

# Fedegari Ultrawashing Units

## Fedegari FOWS Range Introduction

The Fedegari FOWS range has been designed to innovate rather than replicate the competition. Initially developed from Fedegari's integrated stopper processor units, the washers offer huge flexibility and the opportunity for pharmaceutical manufacturers to re-think the conventional product flow in their facilities.

### Process Optimisation: Washing & Drying

When designing the FOWS range, Fedegari decided to improve and innovate on technologies already on the market. Their unique Ultrawashing process offers the following advantages over conventional systems:

- Static or completely rotating load for optimal wash flexibility
- Either steam or superheated water initial rinse phase to optimise wash and possibly eliminate additives
- Vacuum drying is more efficient and has lower running costs than HEPA air drying
- Lower utility consumptions
- Circular pressure vessel chamber, lowers build costs without compromise on cleanability and operating life
- Increased GAMP 5 process control & batch registration
- Increased GMP standard supply due to autoclave inheritance
- Additive dosing via metered pumps and weight controlled
- Conductivity control of final rinse and optionally also for dosing
- Chamber is fully CIP and SIP compatible as standard.



### Process Optimisation: Hybrid Washing/sterilisation

The FOWS range has been designed to flexibly run washing, sterilisation or combined cycles even including pathogen decontamination. The advantages of a single cabinet for multiple processing depend on the nature of the facility but can include:

- Lower capital, maintenance and validation costs with smaller footprints for low-usage installations such as laboratories, and pilot plants.
- Increased redundancy, operational flexibility and overall bioburden reduction for high usage production installations
- Greater flexibility in facility flow paths



### Complete Flexibility

As the FOWS range has been developed from the FOF porous load sterilisers, the complete range of configurable chamber sizes and configurations are also available making the FOWS a truly remarkable unit able to not only meet URS's but to totally redefine what is achievable from bioburden reduction systems.

Fedegari's ranges of washers, steam sterilisers and chemical decontamination units all use the same load handling mechanisms, and process controllers to offer real synergies for customers looking for the complete aseptic or terminally sterilised solutions.

# 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 Ultrawashing Units

## 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:

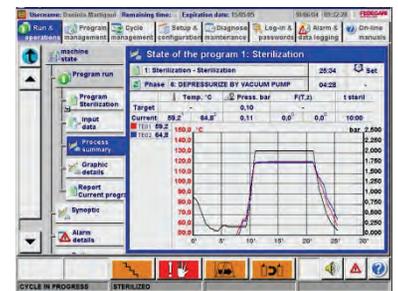
- HTM01 & 2010 (where applicable)
- EN285 & 554 (where applicable)
- EN Directives and associated standards
- ISPE cGMP and GAMP5 compliant (GAMP including supplier pre-validation)
- FDA CFR's including 21CFR parts 210, 211 and part 11
- ISA, ISO and DIN where required
- ASTM A240, 213, 270, SA312 for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



## 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



The screenshot displays the 'Description of the equipment 1: FlexiO' window. It shows a detailed configuration table for the equipment. The table has columns for 'Equipment type', 'I/O', 'DIN', and 'DOU'. The equipment is identified as 'FlexiO' and is associated with 'Alan Bradley'.

Equipment type	I/O	DIN	DOU
1. FlexiO	2. 2021	3. 2020	
ch. IN1	ch. IN1	ch. IN1	ch. IN1
001	216	017	200
002	218	019	202
003	219	020	203
004	215	016	199
005	217	018	201
006	218	019	202
007	219	020	203
008	200	008	001
009	201	009	002
010	202	010	003
011	203	011	004
012	204	012	005
013	205	013	006
014	206	014	007
015	207	015	008
016	208	016	009

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