VENTICELL® IL
Hot-Air Sterilizer with Depyrogenation
in Laboratories, Pharmacy and Industry
Tradition, Quality, Innovation

Individually Designed Laboratory Technology

Since its establishment in 1921, BMT Medical Technology s.r.o., the traditional manufacturer of medical and laboratory technology, has been gradually transformed from a small regional company to an international corporation.

In 1992, it became a member of the European MMM Group which has been operating on the world markets since 1954 as an important supplier of systems for the health care industry, science and research. With its comprehensive offer of products and services, sterilization and disinfection devices for hospitals, scientific institutes, laboratories and pharmaceutical industry, MMM Group has established itself individually designed laboratory technology.

VENTICELL® IL is a series of modular large-size laboratory devices with the chamber volume of 400 up to 3 900 litres. The device is used for items sterilization at the temperature of up to 180°C, or for items depyrogenation at the temperature of up to 300°C and in optional time mode. The devices can be used in laboratories, industry, pharmacy, and research. VENTICELL® IL is intended for thermally resistant, inflammable materials, e.g.: empty glass products – glasses, ampoules, vials, bottles, vessels metal materials in pharmaceutical industry – trays, containers, accessories and device parts thermally stable basic pharmaceutical products and chemical substances

General and Actively Provable Quality

The factory acceptance test (FAT) in the extent pursuant to client’s requirements is taken for granted; the site acceptance test (SAT) can also be performed upon the user’s request and in his presence or in the site of the device installation (SAT) if possible. 27-point measurement according to DIN 12880 can also be performed during the output control. To prove the sustained sterilization quality by the manufacturer (importer) in accordance with the declared device parameters, the VENTICELL® IL hot-air sterilizer users are provided with appropriate documents:

IQ – Installation Qualification
OQ – Operational Qualification
PQ – Performance Qualification (validation)

The tests and validations are performed by our accredited testing laboratory according to the standards.

VENTICELL® IL

Original without Compromises

• modular system allows variable individual device variation
• one-door and passthrough models
• sterilization chamber, doors, device frame and jacket are made of stainless steel for easy maintenance and long service lifetime
• double semi-automatic door lock for maximal process safety
• horizontal air flow in the chamber, powerful heating elements and highly efficient device insulation ensure short work process times and reduction of operating costs
• control by means of an industrial PLC system
• sterilization phase checking and recording both in graphic and numeric form in the course of the whole process
• simple, intuitive device control by means of a touch panel with possibility of user modification of process parameters
• various possibilities of the batch documentation processing
• regulation of pressure inside the chamber by means of air pressure sensors in relation to sterile or non-sterile space
• main doubled temperature sensors for independent work process control
• auxiliary doubled temperature sensors for better process control
• effective use of inner sterilization space
• transport and loading system guarantees easy handling of the sterilized material by the operator
• wide offer of optional equipment and accessories according to individual needs

as an outstanding quality and innovations producer on the global markets. The knowledge and experience gained during the implementations of individual supplies for our customers all over the world, and the technical innovations have been permanently and positively influencing the development, construction and production of our devices. High level of our work has also been confirmed by the number of patents and utility and industrial designs as well as an easy implementation of individual device adjustments.

(non-explosive, flameproof and non-toxic)

Extended functions of the device can be used for incubation or for long-term thermal soaking of materials with two-way operation. The additional functions allow maximally efficient use of constrained space in clean premises by using one device instead of formerly used two devices. The device safety is based on requirements of the standard EN 61010-2-040 and it is further adjusted to individual needs of each workplace. The device is designed and manufactured within the certified quality system in accordance with EN ISO 9001.
Hot-Air Sterilization and Depyrogenation

Sterilization is a validated procedure used for putting the product into condition free of any viable micro organisms. According to EN 285.

The sterilization effect in hot-air sterilizers is reached by the sterilized material heating to high temperatures (160–180°C). Depyrogenation is a procedure reducing the number of bacterial endotoxins (pyrogens) by at least three orders by high temperature (250–300°C) acting for a given period of time.

Important parameters of the processes are the following ones:

- accurate profile reached by sophisticated heated air flow system and perfect construction design of the sterilization chamber
- quick temperature rise and cooling
- compliance with the regulations on clean rooms

<table>
<thead>
<tr>
<th>ISO CLASS (N)</th>
<th>Maximum concentration limits particles m⁻³ of air to ISO 14644-1</th>
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<td>ISO CLASS 9</td>
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</table>

VENTICELL® IL ISO CLASS 5
- complies with regulations on clean rooms according to ISO 14644-1
- external HEPA filters at the input and special internal HEPA filters for high temperature
- sophisticated construction of the sterilization chamber
- loading equipment
- guarantee of compliance with ISO Class 5 in all the sterilization chamber zones
- working temperature up to 300°C
- various sterilization chamber volumes – see table
- one- and pass-through models
- stainless steel fascia panels of the device with possibility of individual installation into a clean room

VENTICELL® IL ISO CLASS 7
- complies with regulations on clean rooms according to ISO 14644-1
- external HEPA filters at the input
- sophisticated construction of the sterilization chamber
- loading equipment
- guarantee of compliance with ISO Class 7 in all the sterilization chamber zones
- working temperature up to 300°C
- various sterilization chamber volumes – see table
- one- and pass-through models
- stainless steel fascia panels of the device with possibility of individual installation into a clean room

VENTICELL® IL EASY

The economical variant of the hot-air sterilizer VENTICELL® IL EASY also meets the conditions for installation in clean rooms. It meets the requirements of EU Directives 2014/35/EU and 2014/30/EU. The device construction is based on the established and well-proved MMM heating equipment devices (COMFORT/ECO/EVO line) and it is intended for long-term use in hot-air sterilization and depyrogenation processes with necessary technical adjustments. (For more details see p. 14)
High Standard of Manufacture

- robust structure, valuable inner space
- stainless steel sterilization chamber DIN 1.4301 (AISI 304) or DIN 1.4404 (AISI 316L)
- sectional stainless steel device frame for easy device installation
- stainless steel outer jacket made of high-strength, chemically resistant, polished steel
- AISI 304 for easy maintenance and long service life
- removable inner stainless steel sheets for easy maintenance of the working chamber
- well-organized and ergonomic control panels
- easy intuitive control and service
- semi-automatic controlled stainless steel door with mechanical opening
- internal HEPA filters for high temperature
- internal overpressure blower with sealed shaft
- temperature sensors PT100 for accurate temperature keeping (4 pieces as a standard)
- optional flexible PT 100 sensors
- digital- or analogue-display pressure sensors for pressure measurement and regulation in the sterilization chamber and for ambient pressure comparison
- "Emergency stop" function - under emergency conditions it allows for the device to come to a standstill
- strengthened water cooling by means of a cooling exchanger inside the chamber
- possibility of use of the transport and loading system in all device types
- input and output flanges facilitating the device connection at the installation site
- wide range of optional equipment

VENTICELL® IL

Sterilization Chamber

- the sterilization chamber is made of chemically resistant stainless steel DIN 1.4301 (AISI 304) or DIN 1.4404 (AISI 316 L)
- precise and tight sealing welds of the sterilization chamber, tested by capillary method during the manufacturing process
- The sterilization chamber surface is made of cold-rolled sheet with roughness below 0,8 Rₐ for easy cleaning and minimization of particles settlement.
- easily removable inner stainless steel sheets for easy maintenance of the operation chamber
- sophisticated construction of the chamber and door to maximize the dilatation stability of the chamber during the working cycle, which eliminates the particles release and increases the temperature homogeneity in the sterilization chamber
- high-quality, 15 cm thick Superwool insulation and third outer insulation jacket
- dimension-optimised rectangular chamber ensures maximum volume usability for standardized containers placement
- for the possibility of the device validation, the sterilization chamber is equipped with an access port with the diameter of 30 mm

Device Door

- double automatic door lock for maximal process safety
- semi-automatic controlled stainless steel door with mechanical opening equipped with a two-stage hinge allowing easy door opening and reliable closing
- welded door construction has a double, heat-resistant, silicone shaped sealing, fully eliminating any contact of the inner environment with the outer one during the work cycle
- door sealing easy to replace
- stainless steel electromotive door lock using significant door weight, ensuring reliable door closing
- ergonomically positioned handles for easy door handling
- emergency door opening allowed by independently supplied electromotors, or by manual drive in case of power supply failure
- one- or passthrough models available
**Unique Heat Transfer Inside the Working Chamber**

- The activity is based on horizontal air flow through air ducts in the back and side device walls by means of a blower in an electrically heated chamber. Thus the spatial air temperature deviation and accurate temperature profile are ensured.
- Sophisticated placement of the ventilation air ducts, heating elements, internal blower and adjustable air suction flap and discharge allow fast temperature rise and accurate cycle course in the sterilization chamber.
- Forced air cooling by an overpressure blower during the final cycle phase ensures the resulting reduction of necessary working cycle duration (e.g. 320 bottles ROUXE 1000 ml, sterilization 250°C / 30 minutes, cooling by air to 90°C, cycle duration 4 – 6,3 hours depending on the flow intensity).
- Temperature range up to 300°C allows the device use in the whole spectrum of industrial applications including the hot-air sterilization and depyrogenation.
- Inner blower with frequency control using a frequency convertor for air flow optimization in the chamber.

**Filters, Overpressure, Particles**

- Thanks to special two-stage HEPA filters of class H 11 and H 14 placed at the air inlet into the device, the requirements of the standard EN 14644, ISO Class 5 and 7, have been met.
- The use of thermally resistant internal HEPA filters H 13 and fluent air flow regulation allow arrangement of perfect continuous cleaning of the inner chamber, thus reducing the particles occurrence during all the cycle phases (only VENTICELL® IL, ISO Class 5).
- The additional overpressure blower ensures overpressure in the chamber 0,45 - 1,5 mbar.
- Door sealing and special sealing of the blower axis eliminates any contact with the outer atmosphere during and after the sterilization cycle.
- The outlet pipework of the device can be fitted with high-temperature hepa filters H13.

**Transport and Loading System**

The sterilized material handling is facilitated by a loading system consisting of the transport and loading cart. The transport cart construction has been designed to ensure a highly stable load handling, even if it is quite heavy. The loading cart with shelves for standardized containers placement is equipped with wheels with thermally resistant bearings so as to arrange safe handling and long service life. That guarantees the load placement into the device without any risk of parts release from the cart. The loading device construction allows fluent air flow in the chamber, thus contributing to the working cycle duration shortening and temperature homogeneity increase in the sterilization chamber.

**Environmental Awareness**

Both the device production and the devices as such comply with the strict European ecological criteria. They do not burden the working and living environment. Multi-stage controlled cycle and fluent regulation of the revolutions increase and run-out prevent useless power surges in the power supply mains. The design of the device construction, e.g. effective flow in the chamber, perfect and extremely thick insulation of the sterilization chamber with the rock wool, blower axis sealing or controllable suction and exhaust flaps not only optimize the cycle parameters, but they also minimize power consumption and protect the user’s rooms from uselessly radiated heat. The heat insulation keeps perfect insulating properties even under high temperatures when it retains low thermal absorption. During operation, it does not release any smell or smoke emissions as it contains neither binders, nor lubricants. The device does not produce any harmful waste. Environment-friendly processing methods have been used during its manufacture. More than 90% of the device and the package can be recycled. The device does not contain any dangerous substances or heavy metals and it meets the Directive on use of dangerous substances RoHS No. 2011/65/EU and wastes WEEE No. 2012/19/EU.

**Laboratories and Pharmacy**

BSL 3 / BSL 4

**Simulation of Air Flow Velocity in the Chamber**

The latest simulation methods of air flow in chambers were used during the development in cooperation with the university (Brno University of Technology).
Intuitive Touch Control Panel

Unique Properties, Safe Work procedures

- high operational safety, doubled system of collection and evaluation of process information and its continuous comparison and evaluation
- any established deviation exceeding the permitted value deviation induces an error message issued by the industrial PLC system with own control software
- with basic device functions on both device sides (in a passthrough model) and extended offer of user functions on the main panel
- main comfortable colour 12.1” touch panel ensures clear and simple operation, diagnostics and service at the loading side
- colour 7” touch display on the unloading (clean) side (in a passthrough model)
- visual and acoustic (optional equipment) status and process signalling (during the process, the display shows the process course and time till the working cycle end in both digital and analogue form)
- Naturally, there are included visual and sound adjustable alarms as well as many individual adjustments of configurations (valves, flaps, communication language, print or data output, process control using flexible PT 100 sensors, etc.)
- clock – an indicator of supposed remaining time of the program and real time indicator – after the cycle finishing, the automatics confirms correct course, prints the protocol for the given cycle and allows the device door opening
- the "delayed start" function allows the device switch-on in a pre-defined time without the operator's presence
- the diagnostic section allows easy service diagnostics and very quick service intervention

Control System PLC – Siemens S7-1500

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Batches Documenting

In addition to both the local and remote continuous checking of the working processes, the working cycle documenting is required in certified plants. It can be ensured by:

- independent documentation with possibility of protocols data saving in the panel memory
- built-in thermo printer (optional equipment)
- connection to PC (Ethernet) for data exchange or for remote diagnostics and saving protocols in the computer memory and displaying in the computer using the „WarmComm“ software – (optional equipment)
- WiFi module for wireless connection to the computer allowing current data transfer (optional equipment)

WarmComm 4.0

special software for MMM heat technology – efficient access to your data

The special WarmComm software allows data storing and managing in a PC simultaneously with the device memory.

On-line support: http://warmcomm.bmt.cz

Sterilization / depyrogenation cycle course

Using forced air flow and water cooling system

Pre-heating

Sterilization

exposure

Temperature rise

Cooling

Sterilization / depyrogenation cycle course

Adjustable overheating of the material to shorten the cycle time
Thanks to modular construction of our devices even VENTICELL® IL may be additionally equipped according to your preferences with many additional options.

1. one-door or pass-through version
2. chamber design of high-quality stainless steel 316 L
3. surface treatment of the chamber R<sub>ν</sub>≤0,4 µm
4. surface treatment of the chamber "mirror shine" R<sub>ν</sub>≤0,125 µm
5. water cooling – it reduces the cooling phase time up to half
6. output high-temperature HEPA filter with a flange
7. Access point for DOP test (depending on equipment with HEPA filters)
8. CLAMP DN 15 DIN 32676
9. transport and loading equipment made of stainless steel AISI 304 or 316 L, equipped with special resistant castors without release of particles and high-temperature bearings, the loading cart is optimised for usual sizes of cartridges with material or it may be adjusted according to client's requirements
10. validation port terminated with a Clamp ISO KF-40 or according to client's requirements
11. fluently adjustable outlet flap
12. built-in thermo printer with 10-year guarantee of printing stability and print width of 112/104 mm
13. Differential pressure sensor with analogue displaying (front of the device)
14. Digital temperature sensor PT-100 for process operation and control in a specific location of the chamber
15. data outputs Wifi or USB for connection of external data loggers
16. display or SW Warmcomm 4.0 possibilities of the building
17. special software WarmComm 4.0 for data saving and administration on PC
18. System for more efficient cooling by air with flaps for switching over the suction of externally pre-cooled and ambient air
19. Air-tight design „BIOSEAL“
20. cover strips made to measure to be built in the device, into pharma partition walls and ceilings
21. basic documentation IQ, OQ, PQ for validation
22. FAT, SAT
23. stand-by power supply UPS for equipment with HEPA filters
24. double-sided operation setting – loading possible from both sides
25. 12,1" touch screen with extended functions for unloading side
26. USB for assemblage on the loading side
27. Input/output HEPA filter assembled in a special position depending on space possibilities of the building
28. compatibility with 21 CFR part 11 and GAMP 5 with outputs to the touch display or SW Warmcomm 4.0

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### Technical Parameters

#### EASY ISO 7 ISO 5

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**Model**

- Pharma partition wall BIOSEAL
- service space for water cooling
The economical hot-air sterilizer variant VENTICELL® IL EASY complies with the requirements for installation in clean rooms as well. It complies with the requirements of EU Directives 2014/35/EU and 2014/30/EU. The device construction is based on the established and well-proven MMM heating technology devices (COMFORT/ECO/EVO line) intended for long-term use in hot-air sterilization and depyrogenation processes with the following necessary technical adjustments:

- sealed chamber and door for installation in clean rooms
- separated control panels on both device sides
- power electronics separated from the basic device body
- reinforced device door for lesser thermal dilatation and better sealing
- levelling legs for stable installation
- modified control SW for the temperature heating up time minimization
- sealed exhaust extension and sealed access port for validation
- varnished or stainless steel covering strips for device installation into the wall.

**Inner volume:** 55, 111, 222, 404, 707 litres
**Temperature range:** 250°C/300°C
**Inner chamber:** stainless steel, DIN 1.4301 (AISI 304L)

**Microprocessor Control**
- 6 adjustable programs
- chip card system offering unlimited program equipment of the RS 232 interface for printer
- or PC connection
- possibility of delayed start and stop function
- acoustic and visual alarm of error state
- time range 0–40 years with 1 minute adjustments
- digital safety thermostat
- real time
- programmable temperature increase or decrease slopes
- “RAMPS” – programming of time sections of the program
- “SEGMENTS” – cycling of individual programs
- digital adjustment of fan speed 10 to 100%
- manual control of the air suction and exhaust flap
- keyboard blocking
- door opening control

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**Technical Parameters**

<table>
<thead>
<tr>
<th>Model</th>
<th>Storage area (w x d)</th>
<th>Maximal weight of the load in chamber (max. kg)</th>
<th>Electricity - mains 50/60 Hz</th>
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The values may differ depending on specific charge and media parameters. Changes in the design and make reserved.
# Unique Line... Cell

<table>
<thead>
<tr>
<th>Designation</th>
<th>Type marking</th>
<th>Laboratory case type</th>
<th>CO₂ line</th>
<th>Line Standard</th>
<th>Line Comfort</th>
<th>Natural air circulation</th>
<th>Forced air circulation</th>
<th>Temperature range in °C (Optional equipment)</th>
<th>Volume 22 l</th>
<th>Volume 50 l</th>
<th>Volume 55 l</th>
<th>Volume 111 l</th>
<th>Volume 190 l</th>
<th>Volume 222 l</th>
<th>Volume 404 l</th>
<th>Volume 707 l</th>
<th>Volume 1212 l</th>
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<td>drying oven</td>
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</table>

The above stated technical data apply and they are valid at the temperature of 22°C and voltage oscillation ±10%.

*  above the exterior temperature

** manufacturer MMM Medcenter Einrichtungen GmbH, Semmelweisstrasse 6, D-82152 Planegg / Munich, tel.: +49 89 89 92 26 20, e-mail: medcenter@mmmgroup.com

*** the STERICELL® line also meets the Directive No. 93/42/EEC, the product is presented in a separate leaflet.

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- Laboratory drying devices and incubators 22–1212 l
- Washer Disinfectors for Medical Usage