

FCDV – Bio decontamination unit

Applications:

Bio-pharmaceutical

Loads:



Processes:

Bio-decontamination



With the FCDV bio decontamination unit you can bring inside the clean rooms all those products and instruments that cannot be thermally sterilized. Surface bio decontamination of the load is carried out with vaporized hydrogen peroxide – H₂O₂.

Among the most reliable sporicidal agents, vaporized hydrogen peroxide (H₂O₂) is nowadays one of the most popular: its antibacterial, antimycotic and antiviral properties are well known and scientifically documented.

This solution is becoming increasingly relevant as the regulators shift their focus away from traditional moist- and dry-heat sterilization processes to address all other bioburden risks. Moreover, Fedegari has applied the Quality-by-design concept to the development of this innovative process equipment, in order to meet the current approach required by the EMA and FDA.

Powered by

Thema4

Key benefits

Process optimization: surface bio decontamination in 30 min.

Reliability: Hydrogen peroxide vaporizer totally engineered and manufactured by Fedegari

Flexibility: The unit can be used as a pass-through hatch aired with synchronized doors and pressure control

Easy validation & integration: all processes managed by Thema4 process controller

Contact

Steritec Belgium

Av. J. Wybran 45 B
BE-1070 Brussels
T + 32 (0)2 520 11 50
E steritec@steritec.be

Steritec The Netherlands

Van Nelleweg 6060 * NL-3044 BC Rotterdam
Postbox 13060 * NL-3004 HB Rotterdam
T + 31 (0)10 753 72 21
E info@steritec.nl

Design and technical features

- Stainless steel AISI 316 L chamber, polished to strict sanitary standards ($Ra < 0.4 \mu m$).
- Doors are made of stainless steel 316 L with a central glass panel
- 100% air-tight guaranteed: thanks to two separate inflatable gaskets seating in two slots mechanically machined all around the door with an additional leak-monitoring system.
- Optimized process: surface bio decontamination is achieved in 30 minutes.
- Fedegari hydrogen peroxide vaporizer with control loop (PID based), which provides superior reliability and repeatability for easier validation.
- Great flexibility: FCDV can be used as a pass-through hatch aired with synchronized doors and pressure control.

