final container.	Component sterilization: GSS-P Terminal sterilization: GEV, GEC Closure processing system: CPS
Biomedical research	Sterilization and decontamination in vivarum applications. Typical load is cages and other items related top operation like fodder, bedding, and glassware. Barrier function integrated in equipment for prevention of cross contamination. There is a sub-segment for BSL3/4, where research is being performed on dangerous micro-organizms, with increased containment requirements.	Steam sterilizer: GSS-R, LS-series 700 & 800 Biocontainment applications: GEB
Laboratories	Sterlization in lab applications – Various labs within universities, pharmaceutical production, quality control, food and chemical industry. Typical loads are lab-/ glassware, culture media for sterile testing, liquids in open or closed containers.	Lancer LSS, HS Lab, GSS-L
Heat sensitive goods	Low temp sterilization of heat sensitive goods. Example disposable kits of surgical instruments and other medical devices.	GEE (EtO, Ethylene oxide sterilizer)

Quality without compromise



Vertical or horizontal sliding doors for safety and convenience.

The GSS L & R Series is the latest version of our steam sterilizers. It is optimized to meet the core functionality and safety levels needed in a modern cutting-edge biomedical research environment.

The GSS L & R is engineered with high-quality components chosen to enhance contamination control, encourage a sanitary process, promote best practices and deliver dependable outcomes critical to research, personnel and environmental protection in a biomedical research facility.

Construction and design details, from highly polished stainless steel surfaces to enhanced ergonomic machine interfaces, are carefully integrated into a highly functional system critical to quality assurance.

The GSS L & R can swiftly be put into operation thanks to the refined Quality Process Management System that secures ease of validation and compliance to the intent of the Good Automation System and ensures compliance to global and regional regulations.

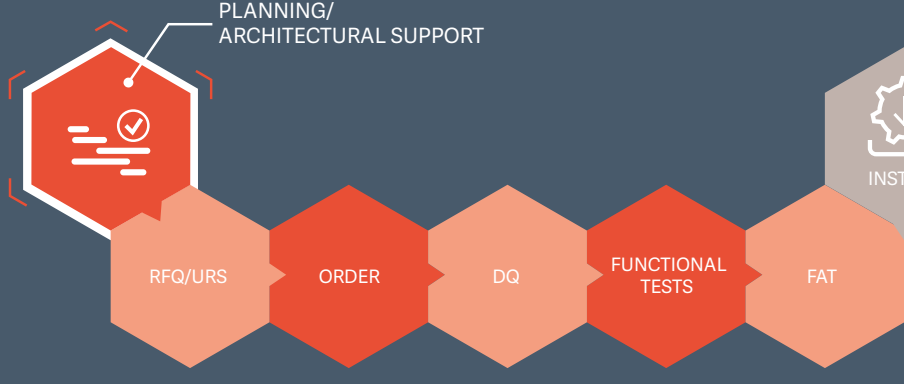
The result is an improved process and solution, designed for easy use and integrated in a controlled biomedical research environment. It is also engineered to reduce your eco-footprint, with several factors that optimize energy and water use, including efficient insulation and minimal mass of pressure vessel.

Stainless steel components are the foundation of reliable piping systems.

With you every step of the way

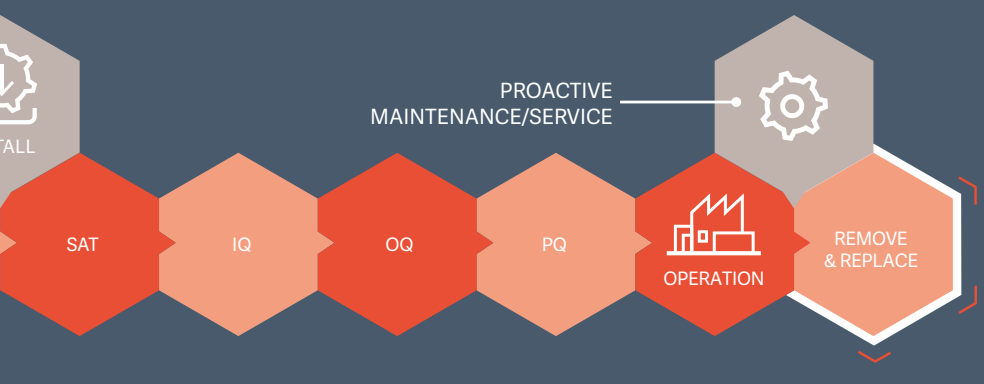
Securing the right level of biosafety for your biomedical facility demands thoroughness and expertise. To optimize space and resources, we help you with architectural layout and planning. We ensure that putting your new GSS L & R Steam Sterilizer into operation is seamless and consistent with best practices every step of the way.

Our support also includes functional tests in our factory, and service to maintain machine uptime through regular and proactive service.



User-friendly display and intuitive HMI for quick, easy use.

High performance liquid ring vacuum pumps for optimal air removal and short process time.



Examples of core features:

- Program combination adapted for lab and research applications
- Intuitive and user-friendly HMI
- Uniform temperature distribution and accurate process control
- Air removal by highly efficient liquid ring vacuum pump
- Fully automatic leak rate test
- ECO-system, recirculation of vacuum pump sealing water
- Stainless steel process and non-process piping
- Stainless steel chamber construction
- Robot welded and highly polished chamber
- Ergonomic and safe automatic sliding doors

Processes

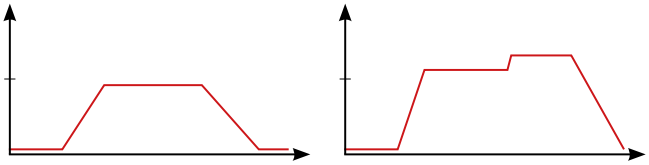
Cycle selection is based on the type of load to be sterilized and how air removal is most efficiently managed for proper sterilization.

Pre-vacuum processes

A saturated steam process with optional pressure pulses to enhance steam penetration covers most sterilization applications where hard or porous goods is to be sterilized. Configurable cycle through adjustable parameters and pressure ramps.

For liquids in open/vented or closed containers

Natural cooling **Jacket cooling**



- Cycles for liquids in open or vented containers are provided as standard. Closed liquids cycles are optional.
- Includes load temperature probe.
- Open liquid process utilizes natural cooling,
- Closed liquid process utilizes support pressure during cooling and indirect jacket cooling.
- Provided with stainless steel filter housing with 0.2 µm sterile filter for support air pressure for sterilization of liquids in closed containers.

For multi-use bioreactors

The bioreactor parts and sterilization process itself has challenges like:

- Vented bioreactor vessel
- Liquid bottle
- Tubing

The bioreactor sterilization concept includes a combination of a single pre-vacuum followed by pressure pulses.

- Pre-vacuum removes the majority of ambient air.
- Multiple steam pressure pulses follow the pre-vacuum to remove any remaining air and provide maximum steam penetration into the vessel and flexible tubing.
- To avoid the boil-over effect in liquid media, pressure pulses must be at a pressure level above the saturation pressure for the given liquid load temperature.
- Integrated process yields a complete bioreactor assembly, with liquid media, sterile and ready for service.

For more information see: application brief "Best practices for sterilization of bioreactors"

Loading equipment
– for safe and ergonomic handling

It is vital to protect both product integrity and staff in the biomedical research laboratories.

The loading and unloading trolleys, shelves and racks are designed to optimize a safe work environment and ensure product quality within the biomedical research laboratory,

For ergonimic and safe loading/unloading Getinge provide with the following loading equipment for the GSS R&L-series

- Shelf racks, with additional shelfs and rails to be added if needed.
- Fixed or height adjustable trolley for transportation of shelf racks within the facility.
- Shelf trolleys for pit mounted units
- Trolleys in stainless steel with electropolished shelves
- Multiple shelf placement locations on rack for high flexibility

Designed for flexibility

GSS L & R Steam Sterilizers come in a range of 17 different chamber sizes with a flexible set of options and customization possibilities.

Although there is a basic GSS L & R range for core functionality – with standard chamber capacities ranging from 10 to 400 ft^3/0.4 to 9 m^3 – the built-in flexibility of the GSS L & R allows for customization. Working closely together with you, we design a contamination prevention solution that suits your needs.

Examples of configuration options:

- Single-door or double-door, pass-through models
- Floor or pit-mounted
- Right or left side service access
- Cross contamination barrier (CCB) or bioseal for integration in building
- Door interlock to prevent cross contamination for barrier pass through models
- Integral steam generator options
- In-situ steam sterilization (SIP) of air filter
- In-situ filter integrity test (WIT)
- Effluent retention options for biocontainment applications
- Process for liquids in open or closed containers
- Jacket cooling with water recirculation
- Network connectivity/SCADA
- Data integrity/21CFR Part 11
- Loading equipment: trolleys, shelves and racks

A legacy of engineering

All our steam sterilizers are developed and manufactured in Getinge, Sweden, where it all started in 1904. Since then we have grown to a global company, but still keep the core of our manufacturing close by to ensure quality and control. We take pride in our engineering and give full attention to detail.

Our processes are constantly updated with new technology in full compliance with changing regulations. When visiting our state-of-the-art factory, with a production area of 16,200 m^2, you find the latest welding robots working side by side with engineers and technical experts with welding qualifications applicable to a global market. All production facilities are certified to ISO 9000 and ISO 14000 standards. We work consciously with our manufacturing and supply chain to reduce environmental impact.

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