



MMM Group



# cGMP Sterilizers for Life Science

Pharma & Industrial Applications

- | Vakulab® HL – Steam Sterilizer
- | Flui pharm® – Hot Water Cascade Sterilizer
- | Unotherm® HL – Pure Steam Generator

**MMM.** Protecting human health.

# MMM. Protecting human health.

Since 1954, MMM has been operating worldwide as one of the leading system providers in the service of health. With a complete range of products and services related to all aspects of cleaning, disinfection and sterilization systems for hospitals, scientific institutes, laboratories, and the pharmaceutical industry, the MMM Group has positioned itself as a major driver of quality and innovation in the international market.

The products of MMM – manufactured in four of its own production facilities with approx. 30,000 m<sup>2</sup> of production area – combine industrial precision manufacturing and high-quality craftsmanship “Made in Germany” with state-of-the-art control systems and uncompromising quality to meet the high demands of our customers.

## MMM Group in the field of Life Science – Tailor-made innovations

Our innovative solutions in the Life Science business sector are as individual as our customers. Whether in laboratories or in pharmaceutical sterile production – wherever sensitive goods are handled, MMM Group creates safe working environments that protect both products and human lives.

And with success:

**MMM sterilizers meet the highest requirements for reliability, hygienic design, safety, and sterilization effectiveness.**

Numerous laboratories of renowned research institutes, in testing offices, the pharmaceutical, chemical and food industries, as well as well-known pharmaceutical production companies, rely on our innovative technologies. Our customers value our ability to develop tailored, holistic solutions and to implement them with a high degree of flexibility. More than 1,300 employees worldwide are committed with expertise and enthusiasm to the exact right solution, the optimal production process, and optimal project management.



# Sterilizers from MMM

## Individual in Design & Equipment

In personal consultations, we develop solutions that are precisely tailored to the specific requirements of our customers. MMM sterilizers are modular in design, individually configurable, and stand for maximum safety, efficiency, reliability, and sustainability.

### Areas of Application



Process Development



Pharma Production



Terminal Sterilization



Industrial Applications



## Overview of Processes – Tailored to your Application

Depending on the type and nature of the sterile goods, different technologies are used.

### Vacuum Process

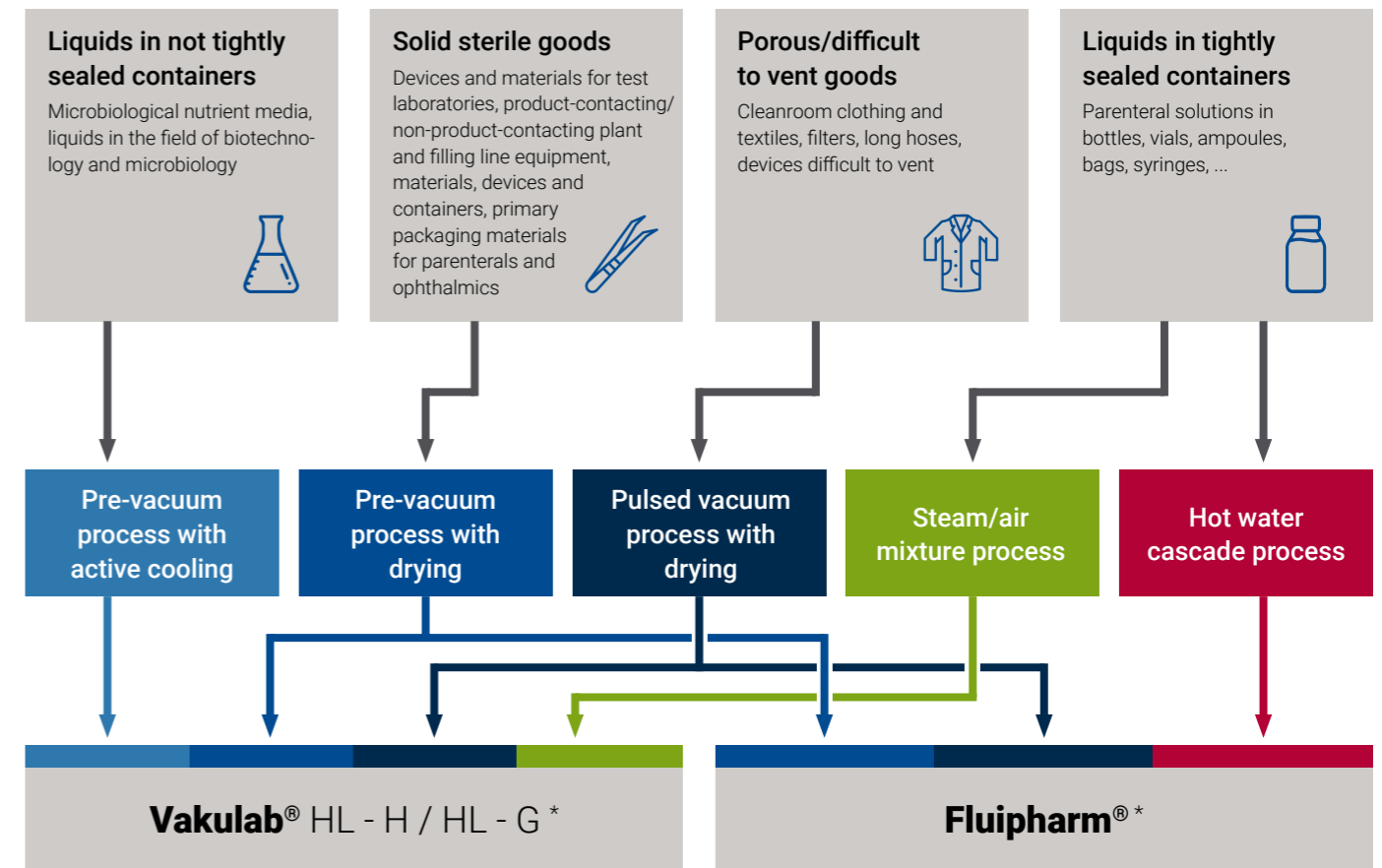
- | Pre-vacuum process with drying (solid goods)
- | Pulsed vacuum process with drying (porous goods)
- | Pre-vacuum process with active cooling (liquids in open or loosely sealed containers)

### Steam/Air Mixture Process with Active Cooling

(Liquids in tightly sealed containers)

### Hot Water Cascade Process

(Liquids in tightly sealed containers)

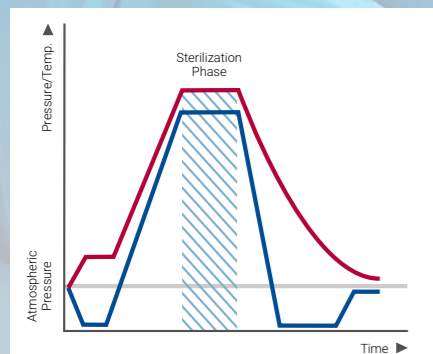


\* with option ventilator and equipment package "Closed Solutions"

\* with option vacuum programs

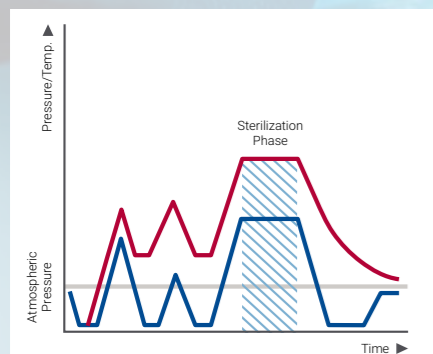
# The Right Technology for Every Requirement

## Solid & Porous Goods



### Pre-Vacuum Process with Drying

The pre-vacuum process enables economical and effective sterilization of solid goods with simple surfaces. The air is first evacuated from the chamber and then saturated steam, i.e. saturated water vapor, is introduced until a specified sterilization pressure is reached. After the sterilization phase, the goods are dried using a vacuum. The temperature range of the sterilization phase can be set between 105 °C and 134 °C.

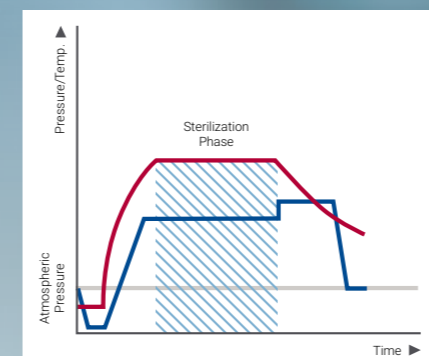


### Pulsed Vacuum Process with Drying

For goods with a porous surface that are difficult to vent, the pulsed vacuum process is suitable, as it removes the existing air particularly effectively by repeatedly applying a vacuum in combination with steam pulses. The drying phase can also take place in several fractions if required. The temperature range of the sterilization phase can be set between 105 °C and 134 °C.

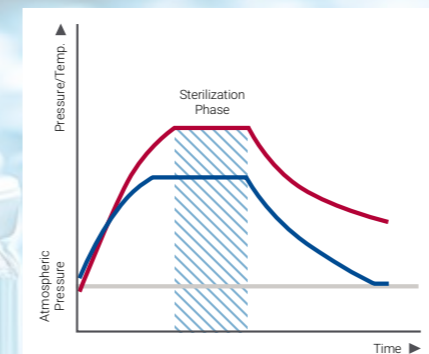
● Temperature ● Pressure

## Liquids



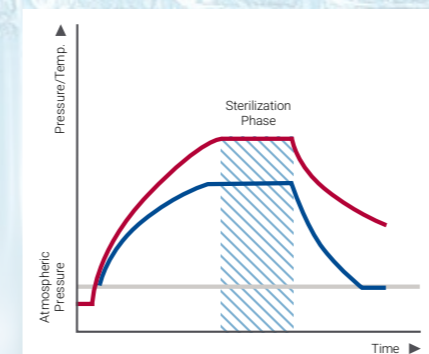
### Pre-Vacuum Process with Cooling

Liquids in open or lightly sealed containers can be sterilized quickly and effectively using the simple pre-vacuum process. The temperature range of the sterilization phase can be set between 105 °C and 134 °C. Subsequently, the goods are cooled to below 80 °C using active jacket cooling. At the same time, the support pressure prevents the liquid from boiling over.



### Steam-Air Mixture Process

During the sterilization of liquids in sealed containers, the internal pressure increases significantly due to heating. To prevent deformation, an appropriate support pressure is generated in the chamber using compressed air. A steam-air mixture, which is circulated evenly by a fan, serves as the heat carrier. The fan is driven without seals and gaps via a magnetic coupling – for maximum process safety and hygiene. For efficient steam-air mixture circulation in large production plants, a high-performance fan with shaft drive and a unique sealing system is available.



### Hot Water Cascade Process

The hot water cascade process is suitable for the rapid and gentle sterilization of large quantities of liquids in sealed containers. The chamber is filled with water up to a defined level; the water is circulated by a recirculation pump via a steam-heated heat exchanger and uniformly sprays the goods to be sterilized. Compressed air creates a support pressure cushion to protect the containers. During the cooling phase, the sterile goods are cooled to below 80 °C.

● Temperature ● Pressure



## Custom-Made Sterilization Chamber

The central component of every steam sterilizer is the sterilization chamber. Robotics and manual precision work ensure chamber construction at the highest quality level. Made in Germany.

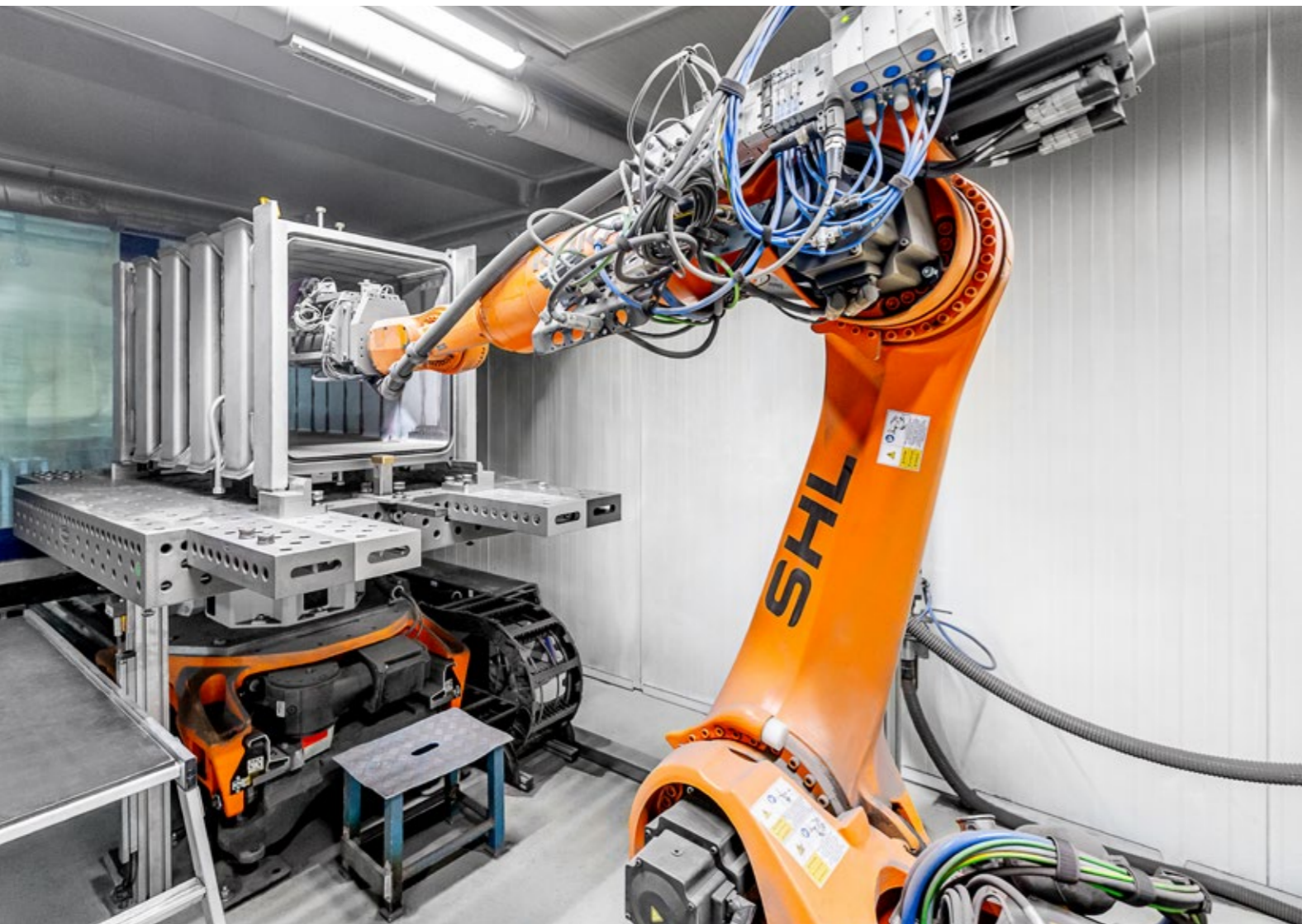
## Example of Chamber Sizes

MMM sterilizers are available in almost all chamber sizes and volumes. The table below shows examples of our standard sizes. Customized versions are available on request up to clear internal chamber dimensions of 2200 x 1500 x 3950 mm (H x W x D) to meet individual requirements.

Models	Clear Internal Chamber Dimensions in mm (H x W x D)	Overall Unit Dimensions in mm (H x W x D)	Chamber Volume in L	Door Opens	Installation	Weight (kg)*
<b>Vakulab® HL</b>						
669	710 x 650 x 990	1918 x 1900 x 1360	460	Horizontal	Floor	1550
969	1000 x 650 x 990	1918 x 1900 x 1360	644	Horizontal	Floor	1860
181015	2010 x 1100 x 1640	2550 x 3100 x 2210	3626	Horizontal	Pit	4500
<b>Fluipharm®</b>						
669	830 x 650 x 990	1898 x 2200 x 1380	534	Horizontal	Floor	1500
969	1120 x 650 x 990	1898 x 2200 x 1380	644	Horizontal	Floor	2200
9612	1120 x 650 x 1340	1898 x 2200 x 1730	976	Horizontal	Floor	2500
9618	1120 x 650 x 1940	1898 x 2200 x 2330	1412	Horizontal	Floor	2800

Custom sizes on request. Technical changes reserved.

\* Minimum weights depending on equipment.



### Pressure Vessels from MMM

- | Certified according to AD 2000 data sheet HP 0 and DIN EN ISO 3834-2
- | Design and manufacturing according to Pressure Equipment Directive 2014/68/EU, AD 2000 and DIN EN 13445, ASME
- | Cubic welded construction with U-shaped, circumferential heating channels designed for the highest number of load cycles
- | Pressure vessel and chamber door in stainless steel (inner shell 1.4404/AISI 316L, outer shell 1.4571/AISI 316Ti) for maximum durability
- | Design pressure at least 3.2 bar relative (optionally 4.5 bar)
- | Surface quality:
  - blasted
  - grinded Ra < 0.8 µm (optional)
  - electropolished (optional)

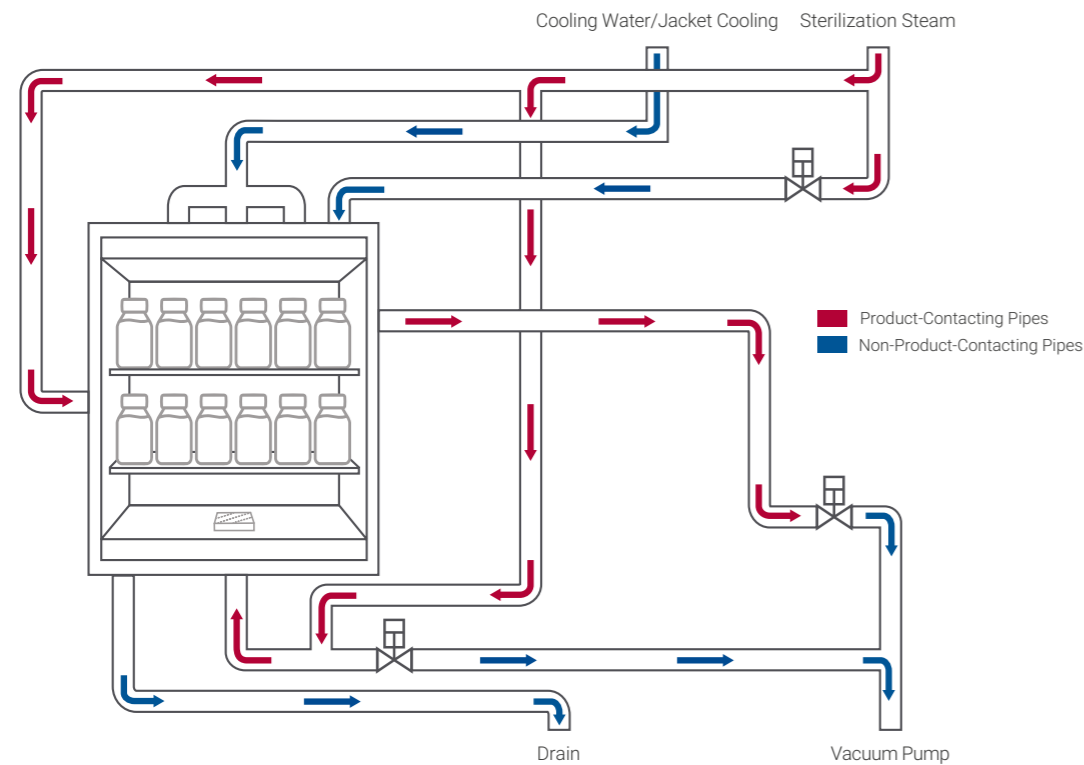
### Hygienic Design Chamber & Sensors

- | Chamber nozzles with hygienic process connections (clamp according to DIN 32676, optionally aseptic flange according to DIN 11864-2 or aseptic clamp according to DIN 11864-3)
- | Horizontal nozzles sloped towards the chamber (self-draining)
- | Chamber bottom with all-round slope towards the chamber outlet for complete drainability
- | Product-contacting sensors with high-temperature-resistant diaphragm pressure transmitters
- | Seals FDA-compliant
- | 3D / 6D rule (optional)

# Piping with System

The more sensitive the treated goods, the higher the requirements for the quality of execution of all components that come into contact with the sterilizing medium – and thus potentially with the product.

MMM offers different quality levels in the piping system for this purpose. Our predefined pipe classes help you choose the right combination of material, surface finish, and process connections.



- | Pipelines with slope for full drainage
- | Design adapted to customer needs
- | Pipeline insulation against heat loss
- | 3D/6D rule
- | Variable process connections
- | Sensors with diaphragm seal
- | Orbital welding technology
- | Durable and low-maintenance angle seat valves or fully drainable, aseptic diaphragm valves (optional)

## Excerpt of Pipe Classes for Product-Contacting Area

MMM Pipe Classes	H10	H14	H20	HE30
<b>Piping</b>				
Material	1.4571 (AISI 316Ti) / 1.4404 (AISI 316L)	1.4404 (AISI 316L)	1.4404 / 1.4435 (AISI 316L)	1.4435 (AISI 316L)
Internal surface	Metal bare	Metal bare	Ra < 0.8 µm (grinded)	Ra < 0.5 - 0.6 µm (electropolished)
External surface				Ra < 0.8 µm (K400 grinded)
Material certificates			3.1 EN 10204	3.1 EN 10204
<b>Connections/joints</b>				
	Weld end / ISO 1127	Weld end / ISO 1127	Weld end / ISO 1127	Weld end / ISO 1127
	O-ring fittings	Clamp connection DIN 32676 / ISO 1127	Clamp connection DIN 32676 / ISO 1127	Aseptic flange DIN 11864-2 / ISO 1127 (>= DN 50)
				Aseptic clamp DIN 11864-3 (ISO 1127) (<= DN 40)
<b>Seals</b>				
	Viton	EPDM FDA-compliant	EPDM FDA-compliant	Viton (FKM) / FEP-coated (FDA, USP Class VI, ADI free)

In addition, individual customization is possible.





## Perfected Down to the Finest Detail

### From Planning to Installation

The installation of the heavy pressure vessels often presents a challenge during setup. This is why MMM already takes into account aspects such as transport, assembly, and the later workflow at the site during the planning and design phase.

Our sterilizers feature a compact design with a small footprint and an ergonomic loading and working height. In addition, both single-door and double-door variants are available.

For chambers accessible at floor level, we offer a height-adjustable frame that enables precise and secure integration into the structural conditions.



### Service-Friendly Design

We consider the entire lifecycle of our devices already during development.

Especially for long-lasting capital goods such as MMM sterilizers, maintenance and servicing are crucial factors for efficiency and operating costs. That is why we place special emphasis on a well-thought-out arrangement of components and easy maintainability via software.

#### Service-Supporting Design Features

- | Front maintenance access
- | Front panel can be opened without disassembly
- | All sensors with plug connections (optional)
- | HMI with display of the P&I diagram (optional)
- | Clear visualization of device status (actuators, valves, sensors, pumps, etc.)
- | Anti-pinch protection via maintenance door switch
- | Easy cleanability

## Control, Software & HMI

# High-Tech Used Intelligently

The latest generation of Siemens SIMATIC control in combination with MMM control software Sisoft enables intuitive operation, password-protected data management, and free, parameter-controlled programming of all processes – precisely adapted to project-specific requirements.

### Process Control with Highest Precision

- | Latest-stage industrial control system
- | Redundant sensors for maximum process safety
- | Verification of process parameters
- | Flexible interfaces for optimal system integration

## Software – Safe and User-Friendly

Software development and validation are carried out in accordance with DIN EN 62304 (FDA-recognized standard) and GAMP 5. A sophisticated parameter structure enables maximum configuration flexibility. The integrated user management ensures clearly defined access rights and comprehensive security.

### Individual Device Configuration & Connectivity

- | Visualization via HMI or customer-side virtual machine
- | Seamless monitoring of all measured values
- | Precise control of actuators
- | Barcode scanner with automatic program preselection (optional)
- | Autostart function, e.g. for vacuum test or heating up (optional)
- | Recipe management: Revision and release of recipes (optional)
- | Active P&I diagram (optional)
- | External communication interfaces, e.g. Profinet (optional)
- | Central user management via Siemens SIMATIC Logon (optional)

### 21 CFR Part 11 Compliant

- | User management with access rights management
- | Data archiving with checksum
- | Complete audit trail



## HMI

### Modern & Intuitive

The Human Machine Interface (HMI) forms the central interface between operators and the machine.

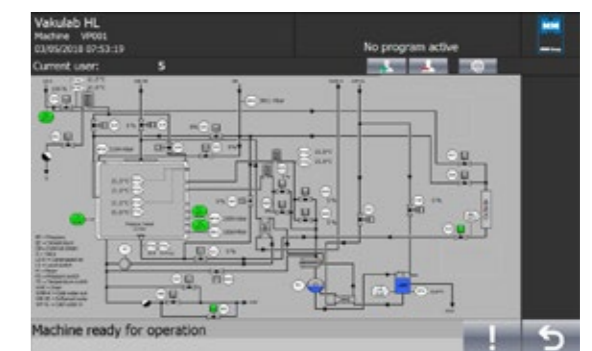
All process-relevant information such as status of the device, process steps, measured values, and process curves are clearly displayed – for safe and comfortable operation.

### Operating Comfort in Detail

- | Intuitive menu navigation via color touch display
- | 12" or 15" display size (optional)
- | 22" Thin Client for virtual machine (optional)
- | Large remaining cycle time display
- | Smooth, easy-to-clean surface
- | Active P&I diagram (optional)
- | PDF print screen function



Program sequence



Active P&I diagram

Parameter management (recipe management)

# Standard programs

Predefined process sequences for solid and porous goods according to the pre-vacuum process as well as for liquids in open and sealed containers. All processes are parameterized in the control system and can be configured by authorized users within technically relevant limits.

Application	Temperature	Description
<b>Programs for solid, porous goods and goods that are difficult to vent</b>		
Solid goods	134°C	Program for solid, temperature-resistant sterilization goods with simple surfaces
Solid goods	121°C	Program for solid sterilization goods with simple surfaces and lower temperature resistance
Porous goods	134°C	Program for solid and porous goods with high temperature resistance
Porous goods	121°C	Program for solid and porous goods with lower temperature resistance
Filter	121°C	Program for pressure-sensitive membrane filters (e.g. made of cellulose acetate, polyamide, etc.), also in assembled condition
Heating up		Program for heating up the sterilization chamber and pipelines
Bowie-Dick test	134°C	Steam penetration test
Vacuum test		Device for automatic chamber leak testing
<b>Programs for liquids in open containers</b>		
Solutions cold	121°C	Program for cold liquids, preparatory sterilization: nutrient media and suspensions. Disposal sterilization: cultures or contaminated laboratory utensils to be processed
Solutions warm	121°C	Program for warm-introduced liquids (preparatory or disposal sterilization)
<b>Programs for liquids in tightly sealed containers</b>		
Solutions sealed	121°C	Program for liquids using the hot water cascade process
Solutions sealed	121°C	Program for liquids using the steam-air mixture process

## Guidelines and Standards

Needless to say, MMM cGMP sterilizers meet the relevant guidelines, standards, and regulations depending on equipment and customer requirements.

- | DGRL 2014/68/EU
- | ASME BPE
- | cGMP
- | MRL 2006/42/EC
- | DIN 58950
- | ISPE Baseline Guide
- | AD 2000
- | ISO 12100
- | PDA reports
- | DIN EN 13445
- | DIN EN 62304
- | CFR21/Part 11
- | ASME Code
- | GAMP 5
- | EU GMP Annex 1



## Clear Process Documentation

For GMP-compliant verification of a successful batch processing, all cycle data is stored directly on the sterilizer control system. The batch report includes all relevant information such as the program (recipe) name, cycle number, sterilization temperature, pressure, as well as the start and end time of the process.

### Nothing is lost

- | Cycle log in plain text with colored curve display
- | Power-failure resistant data storage in the control system
- | Sicon – Direct printing via connected network printer (optional)
- | PDF generation of the batch report and export to server/external PC (optional)
- | RUMED360® software for searching, analyzing, and printing cycle data (optional)

## Safety First – Data Management with RUMED360®

With the RUMED360® software package, cycle data can be automatically stored on an external computer – for complete traceability and versatile evaluation options at various management levels.

### Available at any time

- | Long-term archiving of cycle data as a file
- | Can be reprinted as often as desired
- | Subsequent analysis and review
- | Export to Microsoft® Excel
- | Optional storage in PDF format



# Sustainability & Resource Management

The sustainability concept of MMM actively contributes to environmental protection in daily operations. Only water is used as the sterilizing medium in steam sterilization. To further reduce resource consumption, MMM devices can be equipped with innovative energy and media recovery systems.

Additionally, MMM has a certified environmental management system according to DIN EN ISO 14001 as well as an energy management

system according to DIN EN ISO 50001 – both cover not only the products but also all operational processes.



## Water-Saving System

By connecting to an on-site cooling circuit, the vacuum pump is efficiently cooled in a circulation process. Cold water is only required as an operating fluid for the vacuum pump. In combination with an optional media recovery system, cold water consumption can be reduced by up to 95%.



## Sleep Mode & Autostart

The control system offers an energy-saving standby function that is automatically activated during longer operating interruptions (deactivation of the jacket heating). In addition, an individual autostart can be programmed for each day of the week. This allows predefined program sequences – e.g. vacuum test or heating up – to be started automatically. This leads to a noticeable time saving for the operating personnel.



## Intelligent Steam Manager

The optional MMM steam manager controls the timing of several sterilizers via an external controller. The steam output is evenly distributed to avoid peak loads in the supply network. This allows the design of the steam supply to be optimized and investment and operating costs to be significantly reduced. Communication takes place via Ethernet / Profinet.



## Certification

**EGNATON** (European Association for Sustainable Laboratory Technologies e.V.) – the certification system for laboratory equipment.

# Efficient Cooling & Water Saving

For safety reasons, sterilized liquids may only be removed from the chamber once their temperature has dropped below 80 °C. Depending on the desired cooling rate, various methods are available for this:

## Passive Cooling – Self-Cooling

- | No cooling water consumption
- | Long cooling times

## Active Cooling – Jacket Cooling

- | Temperature-controlled cooling water consumption
- | Recirculation cooling (optional)
- | Short cooling times

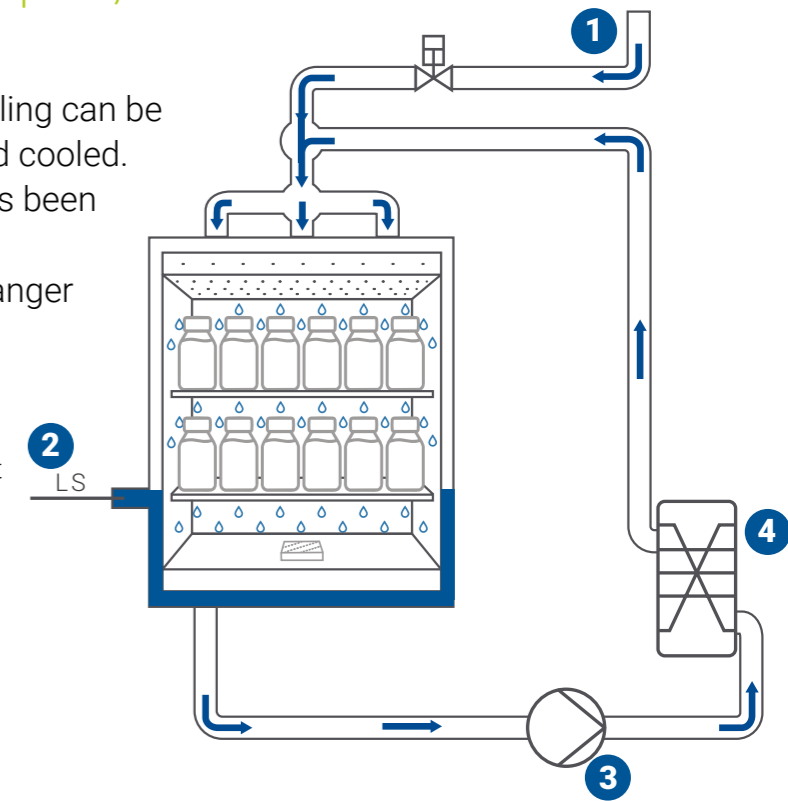


# Recirculation Cooling

Minimized Cooling Water Consumption, Short Cooling Times.

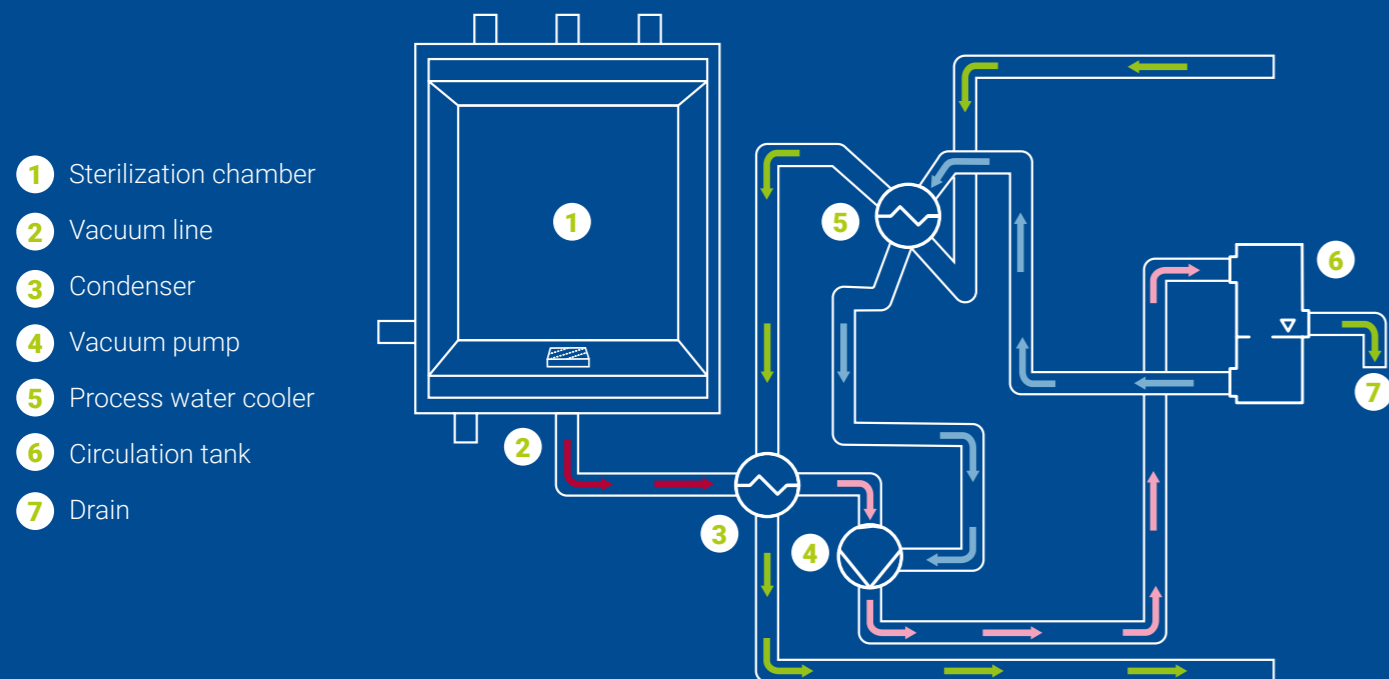
The consumption of water for jacket cooling can be drastically reduced if it is recirculated and cooled. In this process, the cooling water that has been filled once is circulated by a recirculation pump through a water-cooled heat exchanger and cooled.

- 1 Softened water as cooling medium for the jacket
- 2 Level switch
- 3 Recirculation pump
- 4 Water-cooled heat exchanger



## User Savings Potential

- | Short cycle times thanks to active jacket cooling – ideal for temperature-sensitive products
- | Efficient – Reduction of softened water consumption by up to 90%
- | Maximum savings potential – Connection of the heat exchanger to an on-site cooling circuit



# Cooling Circuit

## Economical Cooling and Water Saving

The cooling circuit is an additional feature that can reduce cooling water consumption by up to 90%. For this purpose, the vacuum pump unit is connected to the on-site cooling circuit. An additional heat exchanger ensures the recooling of the process water of the vacuum pump. Additionally, both the supply and return lines are each equipped with an analog thermometer. Optionally, the cooling water flow can be automatically shut off after the end of the program. A potential-free contact for controlling on-site switching functions is also included. In the event of a malfunction or shutdown of the cooling system, a manually operated switching device for cold water operation is integrated to ensure uninterrupted operation.

up to **90%**  
Water saving

# Precise Technology – Sophisticated Details

In the manufacturing of sterile products, every batch is of the highest value. Especially in the pharmaceutical industry, it is important to reliably sterilize sensitive goods while treating them gently. Additional equipment components from MMM provide exactly this level of safety.

## Sterile Filtration of Compressed Air

For maximum safety during sterilization, only sterile-filtered compressed air is used – both for ventilation and for support pressure. This reliably eliminates any possible contamination.

- | Inline sterilization of the compressed air filter for consistently sterile process air
- | High sterilization safety – contamination of the compressed air is excluded
- | Optional temperature and pressure monitoring of inline sterilization
- | Connection options for external filter integrity test (optional)
- | Automatic filter integrity test of the compressed air filter (optional)

## Fan and Cooling Systems

### For Steam-Air Mixture Processes

The fans ensure a homogeneous temperature distribution in the chamber and thus an effective sterilization process.

- | For the highest demands on process safety – use of a fan with hermetically sealed magnetic coupling (optional)
- | High-performance fan with shaft feedthrough for large production sterilizers. The engine is installed outside the chamber and connected to the fan wheel via a unique sealing system, which allows for easy inspection and maintenance (optional)
- | Internal cooling coils for particularly rapid cooling of the sterilized goods (optional)



High-performance fan



Internal cooling coils

## Test Systems / Test Ports

For GMP-compliant safety and the highest process quality, our sterilizers are equipped with practical test systems for monitoring steam quality.

- | Test ports for pure steam according to EN 285 – for safe and standard-compliant sampling (optional)
- | Integrated sample cooler for easy collection of pure steam condensate samples (optional)
- | Convenient collection of pure steam condensate samples via integrated flap in the "Coffee Shop" front panel (optional)
- | Verification of air removal according to EU GMP Annex 1, either by Bowie-Dick test cycle using indicators or via an integrated air detection device Air Detector



Coffee Shop



## F<sub>0</sub> Value Calculation and Control

For the safe production of sterile solutions, the lowest possible thermal load is crucial. The F<sub>0</sub> value calculation ensures that your products are reliably sterilized and simultaneously protected.

- | Online display of the current F<sub>0</sub> value for full process control
- | Complete documentation for traceability and quality assurance
- | Intelligent control of the program sequence based on the F<sub>0</sub> value

## Doors & Quick Release

The automatic sliding doors are equipped with a safety system consisting of redundant pressure sensors and position switches. This reliably prevents opening during the program sequence or when there is chamber pressure.

### Safety & Quality First

- | Automatic mechanical locking of the pressure vessel doors via massive door claws for maximum safety
- | Door safety system – No opening under pressure and no closing if there is an obstacle in the door path
- | Door seal pressurized with either steam or compressed air
- | FDA-compliant silicone round cord seal
- | Touch-sensitive safety bar
- | No door opening when the chamber is not completely emptied (Fluipharm)
- | Additional acknowledgment function for walk-in chambers



Door sealing system

## Separation of Classified Zones / Airtight Barrier

The sterilizer often separates two areas with different cleanroom classification based on air cleanliness requirements. To reliably maintain the required pressure difference between the zones, it is equipped with an airtight partition wall in the equipment room.



Airtight wall in stainless steel

The control system also prevents both chamber doors from being opened simultaneously. Even when switched off, at least one door always remains pressurized, thus ensuring the airtight separation.

### Tightness

- | Airtight wall made of stainless steel 1.4301 (AISI 304)
- | Use of the chamber as an airlock
- | Prevention of simultaneous door opening
- | Sound-insulated wall design for noise reduction to approx. 40 dB (optional)
- | Automatic swapping of the door sealing medium to ensure the partition effect in case of pressure drop
- | Additional airtight wall for realization of 3-zone concepts (optional)
- | Gas tight design (optional)



## Communication & Automation

In industry, sterilizers are rarely used as fully autonomous machines anymore. They are increasingly networked with other machines or systems. The communication requirements can be divided into the following groups:

### Direct Communication with Other Machines

#### Automatic loading and transport systems

The sterilizer acts as a command receiver and executes commands from a transport system, e.g. opening or closing the loading door, program selection, and program start. The loading and unloading of the sterilizer can be carried out entirely by its own transport system or by a third-party system.

#### Connection to H<sub>2</sub>O<sub>2</sub> Generator

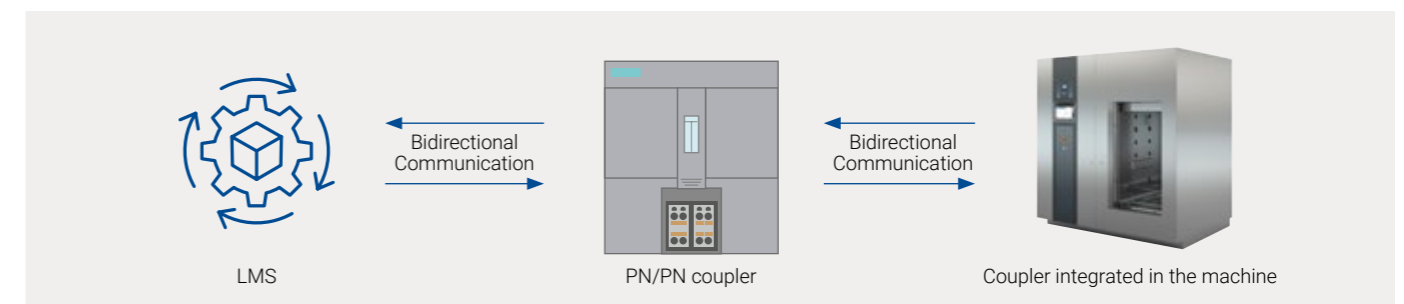
The sterilization chamber is used by the generator as a gassing room. The sterilizer informs the generator when the chamber is dry and cool enough for an effective decontamination process. Malfunctions are communicated mutually and appropriate actions are initiated.

### Data Provision for Other Systems

The defined process data (such as program name, process step, alarm information, etc.) are provided unidirectionally for a building management system or a data historian.

### Communication with Logistics Management Systems (LMS)

The sterilizer communicates bidirectionally with an LMS. The LMS takes over the control and monitoring of an entire production line consisting of several individual units, from the filling system through transport systems to the sterilizer.



# Vakulab® HL - H

## Universal Pharma Steam Sterilizer for Maximum Process Safety and Reproducibility in the GMP Area

Hygienic design and customer-specific optional equipment meet the demanding requirements of manufacturing sterile goods, such as solutions or filled syringes, as well as production-related applications where the sterilization of fermenters, machine parts, filling line equipment, cleanroom clothing, filters, etc. requires individual solutions.

### Highlights

- | Sanitary design for the highest hygiene requirements
- | Flexible equipment options
- | Individual design
- | 1- or 2-door (pass-through operation)

### Standard Equipment

- | Siemens SIMATIC control
- | 12", 15" display or customer-specific size
- | Clamp or aseptic fittings
- | Sealing and lubricating materials according to FDA (21 CFR)
- | F<sub>0</sub> value-controlled process sequence
- | Inline sterilizable filter housings and elements
- | Active jacket cooling
- | Recirculation cooling and cooling circuit connection
- | Cooling coil
- | Sterile filtration of compressed air
- | Air detector
- | Airtight partition wall
- | Fan for steam-air mixture process
- | Equipment package "Closed Solutions"





(Selection of equipment variants)

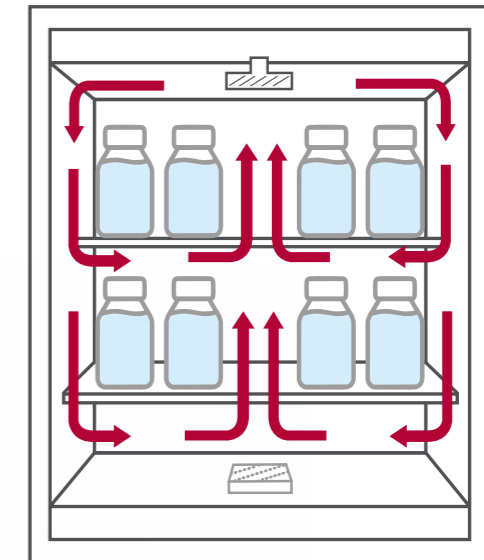
### Standards

The Vakulab® HL - H is a Pharma sterilizer according to DIN 58950-2



### Possible Processes

-  **Steam-air mixture process**  
Liquids in tightly sealed containers
-  **Pre-vacuum process with drying**  
Solid sterile goods
-  **Pulsed vacuum process with drying**  
Porous/difficult-to-vent sterile goods
-  **Pre-vacuum process with active cooling**  
Liquids in not tightly sealed containers



Steam-air mixture process

### Typical Items for Treatment

- | Filters
- | Process equipment
- | Filling line equipment
- | Textiles
- | Hoses
- | Liquids, especially pressure-sensitive containers such as syringes, bags, plastic and glass bottles

# Vakulab® HL - G

## Floor-Level Loadability for the Sterilization of Large-Volume Goods and Trolleys

Hygienic design and customer-specific special equipment meet the demanding requirements of manufacturing sterile goods, such as solutions or filled syringes, as well as production-related applications where the sterilization of fermenters, machine parts, cleanroom clothing, filters, etc. requires individual solutions.

### Highlights

- | Sanitary design for the highest hygiene requirements
- | Flexible equipment options
- | Individual design
- | 2-door (pass-through operation)
- | Unloading at floor level

### Standard Equipment

- | Siemens SIMATIC control
- | 12", 15" display or customer-specific size
- | Clamp or aseptic fittings
- | Sealing and lubricating materials according to FDA (21 CFR)
- | F<sub>0</sub> value-controlled process sequence
- | Inline sterilizable filter housings and elements
- | Active jacket cooling
- | Recirculation cooling and cooling circuit connection
- | Cooling coil
- | Sterile filtration of compressed air
- | Air detector
- | Airtight partition wall
- | Fan for steam-air mixture process
- | Equipment package "Closed Solutions"





(Selection of equipment variants)

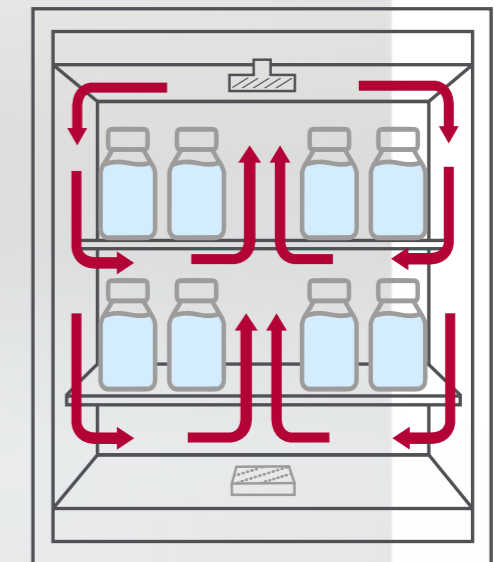
### Standards

The Vakulab® HL - G is a Pharma sterilizer according to DIN 58950-2



### Possible Processes

-  **Steam-air mixture process**  
Liquids in tightly sealed containers
-  **Pre-vacuum process with drying**  
Solid sterile goods
-  **Pulsed vacuum process with drying**  
Porous/difficult-to-vent sterile goods
-  **Pre-vacuum process with active cooling**  
Liquids in not tightly sealed containers



Steam-air mixture process

### Typical Items for Treatment

- | Filters
- | Plant components
- | Glassware
- | Textiles
- | Hoses
- | Liquids

# Fluipharm®

## For Rapid, Gentle, and Efficient Terminal Sterilization of Liquids in Sealed Containers

Perfected for the application of the hot water cascade process, the cGMP-compliant Fluipharm® offers everything required in the process development, in the manufacturing of sterile goods, and not least in the handling of parenteral solutions in the hospital pharmacy. Because in the pharmaceutical and biotech industry, rapid sterile processing is an important success factor.

### Highlights

- | Reliable and fast in process sequence
- | Individual design and equipment
- | 1- or 2-door (pass-through operation)
- | Special programs: vacuum drying, ampoule testing, washing and rinsing program for ampoules

### Standard Equipment

- | Siemens SIMATIC PLC
- | 12", 15" display or customer-specific size
- | Clamp or aseptic fittings
- | Sealing and lubricating materials according to FDA (21 CFR)
- | F<sub>0</sub> value-controlled process sequence
- | Sterile filtration of compressed air
- | Airtight wall for the separation of classified zones
- | Equipment package "Vacuum programs"
- | Additional programs: "Vacuum drying, ampoule testing, final rinse"
- | Heat exchanger with heating steam
- | Connection to cooling circuit
- | Heat exchanger can be completely drained on the product side, hygienic process connections




(Selection of equipment variants)

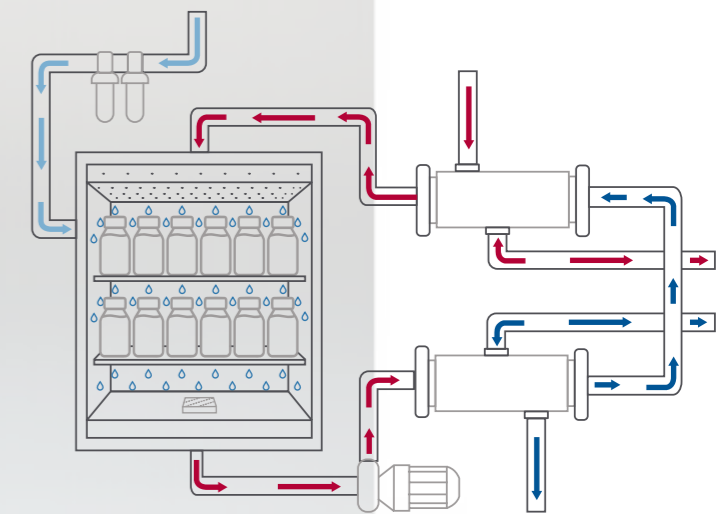
### Standards

The Fluipharm® is a Pharma sterilizer according to DIN 58950-2



### Possible Processes

-  **Hot water cascade process**  
Liquids in tightly sealed containers
-  **Pre-vacuum process with drying**  
Solid sterile goods
-  **Pulsed vacuum process with drying**  
Porous/difficult-to-vent sterile goods



Hot water cascade process

### Typical Items for Treatment

- | Liquids in sealed containers
- | Vials
- | Ampoules
- | Infusion bottles / infusion bags
- | Syringes
- | BFS containers

# Unotherm® HL

## Electric Pure Steam Generator for Pharma and Industry

With the Unotherm® HL you are independent of external pure steam generation. No matter whether installed space-savingsly next to or above the sterilizer or flexibly away from the steam consumer – the systems adapt optimally to your spatial conditions.

Developed especially for cGMP sterilizers with high requirements for pipe classes and welding technology, it impresses with the use of first-class materials, excellent surface qualities, and precise weld seams. Powerful tube bundles and heating elements ensure reliable pure steam generation in consistently high quality – the basis for safe processes and economical operation.

### Highlights

- | Pure steam generator in horizontal design for pharma sterilizers
- | cGMP-compliant design
- | Reliable Siemens SIMATIC control system, FDA CFR 21 Part 11-compliant
- | Feed water module for thermal degassing

### Standard Equipment

- | GMP-compliant sanitary design: optimally drainable / product-contact materials 1.4404 / 1.4435 (AISI 316L) / product-contact sealing materials FDA-compliant / product-contact surface Ra < 0.8 µm / product-contact pressure sensors with hygienic, temperature-stable membrane pressure transmitters
- | Versions NEXT TO and ON available
- | Available with two power levels (54 or 81 kW)
- | Optimally compatible with MMM pipe classes H14, H20 and higher of MMM cGMP sterilizers
- | Closed feed module with ventilation via sterile filter and device for thermal feed water degassing available as an option, use of hot feed water without upstream cooling possible (e.g. hot WFI)
- | Siemens SIMATIC PLC with 7" HMI
- | Control software, CFR Part 11-compliant

### Standards

Pure or ultrapure steam generator in horizontal design according to DIN EN 14222 with CE marking in accordance with Directive 2014/68/EU on pressure equipment or Pressure Equipment (Safety) Regulation 2016 No. 1105 (UK CA).

### Technical Data

External Dimensions of Device	in mm (H x W x D)
with base and front panel	1918 x 1040 x 970
without base and front panel	1798 x 1000 x 950

Technical changes reserved.



Control cabinet

Pressure vessel  
(93 L volume)

Feed water module  
(34 L volume)

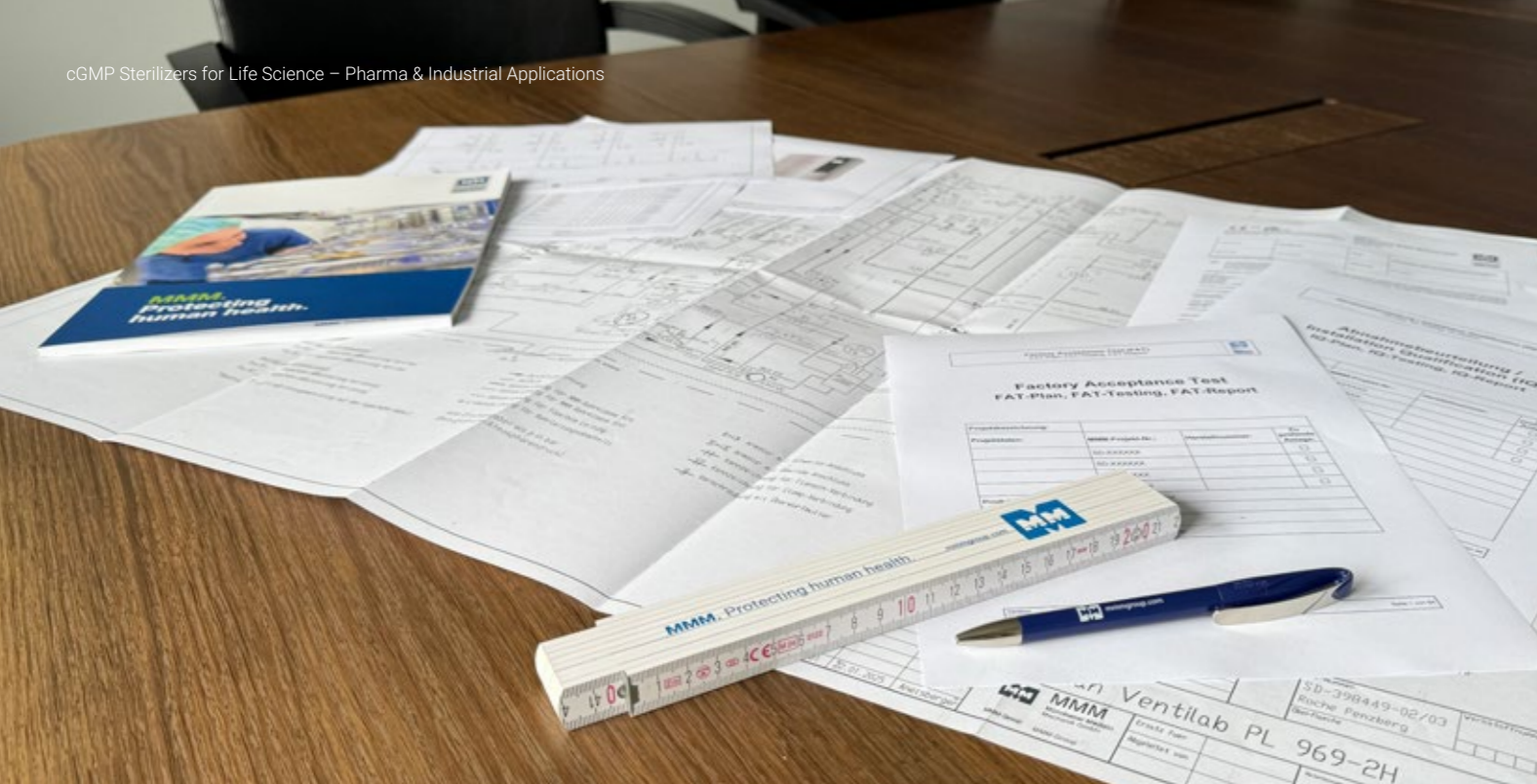
Feed water pump

# MMM Sterilizers at a Glance

Technical Features	Vakulab® HL	Fluipharm®
<b>Guidelines, standards and regulations</b>		
PED 2014/68/EU, MD 2006/42/EC, DIN 58950	●	●
<b>Mechanical design</b>		
Material chamber inner shell (1.4404 / AISI 316L)		●
Inner surface of chamber blasted	●	●
Inner surface of chamber grinded Ra < 0.8 µm	○	○
Inner surface of chamber electropolished	○	○
Hygienic design - chamber & sensors	○	○
Airtight separation of classified zones	○	○
<b>Piping</b>		
MMM pipe class H10	●	●
MMM pipe class H14	○	○
MMM pipe class H18		●
MMM pipe class H20	○	○
MMM pipe class HE30	○	
<b>Insulation</b>		
Silicone foam	●	●
Aluminum-laminated mineral wool	○	○
Cleanroom-suitable special insulation	○	○
<b>Cooling</b>		
Self-cooling (passive cooling)	○	/
Jacket cooling (active cooling)	●	/
Circulation cooling (active cooling)	○	/
Sterilization water cooling (hot water spray method)	/	●
Cooling circuit connection	○	○
<b>Sterilization processes &amp; additional programs</b>		
Equipment package "Closed solutions"	○	/
Equipment package "Hot water cascade method"	/	●
Equipment package "Vacuum programs"	●	○
Fan (magnetic coupling)	○	/
High performance fan	○	/
Inline sterilization compressed air filter	○	/
Program autostart	○	/
Program standby mode	○	/
F <sub>0</sub> value display and control	○	○
H <sub>2</sub> O <sub>2</sub> connection	○	/

● = Standard ○ = Optional / = on request (subject to change)

Technical Features	Vakulab® HL	Fluipharm®
<b>Control &amp; software</b>		
PLC control	●	●
Siemens SIMATIC touch panel 4", 12", 15" (sizes optionally selectable)	●	●
UPS for control system SiSoft	○	○
Active P&ID diagram	○	○
Electronic signature for batch release	○	○
Siemens SIMATIC Logon	○	○
<b>Process engineering components</b>		
Internal vacuum pump	●	○
External vacuum pump	○	○
Compressed air filter	○	○
Connection for manual filter integrity test	○	○
Automatic filter integrity test (Water Intrusion Test, WIT)	/	/
Test ports for pure steam according to EN 285	○	○
Sampling point for pure steam with integrated sample cooler	○	○
<b>Technical documentation</b>		
Installation drawing, P&ID, I&C list with calibration instructions, electrical diagram, electrical documentation, pneumatic diagram	●	●
Operation and maintenance manual, spare and wear parts list	●	●
Technical data sheets	○	○
Functional specification (FDS), hardware design specification (HDS), software design specification (SDS), input and output list (I/O list), alarm list	○	○
Qualification master plan with IQ/OQ documentation	○	○
Material certificates 3.1	○	○
Welding documentation	○	○
Test documents (e.g. video endoscopy, X-ray inspection, roughness measurement ...)	○	○
Risk analysis according to Machinery Directive	○	○
<b>Factory acceptance &amp; qualification</b>		
Factory Acceptance Test (FAT) Standard	○	○
Installation Qualification (IQ)	○	○
Operational Qualification (OQ)	○	○
Performance Qualification (PQ)	○	○
<b>Batch documentation</b>		
RUMED360®	●	●
Sicon - internal cycle documentation	○	○



# Complete System Documentation

Comprehensive technical system and qualification documentation is essential for the operation of process equipment in a GMP environment.

- | Installation drawing
- | BIM model
- | P&ID
- | Technical data sheets
- | Instrument list with calibration instructions
- | Electrical diagram, electrical documentation, pneumatic diagram
- | Input and output list (I/O list)
- | Functional specification (FDS)
- | Hardware design specification (HDS)
- | Software design specification (SDS)
- | Alarm list
- | Operation and maintenance manual
- | Spare and wear parts list
- | Qualification master plan with IQ/OQ documentation
- | Pressure vessel documentation
- | Material certificates 3.1
- | Welding documentation
- | Positive Material Identification, roughness measurement
- | Video endoscopy, X-ray inspection, dye penetration testing, pressure testing
- | ...

The reliable partner at your side

# MMM Customer Service

With us, you receive more than just repairs. From commissioning and validation right through to maintenance and ongoing support – you can rely on us!

We offer a comprehensive portfolio of services in the proven MMM quality, and solutions perfectly tailored to your needs.



Inspection



Maintenance



Repair



Validation, requalification and testing



Extensions and updates/upgrades



Energy optimization



Spare parts



Training



Software

**MMM.** Our global branches.



## MMM Group

MMM has been operating worldwide as one of the leading system providers in service of health since 1954. With a complete range of products and services relating to all aspects of cleaning, disinfection and sterilization systems for the fields of Healthcare and Life Sciences, MMM has positioned itself as a major driver of quality and innovation in both the German and international markets. Our products are

individually adapted to the requirements of our customers all over the world. The high vertical integration of the manufacturing in our plants ensures that we fulfill the most stringent demands for quality in the medical technology industry. More than 1300 employees apply their expertise and dedication to the mission of the MMM Group:

**MMM. Protecting human health.**



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