

Fedegari Saturated Steam Autoclaves

Fedegari FOF Range Introduction

The Fedegari FOF range is the most technically advanced saturated steam steriliser on the market. The result of over 50 years continuous development and expertise, all units are built to full cGMP standards with the most advanced compliant control system available. Built to a very high standard, each unit is tailored to the customer's specification. Whether it's the ultimate performance you require, or simply a breakdown free unit with complete support from our local highly specialised engineers, Fedegari is the ultimate choice.

Process Optimisation

Optimised, validatable and repeatable cycles are the priority of every Fedegari autoclave. This is evident down to the small design detail and quality of manufacture. Some advanced aspects of the range are:

- Pressure control of cycles, offering superior response to temperature
- Minimum of 4 load probes to monitor sterilisation and ensuring robustness of cycles by allowing even with probe failures
- Up to 200 alarms and monitoring messages for true performance feedback
- Advanced modulating PID control and management of all incoming fluids
- Unrestricted cycle profile creation/editing facility to optimise cycles
- Continuous condensate removal during sterilisation for fine control.
- Full coverage, variably controlled heating jacket to minimise cold-spots.
- Enhanced cycle options for challenging loads or process targets



Design & Build Features

Each autoclave is manufactured in Fedegari's advanced manufacturing facility near Milan. From the incoming raw material inspection through to FAT testing, Fedegari are in complete control of the high manufacturing quality.

Some key design features include:

- Door seal system guaranteed for 4 years operational use without lubrication
- Fully St/St hydraulic system, frame and fascia, fully sanitary as required
- Whole system designed to minimise joints, welding and dead legs
- Units individually laid-out to optimise GMP aspects and to maximise access for maintenance and calibration etc.
- Specific components developed by Fedegari where generic market components are not of equal standard or performance
- Complete pressure vessel system designed to reduce stress and increase life



Complete Flexibility

Fedegari have developed over 150 standard chamber sizes from 200- 28,000 litres, bespoke chamber sizes are also easily provided. All are available in single door or pass-through configurations, with technical sections always designed to match the installation.

Fedegari can choose from hundreds of pre-tested options to truly match their supply to the customer URS.

Options are available to enhance: Process and controls, efficiency, layout, loading, reporting and SCADA integration. Also available are full hybrid units such as mixed porous, liquid and pathogen containment processes, stopper processors and the unique FOWS Washer/Steriliser.



SteriTech

Stilmas Equipment

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

Fedegari Equipment

Saturated Steam Sterilisers
Counterpressure Sterilisers
UltraWashers
Dry Heat Sterilisation
Pathogen Sterilisers
Combined Units
Laboratory Sterilisers

Fedegari non-thermal equipment

Low Temperature Surface Decontamination Stations
Laminar Flow Carts
Isolators and Cleanroom Contamination Controls

Olsa Equipment

Solids: Filtering, mixing and drying
Semi-Solids: Mixing and turnkey plants
Liquids: Preparation vessels, fermenters and bio reactors

Bano Equipment

Stainless Steel Cleanroom Furniture
Specialist Cleanroom Equipment

SteriTech Limited

Complete Turn-Key Projects

Fedegari Saturated Steam Autoclaves

Standards & Regulatory Compliance

As Fedegari have always focused on the regulated pharmaceutical industry, compliance to the following standards is not just 'achievable' but is their standard:

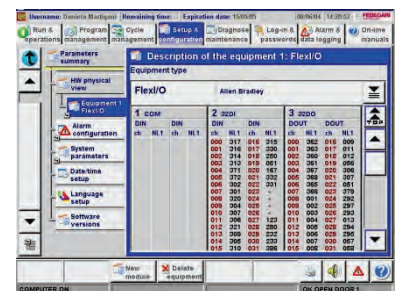
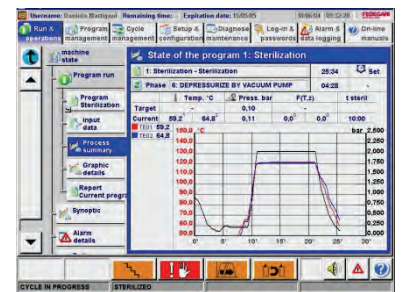
- HTM01 & 2010
- EN285 & 554
- EN Directives and associated standards
- ISPE cGMP and GAMP5 compliant (GAMP including supplier pre-validation)
- FDA CFR's including 21CFR parts 210, 211 and part 11
- ISA, ISO and DIN where required
- ASTM A240,213, 270, SA312 for chamber and piping material
- ISO9001 & 13485 for overall manufacture
- All IMB, MHRA and associated regulations

....plus other local and international standards as applicable.

Thema 4 Control System

All Fedegari process machines are supplied with the Thema 4 Controller. Designed by Fedegari using over 50 years of specific process knowledge, the Thema 4 controller offers the following features and benefits over conventional PLC based controllers:

- User friendliness, colour touch screen with windows style operation
- Core-philosophy that other than safety, the process has priority over all actions and events
- Pre-validated Gamp 5 compliance, 21 CFR Part 11 built in.
- Real-time operating system & open systems architecture
- Practically unlimited memory and storage capacity
- Full functionality open to customers under password control
- Advanced control, monitoring and reporting functions including parametric release options
- Complete integration for SCADA, as future-proofed as possible
- Commercially available hardware



As Fedegari use the same configurable software across all their units, customers with multiple units have significant advantages in terms of quality control, validation and supervision.

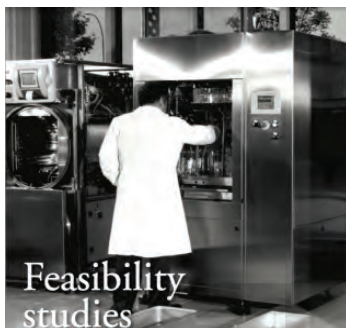
The pre-validation ensures minimal project risk and lower customer effort required to qualify.

SteriTech/Fedegari Customer Support

SteriTech have been Fedegari's sole local partners for over 20 years. Within that we have built a strong reputation for total customer support, such as:

- Feasibility studies, process and selection guidance
- Full project management from order to PQ
- Start-up, commissioning and validation from local engineers
- Preventative maintenance, calibration and routine validation
- Local spares and technical support.

A full lifetime support.



SteriTech Services

SteriTech, like our suppliers are solely dedicated to the regulated pharmaceutical sector. This enables us to fully understand not only the quality of performance required, but the documented evidence of all activities.

Project Management

A dedicated Project Manager follows each sale through to OQ handover. Liaison with customers, suppliers and field operations team to ensure effective project delivery.

Project Sitework

From our local highly trained team offering

- Installation Assistance
- Start-up & Commissioning
- SAT, IQ/OQ
- Calibration
- Thermal Mapping
- Cycle & Process Development

After-Sales

Full life-time local support for equipment including

- Full Training Packages
- Technical & Process support
- Spare parts supply
- Preventative Maintenance
- Calibration
- Routine Validation
- Upgrades and revampings