



Saturated Steam Autoclaves

Fedegari Equipment

- Saturated Steam Sterilisers
- Counterpressure Sterilisers
- UltraWashers
- Dry Heat Sterilisation
- Pathogen Sterilisers
- Combined Units
- Laboratory Sterilisers
- Low Temperature Surface Decontamination Stations
- Laminar Flow Carts
- Isolators and Cleanroom Contamination Controls

SteriTech Limited

- Complete Turn-Key Projects
- Project management
- Commissioning, Validation
- After sales lifetime support

Stilmas Equipment

- Pre-treatment
- Purified Water
- Multi Effect Still
- Vapour Compression Still
- Pure Steam Generators
- PS & WFI Combinations
- Storage & Distribution Systems

Bano Equipment

- Stainless Steel Cleanroom Furniture
- Specialist Cleanroom Equipment

SteriTech Limited
 1 Oxted Chambers
 185 Station Road East
 Oxted RH8 0QE
www.steritech.co.uk

Saturated steam sterilisation is the most versatile, reliable and widely adopted means of sterilising good able to withstand the temperatures and pressures involved. Fedegari's FOF range is the most technically advanced saturated steam steriliser available. The result of over 50 years continuous development and expertise, all units are built to full cGMP standards with GAMP/CFR21part 11 control systems. Built to proven designs and to a consistently high standard, each unit is tailored to the customer's specification. The processing cycles are fully configurable to meet the needs of the loads and load types. There are over 150 standard chamber sizes from 200 to 28,000 litres, non-standard designs can also be made. All are available in single door or pass-through configurations, with sliding or hinged doors.



Sterilisation Processes

As standard, Fedegari FOF autoclaves are fully equipped to sterilise porous loads, tubing, solid glass, plastic or metal items, assemblies with delicate membrane filters, small vials and ampoules. The process is extremely versatile. More specialised loads can be sterilised by incorporating additional optional features. For example:

- Gravity air displacement to sterilise hot media in open vessels;
- Jacket cooling, spray cooling, fan-assisted cooling to process thermolabile loads or to help slow-cooling loads reach safe unloading temperatures.
- Washing, rinsing and siliconisation of vial stoppers.
- Hot air drying where load dryness is a critical factor such as lyo-vial stoppers..
- Chamber vacuum and pressure cycles, blue dye testing for filled vials
- Tyndallisation

Service Cycles and Utilities. Included as standard are vacuum and pressure leak rate tests, in-situ vent sterilisation. *Optionally, these facilities can be extended to include a fully automated filter integrity control system, energy saving recirculation systems for jacket & vacuum pump water; steam generation; pre-sterilisation of spray cooling water.*

Design Features

Sterilisation conditions are controlled to the highest standards of accuracy, uniformity and stability by:

- Advanced PID managed modulated control of chamber steam pressure
- Positive condensate removal throughout the cycle.
- High precision instrumentation. Pt100 four wire flexible, class 0.1, IEC751; Precision pressure transducer with separation membrane.
- All critical instrumentation loops subject to precise three-point calibration
- Steam heated jacket extending over the whole chamber length.
- Robust air-removal capabilities. Reknown leak-free door seal system.



Process Flexibility

Fedegari's Thema 4 control system has been specifically developed to fully exploit the versatility of the equipment. Air removal, cooling, drying; there is unmatched scope to optimise the sequencing and precise settings of the process stages to handle all the different types of load the autoclave has been equipped for. See the factsheet "Fedegari Process Control" for more details on the unique capabilities of this GAMP/ 21CFR11 compliant system..

Build standards

Fedegari autoclaves are built to exacting standards with numerous unique design features. See the factsheet "Fedegari Build Standards" for more details.

- AISI316Ti chamber, polished < 0.4µ Ra, fully jacketed and insulated, 10 year pressure vessel guarantee.
- A uniquely reliable door seal system; AISI316L piping, all sanitary process valves
- Optional integral electric steam generator for chambers up to 1000 litres
- Optional magnetically driven fans – no leaking shaft seals or lubrication

Customer Support. SteriTech and Fedegari have been partners for over 20 years, offering :



- Feasibility studies
- Project management, DQ/HAZOP support
- Commissioning, validation
- Preventative maintenance
- Process Development
- Ongoing Thermal Revalidation.

SteriTech