

# Fluipharm

For the sterilization of pharmaceutical products using the hot water cascade system.

MM

MMM Group



- Reliable and short process time
- Flexible equipment for highest hygienic requirements
- Individual construction

MMM.  
Protecting  
human  
health.

# Fluipharm



Fast and controlled sterilization of liquids is an important factor in research, development and the production of pharmaceuticals as well as in hospital pharmacies where parenteral liquids are processed every day.

MMM Fluipharm offers fast and gentle sterilization of liquids in closed receptacles made from glass or other heat-resistant materials by a hot water cascade system.



## Proven Technology – Individual Construction

Your research, goods, and demand of sterilizers are unique – unique is the result that we deliver: the perfect conjunction of proven MMM technology and customer specific requirements. Based on your specifications we will design and manufacture a quality product corresponding to your demands in every detail, taking all necessary regulations (cGMP, GMAP, FDA etc.) into account.

## Superior Human Machine Interface for Intuitive Operation

The sophisticated MMM touch screen HMI uses the Siemens latest generation multipanel for intuitive operation. The large 10" colour display delivers all the relevant process information at a glance: current batch information, machine status, process stage, remaining cycle time, clear messages in case of errors and deviations from the desired set points etc.

- Software validation according to GAMP
- Control system in conformity with FDA 21 CFR Part 11
- User administration and access authority
- Audit Trail (log book for all actions prompted by the user)
- Barcode administration
- Pass word protected data management
- Free parameter programmability of cycles



Sterilization of vials, bottles, pouches and infusions



## Hygienic Design for Critical Areas

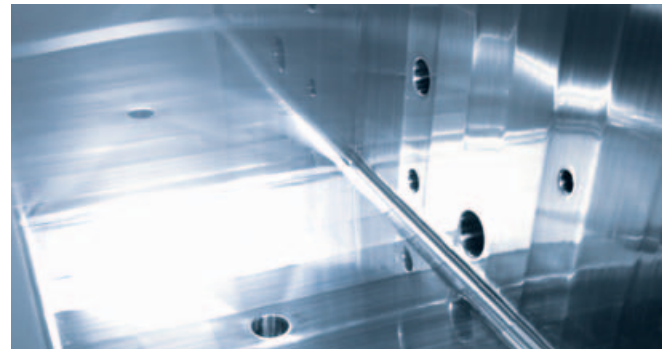
The pressure vessel, the electrically driven sliding doors and all the process pipe work in contact with the product are made from stainless steel (CrNiMo, material number 1.4404 or 1.4435/AISI 316 L). For operation purposes requiring the highest level of hygiene we are able to deliver the chamber with the inner surface polished. All associated process valves and pipe work are also constructed to meet the highest level of hygiene, sanitary valves are available.

All connections, optionally clamp or aseptic screwing, are assembled by orbital welding technique. Weld logging and boroscope inspection are available if required. Of course, all joint sealer and lubricants used are conforming with the requirements of FDA (21 CFR). By means of modern measuring technology according to Hygienic Design requirements, all parts in contact with the product or the product environment are fully drained back to the chamber.

## Performance Boosters for More Efficiency

The extremely short cycle times result from the large capacity circulation pump, which is able to move a significant amount of water in a very short time via a plate heat exchanger, heating the water by means of inexpensive process steam.

The plate heat exchanger is optimized for its use in the extremely sensitive field of pharmaceutical application as its secure construction avoids any possible contamination of the sterilization water.

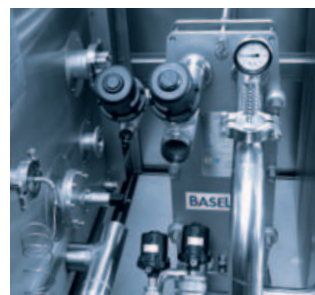


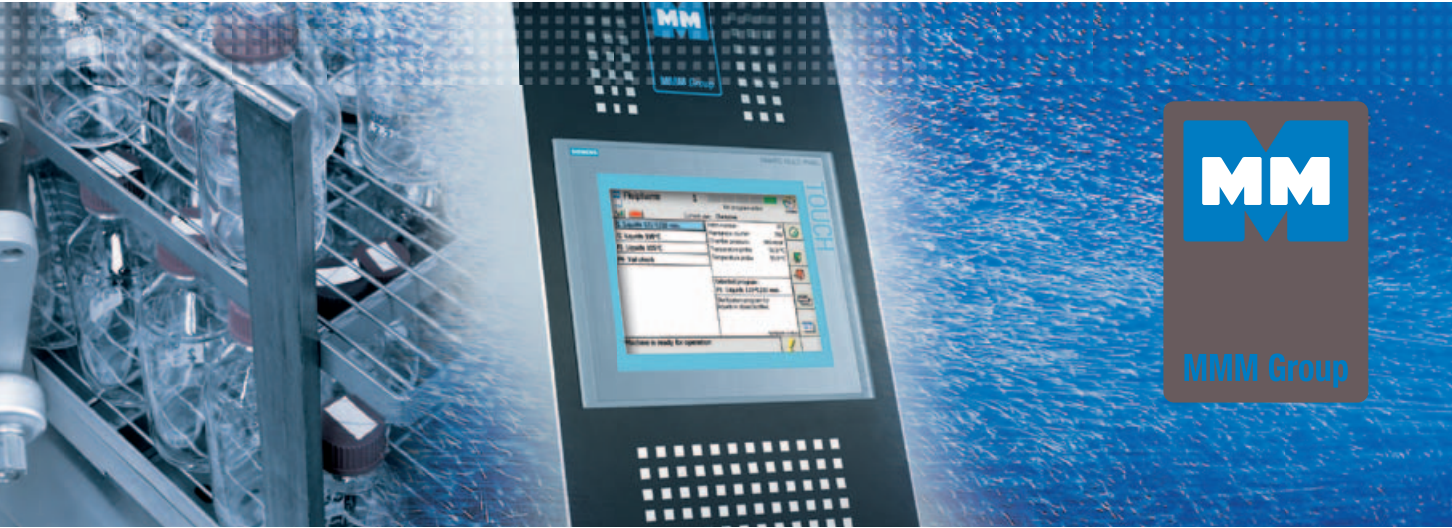
Durable pressure vessel with surface quality conforming to user specification: Abrasive blasting  $Ra \leq 3.5 \mu\text{m}$  or ground and polished to  $Ra \leq 0.8 \mu\text{m}$  (or less)

## Highest Safety for the Production Process

Particularly in the pharmaceutical industry, safety is of highest priority. The stringent separation between the sterile and the non sterile area is ensured by the manufacture of an air tight barrier installed behind the machine facia. This barrier can also be manufactured from stainless steel. The barrier seal is maintained using door opening logic ensuring one seal is always applied. Independent measuring systems increase the reliability of control and recording of the sterilization cycle. If thermal exposure must be reduced for sensitive goods, the process control can be carried out using  $F_0$ -calculations.

- Independent control and monitoring systems
- Temperature or  $F_0$ -value controlled process run
- Air tight barrier
- In line sterilizable filter housing





## Individual Customer Support

Project supervision by our qualified project teams is extremely important. All requirements are coordinated in close cooperation with you during every stage of the project. You can expect high product quality as usual and reliability in the realization of your individual solutions in terms of range, execution and quality. If required, we will be happy to support you in the development of the sterilization cycle necessary for your special products. We have many years of experience and long-standing know-how in sterile processing and assist you if required in the preparation of your URS. MMM will produce all other required validation documents, DS, FAT, SAT, IQ and OQ documentation and all necessary documents contributing to the machine qualification.

## For Nature's Sake

The operation of hot water sterilizers requires only water as sterilant. MMM intends to preserve this life-giving resource. The Fluipharm hot water sterilizer can run with recirculating water loops.

The sterilization water circulates both for heating, sterilization and cooling.

The heat exchanger can be cooled by a cooling loop available on site. An effective heat insulation of the pressure vessel and the pipes helps to prevent heat losses.

## Examples of typical chamber sizes

Individually designed sizes are available.

Type	Clear chamber inside dimensions in mm			Volume in l	Machine outside dimensions in mm		
	Height	Width	Depth		Height	Width	Depth
669	710	650	990	447	1918	1900	1290
969	1000	650	990	644	1918	1900	1290
9612	1000	650	1340	871	1918	1900	1590
9618	1000	650	1940	1261	1918	1900	2190
999	1000	1000	990	940	1918	2500	1290
9912	1000	1000	1340	1273	1918	2500	1590
12912	1360	1000	1390	1890	2070	2200	1720
141114	1550	1200	1460	2716	2070	3250	2190

## The Fluipharm Solution

- Custom-made construction
- Program design according to individual purpose
- cGMP conformity
- Short cycle times
- Use of inexpensive process steam
- High-power circulation pump
- Efficient heat exchanger
- Vacuum programs if required
- Air tight barrier, made from stainless steel
- Gentle treatment of the goods
- Fresh water saving of up to 100 %
- Versatile application



## Water Cascade Method

### Heating

At first the chamber is filled with sterilization water up to a pre-defined level, which is then circulated through the steam-heated heat exchanger. This heated water is then circulated over the product delivering a continuously rising temperature. Due to the efficient heat transfer, the goods are heated quickly and gently in a controlled way. The high volume flow rate and the perforated plate installed at the top of the chamber are responsible for the deluge flow over the whole load.

### Cooling

The circulated water is continuously passing over the load via the heat/cool exchanger. It is cooled down by replacing the heating medium with a cooling medium. This is supplied via a water or chilled water recirculation loop. This action quickly and efficiently cools the product down to an acceptable temperature. A temperature controlled back pressure generated by sterile compressed air prevents any damage of the closed receptacles.



## Process Types and Programs

Fluipharm 1		No program active	
Current user: Christine			
P1 Liquids 121 °C/20 min.	Batch number:	39	
P2 Liquids 110 °C	Membrane counter:	766	
P3 Liquids 105 °C	Chamber pressure:	909 mbar	
P4 Vial check	Temperature probe:	50.0 °C	
	Temperature probe:	50.0 °C	
Selected program:			
P1 Liquids 121 °C/20 min.			
Sterilization program for liquids in closed bottles.			
Machine is ready for operation			

The water cascade method is the fastest method for the sterilization of liquids. Depending on the equipment of the sterilizer, solid and porous products can also be sterilized. The processes can be freely programmed within the range of sterilization reliability.

- Hot water cascade programs ranging from 100 – 134°C for fluids
- Ampoule test program for identification of defective ampoules
- Ampoule drying program
- Ampoule rinsing program for easy further processing
- Vacuum programs for solid and porous goods

## MMM Group

As one of the world's leading suppliers of sterile processing systems, MMM has been working actively to promote good health since 1954. With a full range of sterilization and disinfection products and services – that can be found in every branch of health-care from hospitals and scientific institutes, to laboratories and the pharmaceutical industry – MMM, has over the years, consolidated its position as a pioneer of quality and innovation both in the German and international market. In our two production facilities based in Stadlern, Germany, and Brno, in

the Czech Republic, we manufacture products that meet the highest demands of our customers world wide. The depth and precision of production standards at both plants ensure that we accomplish the rigorous quality requirements of medical engineering.

900 competent employees work together as a committed and enthusiastic team, dedicated to achieving the mission of the MMM Group.

## Protecting human health.



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