



# COMPANY PROFILE

PASSION  
THAT DRIVES  
PERFORMANCES.

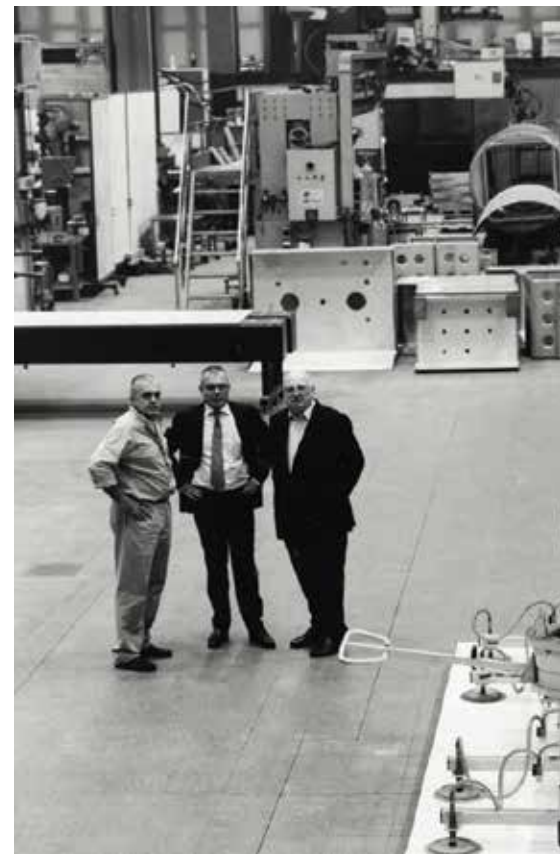
**FEDEGARI**  
*GROUP*





## FEDEGARI AUTOCLAVI SpA

Is the holding company of an Italian industrial group manufacturing customized machines, plants and the relevant components for the bio-/pharmaceutical and food industry worldwide. The know-how of the group lies in the field of sterile and clean processes and encompasses different technologies and products. Fedegari Autoclavi SpA was created by the will of brothers Giampiero and Fortunato Fedegari in the early Fifties in Pavia, Italy, as a small handicraft business dedicated to the manufacture of miscellaneous sheet metal products. It then developed into the production of sterilizers, progressively specializing in the design of these machines for applications in the pharmaceutical field. Today, Fedegari is an industrial group controlling 7 companies worldwide with more than 430 employees and constantly growing revenues, 85-90% of which is exported mainly towards Western Europe, the USA, India and China.



A unique feature of Fedegari is the extreme verticalization of the company, which always rejected the idea of assembling sophisticated machines with standard components (designed for a variety of applications) but always sought to develop and produce components and technologies in-house, so as to acquire always deeper knowledge of the machines and innovate them always better than anybody else.





Today Fedegari is a highly dynamic industrial group controlled by the family, ready to tackle the challenges of a global technological scenario. Fedegari is capable of offering innovative solutions for clean and sterile processes both in terms of products and in terms of pre- and after-sales support all over the world.

Besides Fedegari Autoclavi SpA, the group is composed of the following companies:

### Fedegari (SUISSE) SA

Originally established in the Seventies near Lugano (Switzerland), in 2001 the company moved into the current headquarters in Bedano, with 3500 m<sup>2</sup> of indoor production floor-space and about 30 personnel employed.



FEDEGARI (SUISSE) SA

### Fedegari GmbH

Founded in 2011 in Munich, Fedegari GmbH is the official distributor for all Fedegari products (industrial & laboratory) in Germany and supports all German-speaking markets. Fedegari GmbH provides all the support (sales and after-sales) for any Fedegari product in these countries. In 2019, Fedegari GmbH moved to Frankfurt am Main.



FEDEGARI TECHNOLOGIES, INC.

### Fedegari Technologies Inc.

In 2007, Fedegari established a commercial branch in the United States to support North American customers with commercial and technical personnel.

In 2014, Fedegari Technologies moved into a new facility in Sellersville (PA) with a state-of-the-art technology center. The center enables customers to simulate processes using dedicated equipment and provides specialized technical training.



FEDEGARI ASIA PTE. LTD.

### Fedegari Asia Pte. Ltd. | Shanghai Fedegari Trading Co., Ltd

Fedegari Asia was founded in 2008 in Singapore in order to offer direct support to this market, which is currently the most dynamic one with the fastest growth rate. Other than commercial support, Fedegari Asia guarantees the presence of skilled technical personnel for after-sales support and a spare parts warehouse.

In 2017, Fedegari Asia opened a new branch in Shanghai, China.

### Fedegari RUS OOO

In 2019 Fedegari Group opened a new branch office in Moscow, Russia. In this way the company can be closer to Russian customers for sales and after sales assistance.



NEW INOX SRL

### Fedegari Tech Service Pvt. Ltd.

In 2019 Fedegari Group consolidated its role in the Asian market with the opening of a new Technical Support Center in Hyderabad, India. The new branch provides technical assistance to the many local customers who have been working with Fedegari process equipment for years.

### Qualitech Srl

Established in 1999 with two experienced partners, the company provides all after-sales services for Fedegari products worldwide. Every single technician or engineer is exclusively trained on Fedegari products. Qualitech provides a complete range of services from installation to qualification/validation to any customized service agreement.



SHANGHAI FEDEGARI

### New Inox Srl

New Inox was opened in 2003 as a joint venture with partners of Fedegari with the goal of providing specialized field services where structural works are needed. This specialization is requested where special machines and plants are installed or where structural modifications (like those typical of a revamp) are carried out.



# COST-EFFECTIVE INTEGRATED SOLUTIONS

The recent evolution of Fedegari Group is present on integrated projects where various process machines interact with robotized handling systems for fully automatic high-throughput manufacturing lines.

The processes are totally managed and controlled by Thema4 and can be integrated with the customer SCADA system.



*Some examples of process integration*



**FOFxx + FCISxx**  
Saturated steam sterilizer + Isolator



**FOFxx + FCDVxx**  
Saturated steam sterilizer +  
Chemical bio-decontamination unit



# Thema4 PROCESS CONTROLLER

One process controller for all Fedegari machines

First delivered at the beginning of 2004, Thema4 is today **the most reliable and fastest-developing process controller in the industry.**

Thema4 is defined as a completely configurable standard product (classified by GAMP 5 as Category 4 - Configured Products) and is managing all industrial machines manufactured by Fedegari.

This achievement is the logical consequence of almost three decades of painstaking work on process controllers combined with infrastructure investments, close collaboration with strategic partners and uncompromised values because there is no easy shortcut to durable success.

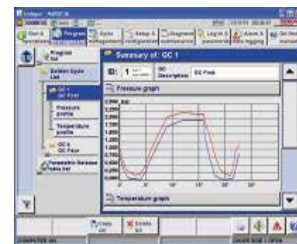
Thema4 in fact, is the natural evolution of the previous generation of controllers (like Thema3 and SuperSpectra before that), that were based on custom-made hardware. While Thema4 has inherited the process management principles of its predecessor, it is absolutely different in terms of hardware components (COTS), software architecture, HMI and general and integration functions.

With Thema4, Fedegari assures the commercial availability of standard components, the integration levels required in modern pharmaceutical plants together with functions and performances to meet quality and safety standards of those production processes for which the application is intended.

NATIVE COMPLIANCE  
FDA CFR 21 PART 11



*Rotating load*



*Golden cycle*



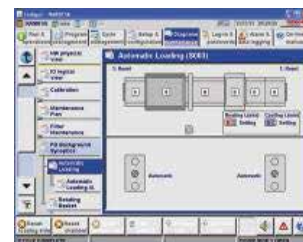
*Alarm configuration*



*Process report*



*IOs logical view*



*Automatic handling*



## PRODUCTS RANGE

Fedegari offers a wide range of products and innovative solutions to meet the most demanding requirements in the field of sterilization, cleaning and decontamination.

*Industrial*

### **Moist-heat sterilizers**

FOFxx

Saturated steam sterilizers



FOAxx

Steam-air mixture sterilizers



FOWxx

Water-cascade sterilizers

### **Washing solutions**

FOWSxx

Washer-sterilizers



FSWxx

Eco-steam Washer



### **Bio-decontamination and contamination control solutions**

FCDVxx

Chemical bio-decontamination units with Hydrogen Peroxide

FCTSxx

Sterility Test Isolators





## Contamination control solutions



FCISxx

Isolators

FCPxx

Down flow booths



FHCxx

Laminar flow mobile safe-carts



## Dry-heat sterilizers

FODxx

Sterilization & depyrogenation ovens



## Special applications



Integrated solutions  
for pharmaceutical closures processing

Sterilizers with rotating loads



## Laboratory

FOB5/FOB4/FOBxx  
Steam sterilizers with horizontal chamber



FVAxx/FVGxx/FVSxx  
Steam sterilizers with  
vertical chamber



BIER  
Biological Indicator Evaluation Resistometer



FGWxx  
Glassware Lab Washer

## Healthcare

FELDAUTOKLAV H2000M2  
Steam sterilizers for mobile field applications







## FEDEGARI | Tech Centers

Our *Tech Centers* are the perfect environment for end-users and experts to meet and exchange experiences for the development of new and cost-effective solutions to real-world problems.

Through state-of-the-art centers, Fedegari aims to increase the interaction with partners and customers for continuous education in the field of sterilization and contamination control.

To accomplish that, our company have invested more than \$10 million in process equipment installed in the facilities in USA, Italy and UK (in partnership with Steritech).

### Locations

Albuzzano (PV) - Italy

Sellersville (PA) - USA

Salfords (Surrey) - UK

### Contact:

[fedegari@fedegari.com](mailto:fedegari@fedegari.com)

## Training & Education

FEDEGARI | Tech Centers

Fedegari offers different technical courses in the fields of sterilization, bio-decontamination and cleaning.

These courses cover the science behind the processes with practical advices on cycle development, performance and validation activities.

### Delivering a unique experience

Developing completely customized solutions is our passion and our Training & Education division is also oriented in the same direction.

Fedegari provides customized technical trainings and seminars tailored to address customers' specific needs.

Each course is developed to be a unique experience. We design custom programs focusing on the application of theory in practice to support customers on achieving the highest process performances.

Our courses will be held at Fedegari Tech Center or at your company site.





## TECH CENTER SERVICES

### Microbiological trials

- Microbiological assessment of sterilization effectiveness
- Microbiological assessment of depyrogenation effectiveness
  - Microbiological assessment of decontamination effectiveness (with hydrogen peroxide)
  - Microbiological assessment of washing cycles (Endotoxins reduction, microorganisms reduction)
- Microbiological assessment of washing/disinfecting cycles
  - Microbiological assessment of washing/sterilizing cycles

### Sterilizers

- Cycle development according to customer's URS
- Evaluation of chemical, microbiological quality of the product at the end of the cycle
- Evaluation of package integrity/quality at the end of the cycle
- Primary packaging stress test
- Cycle time optimization

### Washers

- Cycle development of a washing cycle
- Cycle development of a washing/sterilizing cycle
- Cycle development of a washing/disinfecting cycle
  - Cleaning validation protocol
  - Spray coverage test

### Bio-decontamination units

- Decontamination cycle development according to customer's URS
- Evaluation of chemical, microbiological quality of the product at the end of the cycle
- Evaluation of package integrity/quality at the end of the cycle
- Decontamination cycle time optimization

### Isolators

- Decontamination cycle development
- Process validation support
- Package integrity verification support





## AFTER-SALES SERVICES

Responsible for any issue that arises after the delivery of any machine, the After-Sales department may support the final end-user or the local representatives by providing any part or service needed during the entire life cycle of Fedegari equipment.

According to the specific operation requirements of every end-user, all services can be customized with the aim of assuring the highest level of productivity. Through this department proposals can be prepared for revamping older machines or for upgrading process controllers to the latest generations.

All these services extend the operating life of the machines to the limits of the most critical components (such as the pressure vessels for the autoclaves) thus increasing the return of the original investment.

One of the services with the highest added value is the assistance to the customers in the final phase of validation. Often in fact, sterilizers are validated by personnel that has no deep experience with the specific sterilizer and once all processes and load configurations have been validated nobody is willing to do any effort to optimize process performances.

In several cases we have helped – thanks to the expertise of our service personnel – to optimize their processes before validation is complete, thus achieving the highest performances. This little investment pays big dividends during the entire life cycle of the sterilizer.

### SERVICES OFFERED

- Installation/startup/commissioning
  - Qualification (IQ/OQ/PQ)
    - FAT & SAT
  - Process/load optimization
    - Validation
  - Preventive maintenance plans
- On-demand maintenance services
  - Revamping of old machines
- Process controller updating (SW e HW)



FEDEGARI  
GRUPPO

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For any further information, do not hesitate to contact us at the following addresses:

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