

Sterility Test Isolator



FEDEGARI
GROUP

EN.1.4.1

PROCESSES

Sterilization
Washing
Chemical
bio-decontamination
Contamination
control
Dense-phase fluids plants

SPECIAL APPLICATIONS

Rotating sterilizers
Pharmaceutical closures
processing

COMPONENTS

Pressure vessels
Doors
Piping
Process controller
Wireless sensors

ACCESSORIES

Un/loading conveyors
Customized racks

FCTS- Fedegari Sterility Test Isolator with built-in Hydrogen Peroxide Vaporizer

Innovation in a commodity market?

When creativity is in your blood you cannot settle for basic innovation but you will explore new paths for revolutionary solutions. This was our goal when we started designing our first isolator.

Process control

Given Fedegari's experience in different contamination control processes, our first priority was to assure the highest reliability of the process. We investigated various alternative solutions only to discover repeatability of performances – as it is normally expected in thermal sterilization – was a little more than a dream.

System reliability

Only experience – practical field experience – provides the highest degree of reliability because the single subsystems and solutions in general have already been tested under real operating conditions. In Fedegari when we design a new machine our assembly procedure is unique in that we use several in-house engineered solutions which have already been used in other machines before, thus reducing to a minimum the new developments which have to be validated by the time. Unhappy with the performances and the reliability of third-party H_2O_2 – vaporizers, we have installed the same solutions that we have standardized for our bio-decontamination machines that does not require any proprietary consumables. This innovative design provides real time biocide concentration control (over traditional estimated calculations) and is managed by the very same Thema4 which is today's reference standard for all contamination control machines where process failure is not an alternative. Through the H_2O_2 sensors and other devices, Thema4 assures that vapor concentration remains extremely stable (within ± 15 ppm) thus making process repeatability the obvious consequence.

Efficient bio-decontamination

The unit transfer hatch is equipped with a magnetic-driven fan in the ceiling. This innovative design for homogenizing the H_2O_2 - air mixture allows a uniform distribution of the vapor and avoids any possible leak. Moreover, an UDAF that creates a piston effect, guarantees the correct biocide distribution.



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CONTACT US:

Italy

Fedegari Autoclavi SpA
SS 235 km 8
27100 Albuzzano (PV)
T +39 0382 434111
F +39 0382 434150
E fedegari@fedegari.com

Germany

Fedegari GmbH
Lehrer-Götz-Weg, 11
81825 Munich
T +49 89 42044920
F +49 89 42044918
E info@de.fedegari.com

Singapore

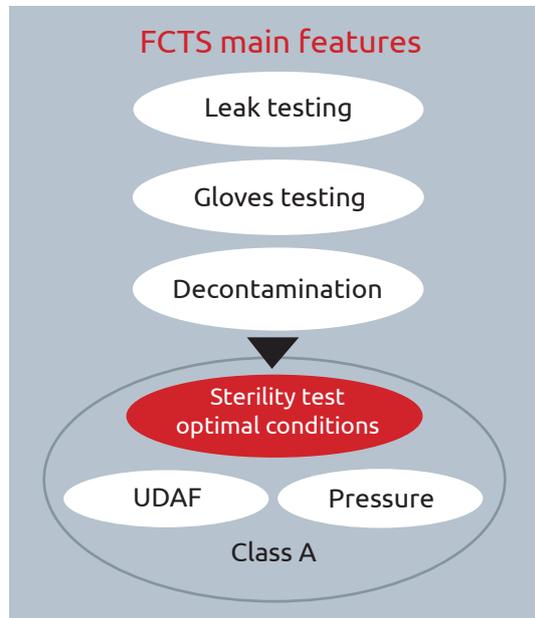
Fedegari Asia Pte. Ltd.
8, Boon Lay Way
#03-16 - Tradehub 21
609964 Singapore
T +65 6 3164761
F +65 6 8967365
E info@fedegariasia.com

Switzerland

Fedegari (SUISSE) SA
Via alla Gerra, 11
6930 Bedano
T +41 91 9352090
F +41 91 9352099
E info@fedegarisuisse.ch

USA

Fedegari Technologies, Inc.
1228 Bethlehem Pike
18960 Sellersville (PA)
T +1 215 4530400
F +1 215 4530406
E info@fedegariususa.com



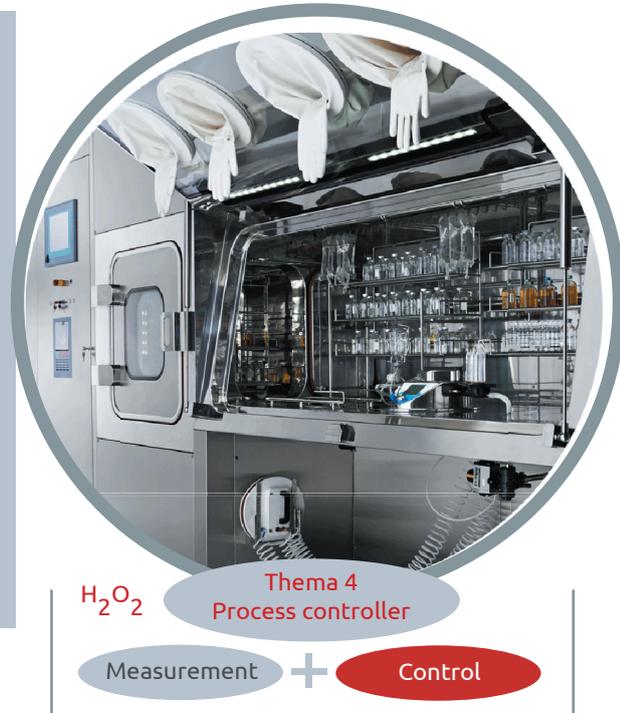
FHPV

Fedegari Hydrogen Peroxide Vaporizer

The dosage is performed by the process controller. The process does not start if there is not enough H₂O₂ liquid into the buffer tank. An H₂O₂ level sensor fixed on the buffer tank, restores the liquid H₂O₂ level from the customer H₂O₂ tank. The fluid metering system checks the amount of H₂O₂ in the chamber and controls the specific amount of liquid biocide to be delivered to the vaporizer unit.

Design features

Compliant to cGMP guidelines, the working chamber has non-directional BA surface finishing (Ra ≤ 0.4 μm). Air-tightness is 100% guaranteed by ultra-safe doors. Two sensors monitor the amount of H₂O₂ in a fixed sampling point of the chamber. The first H₂O₂ sensor (150-1500 ppm) measures the concentration to control the process. The second H₂O₂ sensor (0-300 ppm) is installed for safety (TLV < 1 ppm). The isolator can be equipped with sterility test suits from different manufacturers.



Key-benefits

- Feedback control for superior process repeatability even if load patterns change
- Fixed concentration profile with no impact of H₂O₂ degradation on the process
- Drastically reduced validation time for cycle and load
- Gloves and leak testing totally managed by Thema4 process controller
- Silicon inflatable gaskets for 100% air tightness on all doors
- Significantly reduced operational costs with non-proprietary consumables
- Thema4: easy integration with other Fedegari machines and customers' SCADA systems
- Cost-effectiveness: time and cost-savings on training and maintenance due to standardization of components, procedures and process controller
- Custom designed racking and storage
- Controlled means for loading and removing the processed loads and waste materials