STERIS

VHP™ LTS-V

Low Temperature Sterilizer

The only and original patented industrial scale VHP sterilizer product line for low temperature surface sterilization in Pharmaceutical and Medical Device manufacturing facilities. The largest and growing installed base of sterilizer equipment with FDA-approved terminal sterilization processes applied.

The VHP™ LTS-V Low Temperature Sterilizer is an advanced GMP terminal surfaces sterilization system utilizing Vaporized Hydrogen Peroxide. The LTS-V technology provides biopharmaceutical and medical device manufacturers an in-house solution for sterilizing the packaging, containers and surfaces of temperature or radiation sensitive drug pre-filled syringes, vials, implants, electronics, and various other sensitive medical devices. The sterilization process is designed to achieve SAL 10^{-6} for exposed device and packaging surfaces intended to be sterilized. The sterilization process is validated per ISO 22441 (transitioning from ISO 14937).

STERIS's cycle recipes are developed to meet specific Customer product and throughput requirements. The VHP LTS-V Sterilizer incorporates patented VHP dry vapor technology, renown throughout the industry for its superior efficacy, material compatibility and safety.

Product Applications

- Heat / radiation sensitive injectable drugs in pre-filled syringes (e.g., ophthalmic)
- Hip, knee and skull implants – any implants with sensitive materials and residual concerns
- Implants with electronics (e.g., pacemakers, seizure preventers)
- Subcutaneous applications for monitoring or drug delivery

Advantages

- In-house solution for sterilization of sensitive product loads
- Increased throughput
- Savings in manual labor
- Savings in facility cost
- Proven VHP technology with excellent material compatibility and compliance
- Comprehensive STERIS expert services from feasibility testing to validation and global field services
- Safe and sustainable process

Unit Size	Chamber Volume
VHP™ LTS-V 6912	850 liters
VHP™ LTS-V 91515	2000 liters
VHP™ LTS-V 151818	4000 liters
VHP™ LTS-V 182124	9000 liters

Features and Configurations

- Design conforms to cGMP, cGAMP, EU Annex 1 and applicable standards (e.g. ISO 22441) requirements
- Independent monitoring of sterilization process
- Single or double-door configuration
- 2-4 hour cycles typical, max. 8-10 hours (e.g., sensitive products)
- Processing temperature range 28-50 °C
- Unique patented VHP vaporization and chamber distribution process utilizing a chamber fan and relative humidity (RH%) PID-control
- Utilizes VAPROX™ hydrogen peroxide*
- Low peroxide consumption, low residual levels
- Utility requirements include only RO/DI -water, softened water, instrument air and 3-phase electricity
- Electronic Data Security enabling 21 CFR Part 11 and Annex 11 compliance as standard
- Stainless steel chamber and loading systems
- Standardized loading carts and trolleys
- Customized cart shelves for maximum load capacity

**Vaprox is a trademark for STERIS Corporation*

Product feasibility testing

Manufacturing, FAT Load cycle development

Delivery SAT

Process validation services

Production

By STERIS

By Customer

Comprehensive STERIS Services

- STERIS global application experts provide our Customers comprehensive feasibility, cycle development and process validation services to meet ISO 22441 requirements (transitioning from ISO 14937)
- STERIS global services reach our Customers worldwide
- STERIS technical specialists provide full installation supervision, start-up calibration and IQ/OQ services and Site Acceptance Testing (SAT) services to guarantee a professional migration into the Customer's environment
- STERIS services provide comprehensive training and Preventative Maintenance Plans

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