

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, liaising with customers, suppliers and field operations team to ensure effective project delivery.

Project Sitework

From our local highly trained team offering

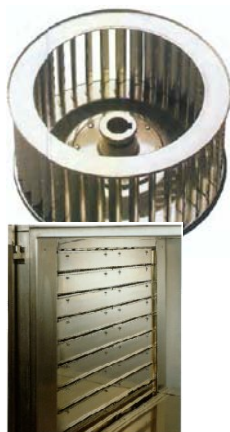
- Installation Assistance
- Start-up & Commissioning
- SAT, IQ/OQ
- Calibration
- Thermal Mapping
- Cycle & Process Development

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

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



Fedegari ovens are built to exacting standards with design features aimed at achieving the best results:

Chamber, doors and ducting supplied in AISI304 (316 option) stainless steel, mirror polished. Louvered chamber walls are adjustable to attain uniform air flow and temperature profiles.

Critical control components are designed and manufactured 'In-house'

- The AISI304 stainless steel fan impeller is produced in house at Fedegari. The special low weight design simplifies balancing, reduces noise and increases efficiency.
- Adjustable louvre sets allow accurate trimming of the air flow.
- Finned AISI304 heating elements extend the full chamber depth to ensure uniform air temperature throughout the chamber. PID control of a thyristor maintains precise temperature stability.
- Finned AISI304 cooling element, coolant flow controlled by a special Fedegari high-pressure modulated valve permitting PID control of temperature gradients during cooling.

Temperature and pressure instruments all to the highest specification.

Build Standards

Thema 4 Control System

All Fedegari equipment in their pharmaceutical range are supplied with the Thema 4 Controller. Designed by Fedegari it embeds the process knowledge they have built up over 50 years.

Cycle Development. As a GAMP Cat.5 parameter-driven system, *no* software modifications are needed to implement new process sequences. These can be freely determined without re-programming. There is *no* effective limit on the number of pre-set programs that can be developed and stored.

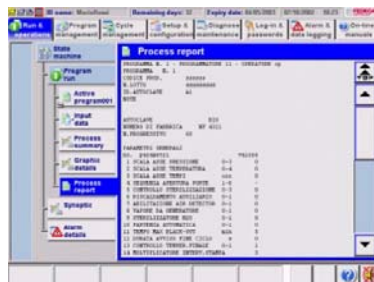
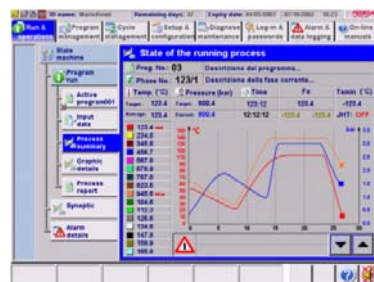
Compliance. GAMP5 compliant. Full audit trail, 21 CFR Part 11 built in **Advanced options**

Parametric release option automates the comparison of every batch cycle to the originally validated cycle

Integrated predictive maintenance option increases plant efficiency

Using the power of an Industrial PC platform Thema 4 offers:

- User friendliness, colour touch screen with windows style operation
- Industry leading real-time operating system, WindRivers VxWorks
- Commercially available hardware (Siemens, Digital Proface or AB),
- Open systems architecture
- Barcode reader option for cycle selection



SteriTech/Fedegari Customer Support

A 20 year partnership between SteriTech and Fedegari allows us to offer customers full support:



- Feasibility studies
- Advice and guidance to machine specifications
- Full project management
- DQ/HAZOP expertise
- Commissioning and Validation
- Sitework/Preventative Maintenance for the lifetime of the machine
- Process Development and ongoing Thermal Revalidation.