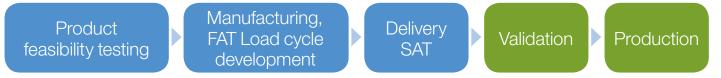
VHP® LOW TEMPERATURE STERILIZATION PROCESS IMPLEMENTATION STEPS



By STERIS

By CUSTOMER

CYCLE DEVELOPMENT AND SERVICE

- STERIS global application experts provide our customers comprehensive feasibility, cycle development and validation support services
- 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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STERIS Life Sciences Science & Solutions for Life

For over 100 years, STERIS has been known as a global leader, trusted partner and solutions provider in the field of sterilization and contamination control. *Today,* STERIS continues building on this heritage by advancing the *Science* of sterilization, cleaning and infection control while offering *Solutions* that meet our Customers' needs and high standards. STERIS is dedicated to helping you enhance the *Life* of your patients and the life of your equipment. From Formulated Chemistries, to Capital Equipment, to Parts and Services, STERIS Life Sciences is *Science & Solutions for Life*.

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STERIS VHP[®] LTS-V Low Temperature Sterilizer

Science & Solutions for Life



Life Sciences



The only production capacity size equipment in the industry for GMP low temperature surfaces terminal sterilization

The STERIS VHP® LTS-V Sterilizer is an advanced GMP terminal surfaces sterilization system using vaporized hydrogen peroxide (VHP®). The LTS-V technology provides biopharmaceutical manufacturers an in-house solution for sterilizing the packaging, containers and surfaces of temperature or radiation sensitive pre-filled syringes, vials and other drug delivery devices.

The system achieves **sterilization** of surfaces based on **proven 6-log reduction**.

STERIS' standard cycle recipes can be customized to meet specific customer product and throughput requirements. The STERIS VHP® LTS-V Sterilizer incorporates patented VHP dry vapor technology, renown throughout the industry for its superior efficacy, material compatibility and safety.

APPLICATIONS

- Surfaces sterilization of heat / radiation sensitive biologicals in pre-filled drug delivery devices
- Ideal for in-house processing that enables complete quality control of product manufacturing

- of sensitive loads

- with excellent material compatibility and compliance
- and field services

UNIT SIZE	CHAMBER VOLUME
VHP LTS-V 91515	2000 liters
VHP LTS-V 151818	4000 liters
VHP LTS-V 182121	8000 liters



FEATURES AND CONFIGURATIONS

GMP design and comprehensive documentation that includes:

- Standard double-door configuration
- air and 3-phase electricity
- and loading configurations
- Annex 11 compliance
- Utilizes STERIS VAPROX hydrogen peroxide
- Utility requirements include only purified water, tap water, instrument
- Standard loading system design with flexibility for different products
- Current GAMP compliant control system with electronic data security (audit trail, batch reporting, e-signature) enabling 21 CFR Part 11 and