

Chemical Bio-decontamination



FEDEGARI
GROUP

EN.1.3.2

PROCESSES

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

SPECIAL APPLICATIONS

Rotating sterilizers
Pharmaceutical closures
processing

COMPONENTS

Pressure vessels
Doors
Piping
Process controller
Wireless sensors

ACCESSORIES

Un/loading conveyors
Customized racks

Fedegari FCDV/FCDM low temperature bio-decontamination units

Application

The pass-through hatches of the FCDV and FCDM series are the latest development of all the process equipment manufactured by Fedegari.

These machines are designed for transferring non-autoclavable material into a clean room with a rapid and validatable surface bio-decontamination process.

This solution is becoming increasingly critical as the regulators shift their focus away from traditional moist- and dry-heat sterilization processes to address all other bioburden risks.

Fedegari has applied the QbD-concept to the development of this innovative project in order to meet the current approach required by the EMA and the FDA.



Process Optimization

Whilst the decontamination and sporicidal action of vaporized H_2O_2 and peracetic acid are quite well understood and generally accepted by the regulatory bodies, process in general is not efficient, difficult to control and critical to validate.

Furthermore, when using COTS vaporizers, is virtually impossible to reproduce

processes with tight tolerance. That's why Fedegari FCDx equipment actively controls all the process-critical parameters such as relative humidity, temperature, airflow, etc..

H_2O_2 Vaporizer - FHPV

One of the most critical elements for guaranteeing high reproducibility of the processes is the vaporizer. In the FCDV machines this element has a proprietary design and is an integral part of process control.

Thanks to Fedegari proprietary design and control, concentration of H_2O_2 is adjusted within ± 15 ppm (typically ± 5 ppm) thus generating the obvious

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advantages during process development and validation.

A further considerable advantage is that the system does not require any proprietary consumable and this, in turn, drastically lowers operating costs.

Process Lethality

All units achieve at least 6-log viable particle reduction with complete cycle times starting from 30 minutes. When total kill is required, the process can be easily adjusted for achieving 10-log reduction.

General Design Features

Like all other sterilizers manufactured by Fedegari, the FCDx machines are designed to meet the most stringent requirements typical of the pharmaceutical market and can be configured to meet all production requirements.

They all use the ultra-safe triple-protected 100%-tight doors and are operated by the same Thema4 process controller that runs on all process equipment of Fedegari.



Safety, Standards & Regulatory Compliance

As much as process performance, safety for the operators is an absolute priority for Fedegari. The door - for instance - is 100%-air tight; this is guaranteed by 2 separate inflatable gaskets seating in 2 slots mechanically machined all around the door with an additional leak-monitoring system. The machines also use different sensors for detecting any harmful residue of the sporicidal agent.

More than this, several other solutions and sub-systems are the same as those that have been in use on other process equipment of Fedegari with extremely high levels of reliability after years of field testing.

Thema4 Process Controller

All process equipment manufactured by Fedegari are controlled by Thema4. This solution makes the FCDx machines much more cost-effective especially where the enduser already operates other process equipment with the same controller.

For more detailed information about Thema4 and all the advantages against conventional solutions please refer to the specific documentation.

