



Latest  
developments



# FCTS

Sterility Test Isolators

with built-in  $H_2O_2$  vaporizer  
engineered and manufactured by Fedegari

 **FEDEGARI**  
GROUP



## Innovation in a commodity market?

When creativity is in your blood you don't settle for physiologic innovation; but will explore new paths for revolutionary solutions. This was our goal when designing our first isolator.

## Our priority

to assure the highest **process reliability**

## Our expertise

various contamination control processes

## A dream

We investigated various alternative solutions only to discover **repeatability** of performances – as is normally expected in thermal sterilization – was 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 development procedure is unique in that we use several in-house engineered solutions and components which have already been field tested, thus reducing to a minimum the risks typically associated with un-tested new products.

# Process control

Unhappy with the performance 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 do 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 option.

Through the  $H_2O_2$  sensors and other devices, Thema4 assures that vapor concentration remains extremely constant (within  $\pm 15$  ppm) thus making

## process repeatability

the logical consequence.

## Sterility Test Isolator

Designed to guarantee aseptic conditions, avoiding:

- Particulate contamination
- Microbial contamination of products under testing
- Cross contamination operator/product reducing false positive risks



Products

Injectable liquids

Ophthalmic ointments

Sterile antibiotic powders

Freeze-dried drugs

Incoming raw materials

In compliance with:

FDA

EMA

WHO

and associated Pharmacopoeia, EN standards and directives

## What sets us apart?

Process control loop for reliable process performances

even with different load patterns.

### Thema4

Easy integration with all other Fedegari machines and SCADA systems



100% air-tightness  
Inflatable gaskets  
on all doors.

Drastically reduced validation time

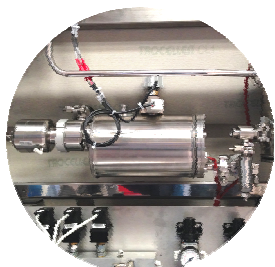
Fixed concentration profile increase reliability and repeatability.

Ergonomic design

sloping glazed front door and wide rounded glove ports.



## What sets us apart?



Built-in H<sub>2</sub>O<sub>2</sub> vaporizer (FHPV)  
engineered and manufactured by Fedegari.

Fixed concentration profile  
with no impact of H<sub>2</sub>O<sub>2</sub> degradation on the process.

All components  
are isolated from the chamber.

### Cost-effectiveness

Time and cost-savings on training and maintenance  
due to standardization of components,  
procedures and process controller.

Significantly reduced operating costs  
with non-proprietary consumables.



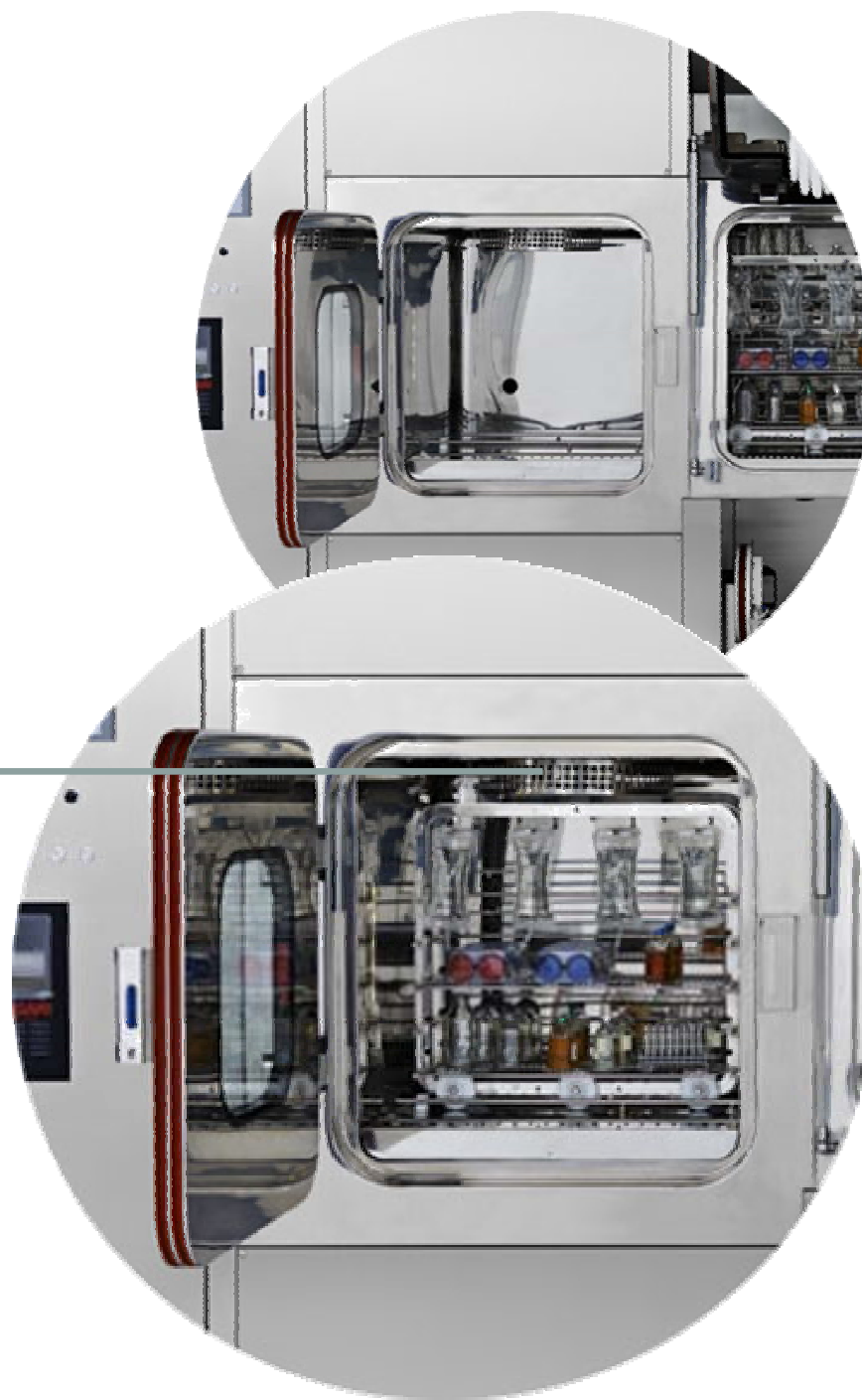
## What sets us apart?

Fedegari's unique experience with thermal sterilization processes.

### Transfer hatch


The unit transfer hatch is equipped with a magnetic-driven fan in the ceiling. This innovative design for homogenizing the H<sub>2</sub>O<sub>2</sub>- air mixture allows for a uniform distribution of the vapor while preventing any possible leak.

An UDAF that creates a piston effect, guaranteeing the correct biocide distribution.






## Main features




Internal trolley  
for material transfer




Continuous loading of  
the isolator with the materials

ISO 5 FDA GMP and  
Class A EU GMP


Integrated pressure  
decay leak test  
both for chambers  
and gauntlets




Turbulent airflow  
transfer hatch for faster  
bio-decontamination




Full environmental monitoring  
(viable and non viable particles)



Custom designed  
racking and storage



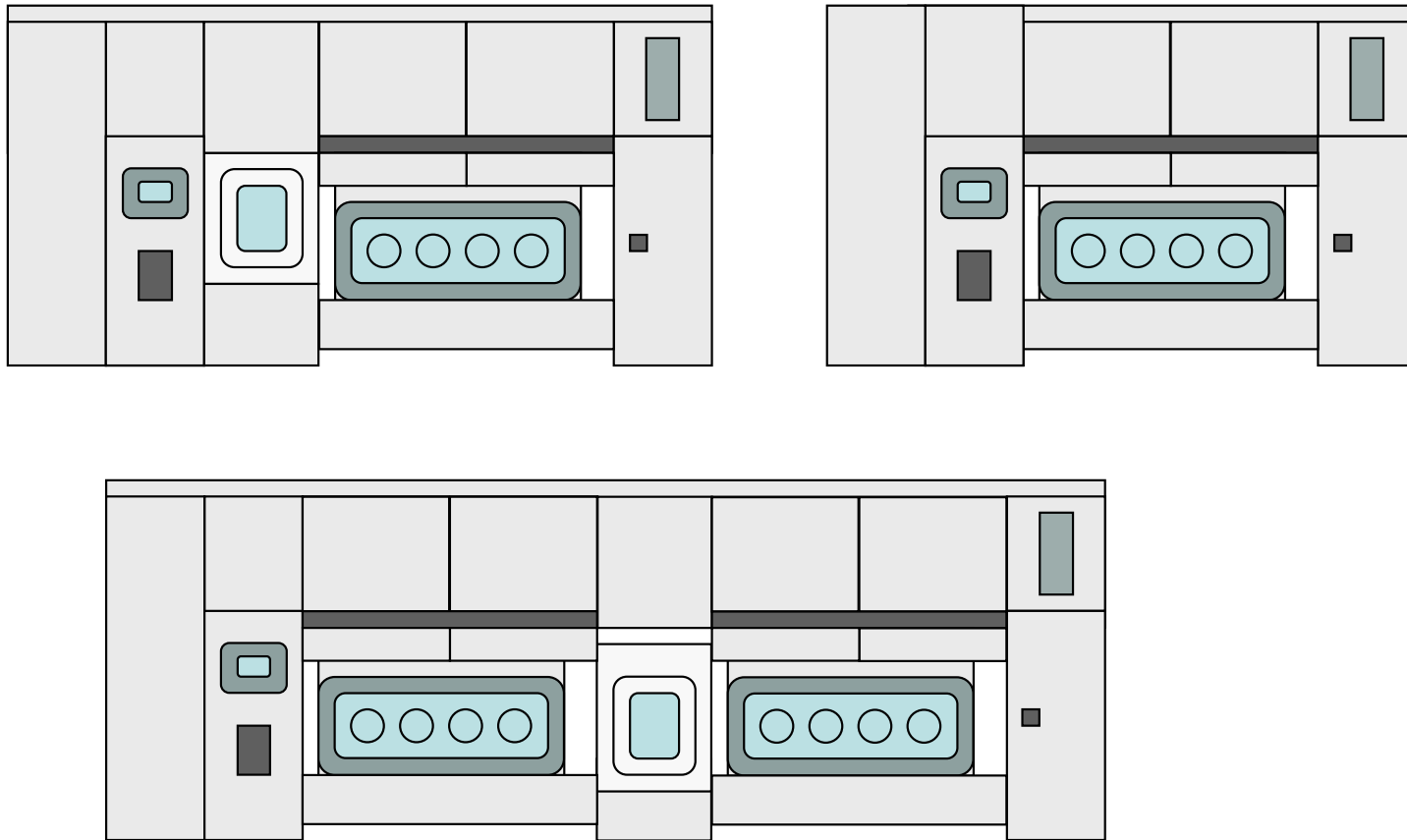
Vertical Uni-Directional  
Air Flow (UDAF)



RTP for loading material  
and removing the  
processed load and waste

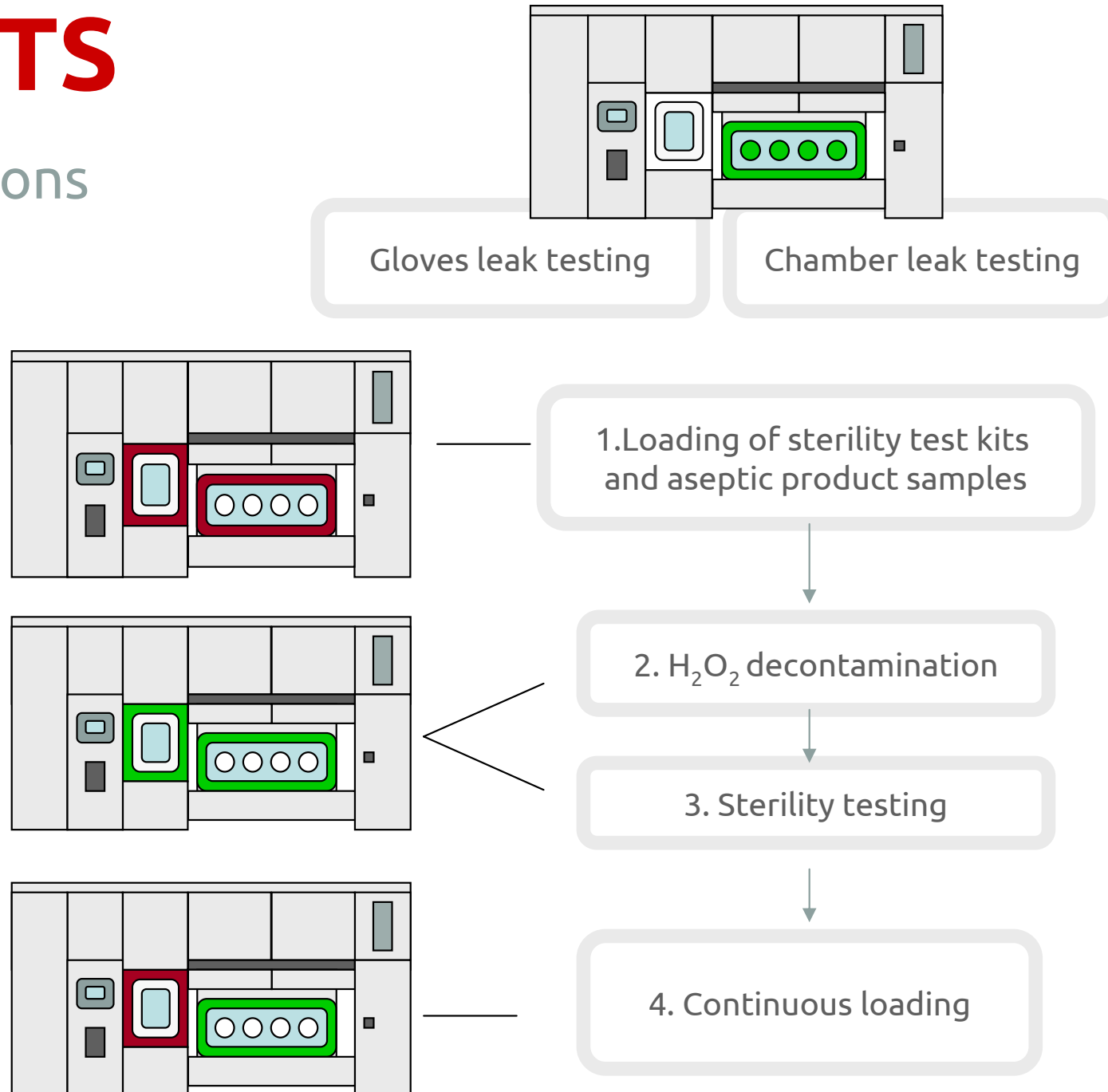
# **FCTS**

Flexibility &  
modularity



\*Ad hoc feasibility analysis.

## Operations



# Thema4

## Process controller

Designed by Fedegari using over 50 years of specific process knowledge, Thema4 offers:

- Online concentration monitoring and control
- Pre-validated GAMP5 compliance, 21 CFR Part 11
- Open system architecture
- Advanced control, monitoring and reporting functions including parametric release options
- Complete integration with SCADA systems
- COTS hardware
- Pre-validation ensures minimal project risk and shortest time in qualification.



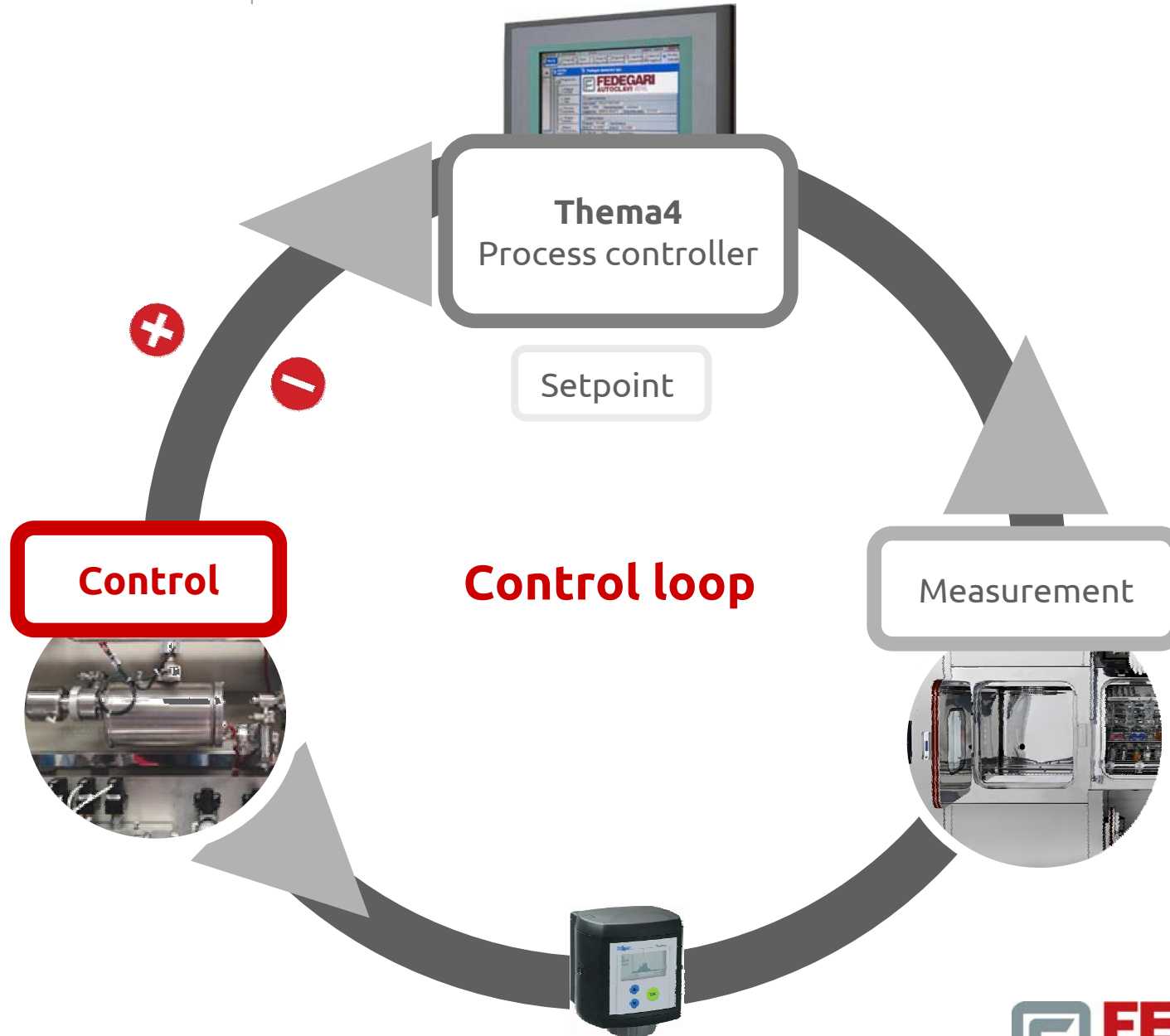
All Fedegari machines are controlled by with Thema4.  
FCTS glove and leak testing are totally managed by Thema4.





FHPV

**Fedegari PID-based  
H2O2 vaporizer**





## **Fedegari: your solution provider.**

Since the acquisition of Bio Com in 2009, Fedegari has progressively developed towards a “total solution provider” capable of integrating different machines and processes for high-performance and cost-effective solutions.



**[fedegari.com](http://fedegari.com)**