VENTICELL IL hot-air sterilizer with depyrogenation





Sterilization and depyrogenation in laboratories, pharmacy and industry



... protecting human health

Tradition, quality, innovation

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 as an outstanding quality and innovations producer on the global markets.

Individually designed laboratory technology

VENTICELL IL is a series of modular large-sized laboratory devices with the chamber volume of from 400 to 1.500 liters. The devices are 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 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, bottles, vessels and others
- Metal materials in pharmaceutical industry - trays, containers, accessories and device parts
- Thermally stable basic pharmaceutical products and chemical substances

General and actively provable quality

A factory acceptance test (FAT) is taken for granted; a site acceptance test (SAT) can also be performed upon the user's request and in his presence. 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, VENTICELL IL hot-air sterilizer users are provided with appropriate documents:

- IQ Installation Qualification
- **OQ** · Operational Qualification

PQ - Procedural Qualification (validation) The testing and validations are performed by our accredited testing laboratory according to the standards.

VENTICELL IL

Original without compromises

- modular system allows a variable device construction
- one-door and two-door models
- sterilization chamber, doors, device frame and jacket are made of stainless steel for easy maintenance and long life
- double automatic door lock for the maximum process safety
- horizontal air flow in the chamber, powerful heating elements and highly efficient device insulation ensure short working process times and reduction of the operating costs
- control by means of an industrial PLC system with an efficient user interface on a panel (touch screen); support of programs, their creation and process recording
- sterilization phase checking both in digital and analogue form during the whole working cycle



and laboratory technology



- simple, intuitive device control by means of a touch panel • various possibilities of the batch documentation processing regulation of pressure inside the chamber by means of
 - sensors depending on the air pressure in the sterile or nonsterile space
- doubled main temperature sensors for an independent work process control
- doubled auxiliary temperature sensors for better process control
 - effective use of the inner sterilization space
- transporting and loading system guarantees easy handling of the sterilized material by the operator
- wide offer of optional accessories according to individual needs.

Sterilization and depyrogenation

Sterilization is a procedure killing all viable organisms including spores and leading to irreversible inactivation and killing of health-endangering worms and their eggs.

The number of Bacillus subtilis microorganisms must be reduced during a sterilization cycle by six orders at least.

The sterilization effect in hot-air sterilizers is reached by the sterilized material heating to a high temperature (160-180 °C).

Depyrogenation is a procedure reducing the number of bacterial endotoxins (pyrogens) by three orders at least by high temperature (250-300 °C) acting for a given period of time.

There are the following important parameters of the mentioned processes:

- · Accurate profile thanks to a well-designed hot air flow system and perfect construction design of the sterilization chamber
- Short duration of temperature rising an cooling
- Compliance with the regulations on clean premises

VENTICELL IL, ISO CLASS 5

- · complies with the regulations on clean premises according to ISO 14644-1
- special internal thermally-resistant HEPA • filters
- ٠ well-designed construction of the sterilization chamber
- loading equipment ٠

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- quarantee of compliance with ISO Class 5 in • all sterilization chamber zones
- working temperature of up to 300°C •
- sterilization chamber volume 1,500 and 700 • liters
- stainless steel device wall panels
- ٠ stainless steel device wall panels

one- and two-door models

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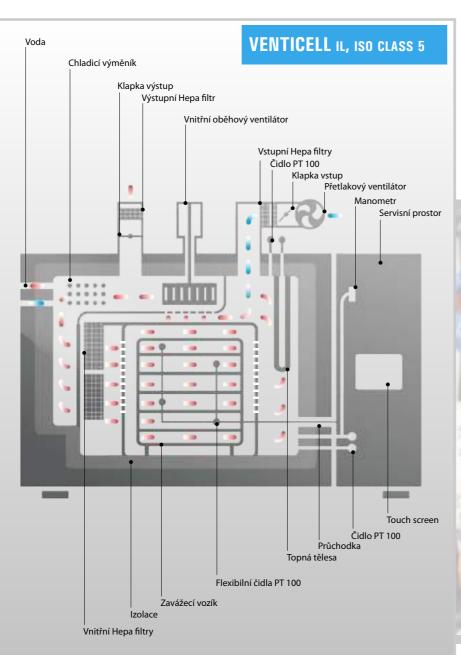
chamber

liters

٠

loading equipment

- VENTICELL IL, ISO CLASS 7 Voda Chladicí výměník Klapka výstup Výstupní Hepa filtr Vnitřní oběhový ventilátor Vstupní Hepa filtry Čidlo PT 100 Klapka vstup Přetlakový ventilátor . - 64 -----.... . . . 0 -5 1000 5



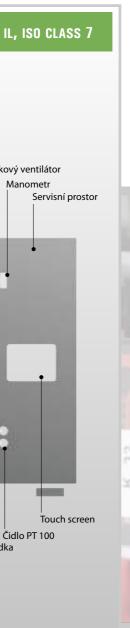




VENTICELL IL, ISO CLASS 7

• complies with the regulations on clean premises according to ISO 14644-1 • special external HEPA filters well-designed construction of the sterilization

• guarantee of compliance with ISO Class 7 in all sterilization chamber zones working temperature of up to 300°C • sterilization chamber volume 1,500 and 700



Průchodka

Topná tělesa

Flexibilní čidla PT 100

Zavážecí vozík

Izolace

VENTICELL IL EASY

VENTICELL IL Easy, an economical variant of the hot-air sterilizer, complies also with the conditions for installation in clean premises. It complies with the requirements of EU Directives 2006/95/EC and 204/108/EC. The device construction is based on the established and well-proved MMM heat technology devices (COMFORT line) and is intended for a long-term use in the hot-air sterilization and depyrogenation processes with necessary technical adjustments.

(For more details see p. 10)





VENTICELL IL

High standard of manufacture

- robust outer covering, valuable inner space
- stainless steel sterilization chamber [DIN 1.4301 (AISI 304)] or [DIN 1.4404 (AISI 316L)]
- robust multi-piece stainless steel device frame for easy device installation
- stainless steel outer jacket made of high-strength, chemically resistant, polished steel DIN 1.4301 (AISI 304) or DIN 1.4404 (AISI 316L) for easy maintenance and long life
- removable inner stainless steel wall panels for easy maintenance of the working chamber
- clear ergonomic control panels
- easy intuitive control and service
- automatically controlled stainless steel door with mechanical opening/closing
- bacteriological HEPA filters for the working chamber aeration
- special internal thermally-resistant HEPA filters
- internal pressure ventilator with sealed shaft
- PT 100 temperature sensors for accurate values maintenances (4 pieces as a standard)
- optional integration of flexible PT 100 sensors
- digital- or analogue-display pressure sensors for pressure measurement and regulation in the sterilization chamber and for the ambient pressure comparing
- "Total stop" function integrated in the control panel, allowing the device standstill if necessary

- strengthened water cooling by means of a cooling exchanger inside the chamber
- possibility of use of a transporting and loading system in all device types
- service access from the front and one side wall only
- flexible positions of input and output flanges facilitating the device connection at the installation site
- wide range of optional accessories

Sterilization chamber

- made of chemically resistant stainless steel DIN 1.4301 (AISI 304) or DIN 1.4404 (AISI 316L)
- tight sealing welds of the sterilization chamber
- · easy removable inner stainless steel panels for easy maintenance of the sterilization chamber
- the particles release and increases the temperature homogeneity in the sterilization chamber
- high-quality 150-mm thick insulation
- · rectangle chamber ensures the maximum volume usability for standardized containers placement
- to allow validation, the sterilization chamber can be equipped with a bushing of optional diameter

Device door

- double automatic door lock for the maximum process safety
- reliable closing
- welded door construction equipped with a double high-temperature silicone labyrinth sealing which eliminates fully the contact of the inner environment with the outer one during the working cycle
- easy the door sealing replacement
- stainless steel electromotive door lock using the great door weight, which ensures reliable door closing
- two ergonomically positioned handles for easy door manipulation
- emergency door opening allowed by independently supplied electromotors, or by a manual drive in case of power supply failure
- one- or two-door (pass-through) models available







well-designed construction of the chamber and door to maximize the dilatation stability of the chamber during the working cycle, which eliminates

semi-automatically controlled stainless steel door with mechanical opening equipped with a unique two-stage hinge allowing easy door opening and

VENTICELL IL

Unique heat transfer inside the working chamber

- The activity is based on a horizontal air flow through air ducts in the back and side device walls by means of a ventilator in an electrically heated chamber. Thus the air temperature deviation (≤ ± 1% from the temperature reached) and accurate temperature profile are ensured.
- Well-designed placement of the ventilation air ducts, heating elements, internal ventilator and controllable air suction flap allow very short duration of the temperature rise and accurate cycle course in the sterilization chamber.
- Forced air cooling by an integrated ventilator during the final cycle phase ensures the resulting reduction of the working cycle duration (e.g. 320 bottles ROUXE 1,000 ml, sterilization 250°C/30 minutes, cooling by air to 90°C, cycle duration 4 – 6.3 hours depending on the flow intensity).

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 Class 7, have been met.
- The use of thermally resistant internal HEPA filters H 13 and a continuous regulation of the space air velocity ensures an absolutely perfect continuous cleaning of the inner chamber, thus reducing the particles occurrence during all cycle phases (applied only to VENTICELL IL, ISO Class 5), which means compliance with EN 14644, ISO Class 5.
- An additional pressure ventilator ensures the overpressure of up to 2 mbar.
- Thorough door sealing and special sealing of the ventilator axis eliminates any contact with the outer atmosphere during and after the sterilization cycle.
- The output device pipes can be equipped with additional H 13 filters to protect the laboratory environment.

Transporting and loading system

The sterilized material handling is facilitated by a loading system consisting of a transporting and loading cart. The transport cart construction has been designed to ensure a very stable load handling, even if it is quite heavy.

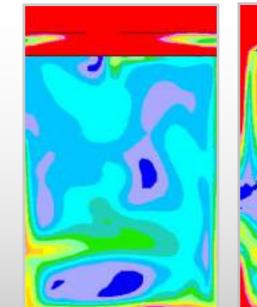
The loading cart with shelves of optimized size for standardized containers loading is equipped with wheels with special thermally resistant bearings, which guarantees the load placement into the device without any risk of particles release from the cart.

The loading device construction allows continuous 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 dev They do not burden the working and liv continuous regulation of the ventilator s in the customer's power supply mains. The design of the device construction, a thick outer insulation of the sterilization settable suction an exhaust flaps not o consumption and protect the user's pre keeps its perfect insulating properties e absorption. During operation, it does no neither binders, nor lubricants. The device does not produce any harmf during its production. More than 90 % of the device and its p substances nor heavy metals and comp hazardous substances and wastes no. 2

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 Brno University of Technology (Czech Republic).





Both the device production and the devices as such comply with the strictest ecological criteria. They do not burden the working and living environment. Multi-stage heating elements switch-on and continuous regulation of the ventilator speed rising and running down prevent useless power surges in the customer's power supply mains.

The design of the device construction, e.g. an effective flow in the chamber, perfect and extremely thick outer insulation of the sterilization chamber by the rock wool, ventilator axis sealing, or settable suction an exhaust flaps not only optimize the cycle parameters, but also minimize energy consumption and protect the user's premises from uselessly radiated heat. The heat insulation keeps its perfect insulating properties even in high temperatures when it retains low temperature absorption. During operation, it does not release any smell or smoke emission because it contains neither binders, nor lubricants.

The device does not produce any harmful by-products. Ecological processing methods are used

More than 90 % of the device and its pack are recyclable. The device contains neither any harmful substances nor heavy metals and complies with the directive on the restriction of the use of hazardous substances and wastes no. 2002/95/EC. The device also complies with the WEEE&ROHS regulations on industrial products recycling.

