



GMP Autoclaves Process Control

All Fedegari industrial autoclaves are supplied with the **Thema 4** Control System

The objective is to precisely match or exceed customers' particular process requirements without incurring *any* software developments that might delay or compromise validation or jeopardise regulatory audit.

Thus Thema4 is a GAMP Category 5 parameter-driven system. *No* software modifications are needed to implement new process sequences. These can be freely determined from a huge library of proven, pre-validated phases. The library has been under continuous development for 30 years, it embeds the process knowledge Fedegari have built up over that time. There is no effective limit on the number of pre-set programs that can be developed and stored.

Hardware Platform.

The current generation of the control system uses the power of state-of-art Industrial PC platforms; Siemens, Allen-Bradley or Digital Pro-face:

- Standard PLC input-output hardware.
- Colour touch screen with intuitive "windows" style operation
- Industry leading real-time operating system, WindRivers VxWorks



Data Management.

Indefinite archiving of all process logs, full audit trails of all actions and parameter changes.



Security.

Password controlled user access, fully compliant with 21CFR11, customer defined parameters determine access limits, password time-out policies etc.

Communications. Open systems architecture.

Ethernet connection to remote user interface (any commercially available PC/printer with MS Windows)

Optional OPC to customers SCADA systems for data archiving, SMTP clock synchronisation; central password management, remote cycle parameter management.

Regulatory Compliance. All control systems are pre-validated to GAMP, fully 21CFR11 compliant

Advanced options

- Parametric release option automates the comparison of every batch cycle to the validated cycle
- Integrated predictive maintenance option increases plant efficiency
- Barcode reader option for cycle selection
- Thema4-EL entry-level "lite" option for less stringently regulated applications.

SteriTech/Fedegari Customer Support

SteriTech and Fedegari have been partners for over 20 years, offering full customer support:

Feasibility studies, advice and guidance to machine specifications

Project management

DQ/HAZOP expertise

Sitework/preventative maintenance

Equipment lifetime support

Process Development

Ongoing Thermal Revalidation.



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 Stills

Vapour Compression Stills

Pure Steam Generators

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Storage & Distribution
Systems

Bano Equipment

Stainless Steel Cleanroom
Furniture

Specialist Cleanroom
Equipment

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