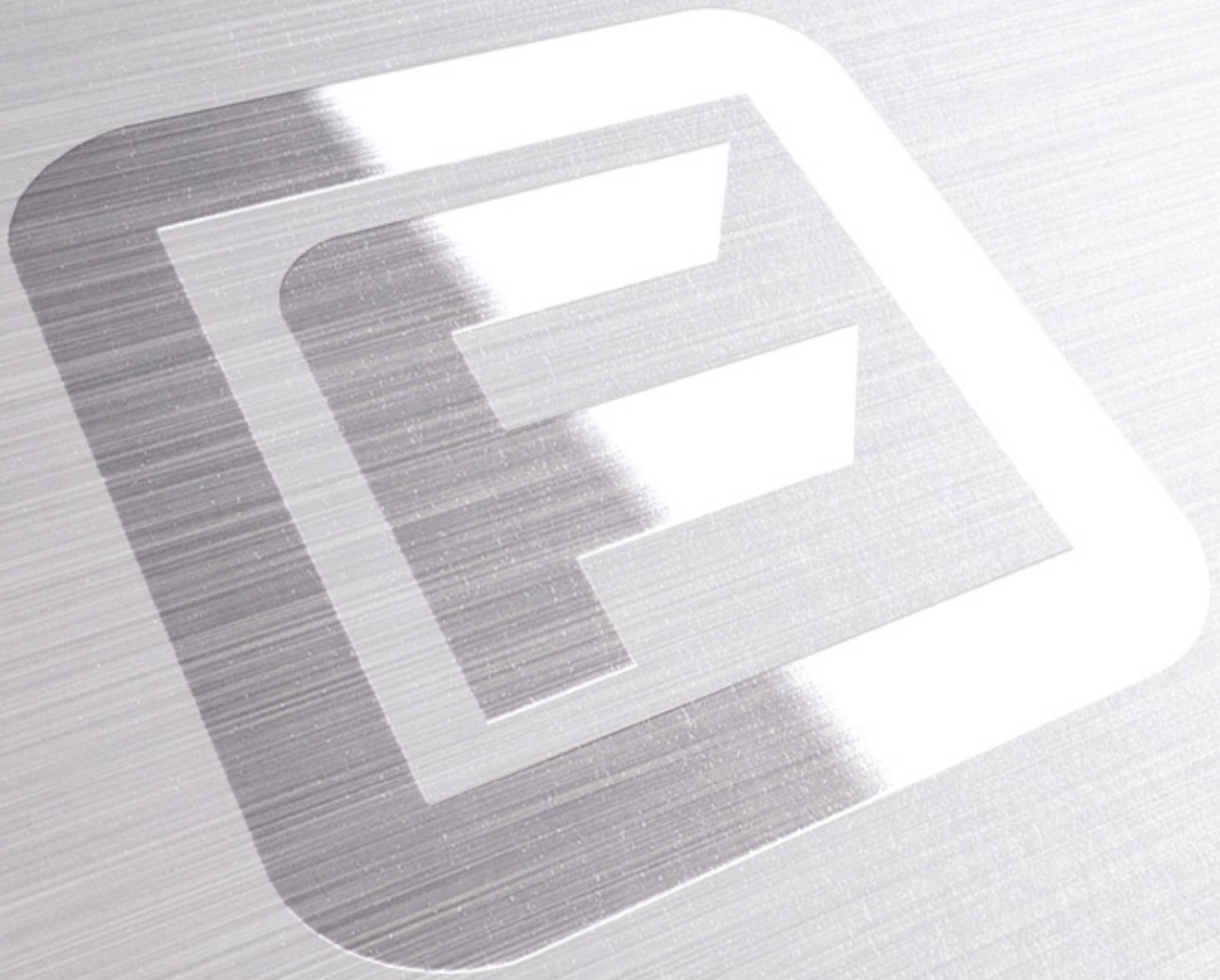


LAB SOLUTIONS





FEDEGARI: EXCELLENCE IN STERILISATION.

Fedegari is an Italian company that stands as a world leader in the design and manufacturing of customised solutions for sterilisation across key sectors such as analysis, research, and industrial applications (bio-pharma, cosmetics, packaging, food, cell&gene). Internationally renowned, Fedegari is synonymous with sterilisation. With complete mastery of sterile processes, Fedegari collaborates with entities worldwide to develop the most advanced sterile therapies, with the ultimate goal of enhancing the quality of life for individuals.

Founded in 1953 in Pavia, Italy, as a small workshop of artisan metal carpentry, today Fedegari leads an international group with 11 branches worldwide, over 700 employees, a global support network, and consistently rising revenue. This success is due to a clear choice: Fedegari is the strategic partner that not only focuses on constructing top-tier machinery, but invests in knowledge and development of sterilisation technologies, aiming for continuous improvement in customer experience. Herein lies Fedegari's strength: the ability to blend a scientific approach, innovative drive, and unique expertise in the field of sterilisation.

INDUSTRIAL EXPERTISE TAILORED FOR THE LAB.

Fedegari laboratory machines represent the synthesis of all successfully tested innovations in the pharmaceutical industry. The knowledge on the sterile process is pivotal to the company: hence Fedegari delivers total excellence from every perspective.

The parameterisation of sterilisation and washing cycles enables the treatment of any type of load, from the most sensitive such as preserves or hyaluronic acid to culture media and glassware. Furthermore, they empower the management of processes for neutralising cultures whether in bioreactors and fermenters or those highly contaminating to the environment.

Process know-how

- Saturated steam and counterpressure process with steam-air mixture
- Multiple options for parametrising sterilisation and washing cycles

Hardware quality

- AISI 316L stainless steel for critical parts such as pressure vessels, sanitary piping and internal plates
- Non-metallic parts compliant with FDA CFR Section 21
- Specifically designed pneumatic gaskets for the best door sealing available on the market

Software reliability (DCS20 process controller)

- Top reliability in process management (time, temperature, and pressure parameters)
- Guarantee of Data Integrity and Active Directory for sterilisation cycles

Regulatory compliance

- Pressure equipment 2014/68/EU PED, ASME BPVC Construction with National Board Registration, Canadian Registration Number (CRN), Manufacture License P.R. China - SELO, NR-13 Brazil, MHLW Japan Regulation, Australian Worksafe Registration, MOM Singapore Regulation, DOSH Malaysia Regulation, KEA Korea Energy Agency, SANS 347 South Africa, EAC Marking for Eurasian Countries
- Performance EN 285 Steam Sterilizer, EN 15883 Washer Disinfector



FVG SERIES

Vertical autoclave

Compact and ergonomic.

The FVG Series vertical saturated steam autoclaves are ideal for sterilisation across various laboratory sectors, thanks to the AISI 316L stainless steel generator with self-priming pump and the integrated air compressor. The unique horizontal sliding lid with pneumatic sealing ensures a quick and safe closure. Additionally, they are equipped with a pressure and temperature sensor system, enabling dual regulation and optimal control of the sterilisation process.

Available capacities

50 L | 75 L | 140 L

Applications

QC | ANALYSIS | RESEARCH

SW options

CONNECTION TO EXTERNAL PC
HEATING AND TEMPERATURE MAINTENANCE

Power requirement

4.5 kW | FVG1
6.5 kW | FVG2
7.5 kW | FVG3

Process controller

TCS09
MULTI-LEVEL PASSWORD PROTECTION
(UNDER CONTROLLER)
14 FREELY CONFIGURABLE PROGRAMS
(UNDER CONTROLLER)



FVA/A1 SERIES

Vertical autoclave



Where technology meets design.

The FVA/A1 vertical autoclaves combine design, ease of use, and excellent performance. Designed for the most demanding applications in analytical and microbiological laboratories, research institutes, and various industrial sectors, they ensure fast and efficient processes, optimised consumption, and reduced operating costs. They feature unique solutions such as vertically positioned filters, a wide front door for immediate access to the technical area, and a horizontal sliding lid with pneumatic sealing for a quick and safe closure.



Available capacities

75 L | 140 L | 188 L

Applications

BIO-PHARMA | COSMETICS | MICROBIOLOGY
PACKAGING | FOOD | QC

SW options

CFR21 PART 11 | ACTIVE DIRECTORY | SCADA

Power requirement

0.5 kW | Without steam generator
6.5 kW | FVA2/A1
7.5 kW | FVA3/A1
9.5 kW | FVA3/A1 PLUS
9.5 kW | High temperature

Process controller

DCS20 | COMPLIANT WITH GAMP5



FOB2-FOB3 SERIES

Benchtop horizontal autoclave

High performance, configurable design.

The FOB2-FOB3 benchtop autoclaves combine innovation, high-quality construction, and outstanding performance with optimised consumption, ease of use, and ergonomic load handling. Specifically designed for the most demanding applications in analytical and microbiological laboratories, they are also suitable for high-pathogen-risk environments, featuring a special execution of the sealing wall. The compact design is configurable with single or double hinged door, equipped with a pneumatic seal.

Available capacities

47 L | 75 L | 90 L | 122 L

Door configuration

SINGLE OR DOUBLE DOOR

Applications

BIO-PHARMA | COSMETICS | MICROBIOLOGY
PACKAGING | FOOD | QC | BSL3/BSL4

SW options

CFR21 PART 11 | ACTIVE DIRECTORY | SCADA

Power requirement

0.5 kW | Without steam generator
6.5 kW | FOB2-TS
6.5 kW | FOB2S-TS
7.5 kW | FOB3-TS
7.5 kW | FOB3S-TS
9.5 kW | High temperature (FOB3 only)

Process controller

DCS20 | COMPLIANT WITH GAMP5



FOB4 SERIES

Stand-alone horizontal autoclave



Flexibility and optimisation.

The FOB4 Series autoclaves feature ergonomic characteristics specifically designed for the sterilisation of medium and large capacities. With a high-efficiency preheating system and complete control over functional parameters, they ensure optimised cycle and drying times. The flexibility of loading via trays or trolleys and the vertically sliding automatic doors allow for optimal management of the laboratory space.

Available capacities

147 L | 210 L

Door configuration

SINGLE OR DOUBLE DOOR

Applications

BIO-PHARMA | COSMETICS | MICROBIOLOGY
PACKAGING | BSL3/BSL4

SW options

CFR21 PART 11 | ACTIVE DIRECTORY | SCADA

Power requirement

2.6 kW | Without steam generator
16 kW | FOB4-TS
16 kW | FOB4L-TS
16 kW | FOB4S-TS

Process controller

DCS20 | COMPLIANT WITH GAMP5



FOB5 SERIES

Stand-alone horizontal autoclave

Cutting-edge technology, continuous innovation.

The FOB5 Series is the embodiment of Fedegari's industrial experience applied to the lab. Excellence is evident in the quality of materials, design features, attention to detail and engineering that combines maximum performance with cutting-edge process technologies. The large loading capacity and the extensive range of implementable accessories make these autoclaves highly versatile, ideal for pharmaceutical companies as well as for BSL3/BSL4 classified laboratories within research institutes and universities.

Available capacities

340 L | 450 L | 600 L | 700 L

Door configuration

SINGLE OR DOUBLE DOOR

Applications

BIO-PHARMA | COSMETICS | MICROBIOLOGY
PACKAGING | BSL3/BSL4

SW options

CFR21 PART 11 | ACTIVE DIRECTORY | SCADA

Power requirement

2.6 kW | Without steam generator
35 kW | FOB5C-TS
35 kW | FOB5-TS
35 kW | FOB5S-TS
39 kW | FOB5L-TS
39 kW | FOB5SL-TS
47 kW | FOB5XL-TS
47 kW | FOB5SXL-TS

Process controller

DCS20 | COMPLIANT WITH GAMP5



Process controller

The perfect user experience.

Designed by Fedegari, the DCS20 process controller integrates years of experience in managing complex processes and cycles for the pharmaceutical industry. The DCS20 is designed, developed according to GAMP5, tested, maintained, and validated in full compliance with GMP (lifecycle, traceability, validation, and change control). Its extreme versatility, thanks to the configurability of recipes, allows for the refining of cycles according to the specific product to be treated and the relevant process.

Main features

- 7" OR 10" TFT CAPACITIVE TOUCHSCREEN GLASS DISPLAY
- MENU NAVIGATION AVAILABLE EVEN DURING CYCLE EXECUTION
- UNLIMITED STORAGE: 3.2 GB HD, 2 GB RAM
- ACCESS VIA USER ID AND ENCRYPTED PASSWORD
- 5 DISTINCT ACCESS PROFILES

Software kit options

- REMOTE CONTROL INTERFACE
- SECOND DISPLAY FOR DOUBLE-DOOR AUTOCLAVES
- CALCULATION AND CONTROL OF THE F_0 FUNCTION
- PHARMACOPEIA CYCLES
- COMPLIANCE WITH CFR21 PART 11
- SCADA MODBUS TCP/IP OR OPC UA
- AUTOMATIC BACK-UP
- DOWNLOAD OF CYCLE REPORT IN PDF FORMAT
- SNTP SYNCHRONISATION
- ELECTRONIC SIGNATURE
- REMOTE AUTHENTICATION



Remote control interface

THE HMI INTERFACE IS ALSO AVAILABLE REMOTELY AS A DESKTOP APPLICATION, SO THAT THE USER CAN:

- REMOTELY CONTROL THE AUTOCLAVE
- CHECK THE MACHINE STATUS (AUTODIAGNOSTIC)
- REVIEW THE CYCLE

Lifecycle and validation

THE DCS20 PROCESS CONTROLLER IS DESIGNED, DEVELOPED, TESTED, MAINTAINED, AND VALIDATED ACCORDING TO A PRECISE LIFECYCLE, IN COMPLIANCE WITH REGULATORY REQUIREMENTS EXPRESSED BY CURRENT GMP:

- GAMP 5
SOFTWARE CATEGORY 4: CONFIGURABLE SYSTEM
HARDWARE CATEGORY 1: STANDARD COMPONENTS
- FDA21CFR PART 11
- ALCOA+

FGW SERIES

Laboratory washer

Washing at peak performance.

The laboratory washers from the FGW Series deliver maximum washing and drying performance with reduced consumption, safety, and ease of use. A key feature is the use of direct steam in different phases of the process: for the softening action on the load, for heating the wash water, and for the final drying with hot air. Thus designed, the system does not require additional heating elements inside the chamber, reducing consumption and avoiding the risk of load contamination.

Available capacities

357 L | 512 L

Door configuration

SINGLE OR DOUBLE DOOR

Applications

BIO-PHARMA | COSMETICS | MICROBIOLOGY
NCN OR LOW CLASSIFICATION AREAS

SW options

CFR21 PART 11 | ACTIVE DIRECTORY | SCADA

Power requirement

4.0 kW | Without steam generator

18 kW | FGW350

18 kW | FGW350S

18 kW | FGW500

18 kW | FGW500S

Process controller

THEMA4LAB | COMPLIANT WITH GAMP5



FOB3BIER



Biological Indicator Resistometer

From a need, the solution.

Fedegari's experience in the pharmaceutical sector and the recent directives from GMP Annex 1 have highlighted the importance of biological indicators and the consequent need to monitor their integrity. The FOB3BIER biological indicator resistometer is a patented device designed to characterise biological indicators, both solid and liquid, with the aim of verifying or determining their thermal resistance (D-value) and temperature coefficient (z-value).

Available capacities

90 L

Applications

EN ISO 11138-3 BIOLOGICAL INDICATORS
FOR MOIST HEAT STERILIZATION PROCESSES

SW options

DATA DOWNLOAD TO AN EXTERNAL PC
VIA ETHERNET LAN CONNECTION

Power requirement

9.5 kW | FOB3BIER

Process controller

DCS PLUS 10



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