BMT

MMM Group

# ...new dimensions of the instrumentation preparation




# in small steam sterilizers

**protecting human health**

# Which sterilizer shall I choose for my medical workplace?

## Take advantage of some proven advice and information from us, BMT Medical Technology s.r.o., a reputable manufacturer of medicine technology.

## What do we recommend?

- The EU standard EN 13060 for small steam sterilizers is already valid, do buy your devices without compromises!
- Pay attention to national regulations that may specify how to perform the sterilization at your workplace.
- Secure also the documentation of sterilization cycles.

## What is to be verified?

### 1. What does the European standard EN 13060 concern?

The standard EN 13060 concerns small steam sterilizers (SSS). It is valid in the EU states since 06/2004 and specifies, which technical parameters shall be fulfilled with the SSS products.

It is applied on steam sterilizers having the chamber volume not larger than 60 litres and the chamber which is unable to accommodate the sterilization unit (dimensions of 300 x 300 x 600 mm).

### 2. Which regulations are to be met by a small steam sterilizer and how to verify it with the specific product?

Before purchasing a device it is suitable to ask for the EC Declaration of Conformity where you can verify whether the product is in accordance with the European regulations. There has to be a reference to the EU Directive No. 93/42/EEC there. The product has to bear the CE mark together with the number of the the notified body that was engaged in the conformity assessment, e.g. CE$_{0123}$.

A reputable manufacturer will give a list of applied harmonized standards and other regulations e.g. EN 13060, EN 554 etc.

### 3. How to identify these facts with the product?

a) The program equipment of the device includes, beside the test programs such as Vacuum test and Bowie & Dick test, also a test program for hollow items type A called Helix test.
b) The software includes a type B sterilization program or a program for hollow loads.
c) The devices are provided with a powerfull vacuun pump that can reach an underpressure of –87 kPa during the evacuation (deaeration) and enables therefore to shorten the sterilization program Wrapped instruments 134 °C/ /10 min. to 134 °C/7 min and the program Unwrapped instruments to 134 °C/4 min.
d) The product, its packing and Instructions for use shall bear the CE mark together with the number of the notified body that was engaged in the conformity assessment.
e) By law, there must be a conformity mark with the number of the notified body e.g. CE$_{0123}$ placed on the product, e.g. next to the serial label. Some manufacturers present the conformity mark also in their hand-out.
f) Verify, whether the circuits of drain and supply water are separated properly and whether the condensate is not used repeatedly.

### 4. What are the risks of hot air sterilization?

a) Hot air sterilization is not able to inactivacte prions at the temperatures of 160–180 °C. It is only possible at the temperature as high as 1 000 °C. (Steam sterilization inactivates prions with the sterilization process of 134 °C/18 min provided that there was an alkaline washing performed during the pre-sterilization treatment)
b) It does not sterilize textiles, cellulose, paper, thermally sensitive materials and hollow items (Steam sterilization sterilizes everything except thermally sensitive materials below 121 °C).
c) The high temperature of the hot air sterilization "makes the blades of instruments blunt".
d) Duration of the sterilization cycle is as much as three times so long as that of the steam sterilization. It saves neither time nor energy.
e) There is usually an insoluble problem with the old technology how to keep the deviation of the actual temperature from the preset one within acceptable limits.

### 5. What are the types of small steam sterilizers or sterilization programs defined by the standard EN 13060?

The standard EN 13060 does not define types of sterilizers, as they were specified in the former version of the draft standard. It defines unambiguously types of sterilization cycles according to the type of the material to be sterilized.

Types of sterilization cycles:

a) type B – is intended for sterilization of all materials and load types, especially with regard to the requirements to sterilize hollow items through fractioned vacuum
b) type N – is intended only for sterilization of unwrapped solid items
c) type S – is intended only for sterilization of items specified by the manufacturer

The sterilization of hollow items without the necessity for the operator to investigate, which type of hollow and of wrapped material is to be sterilized, can be successful only with steam sterilizers having the type B sterilization cycles. In other cases, when using other cycle types (S and N), it is the healthcare provider's responsibility to properly assess the content and type of a load.


### 6. What does the vacuum pump serve for?

Vaccum pump is a device that is a part of the sterilizer and enables to remove the air from porous and hollow items so that the access of the sterilization medium (steam) to all parts of the load to be sterilized is ensured. The power of the vacuum pump is important in the phase of fractioned vacuum with the underpressure of –87 kPa for sterilization of all kinds of porous and hollow items. That is why there are different prices of the devices having the same appearance, nevertheless the vacuum pump of which is cheaper and less powerful.

Therefore it is necessary to consult these aspects with the distributor before purchasing.

### 7. What is fractioned vacuum?

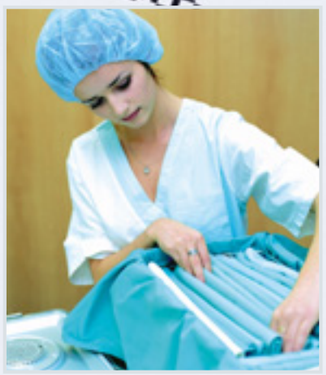
Fractioned vacuum consists of at least three consequent evacuations and is performed before the sterilization process itself so that the condition for sterilization of porous items is fulfilled. In the past and frequently in the recent time, an offer of the sterilization technology with only one vacuum stage can appear on the market. However, this technology is not appropriate for sterilization of hollow items.

### 8. What about the documentation of the sterilization cycle?

The quality system requires to document the courses of sterilization processes. The sterilization process documentation can be arranged in a modern way, so that all records can be identified unambiguously without danger of being affected by a human error. There are offers of communication interfaces RS 232 that enable the application of suitable software with the possibility to be connected to your computer directly at the workplace.

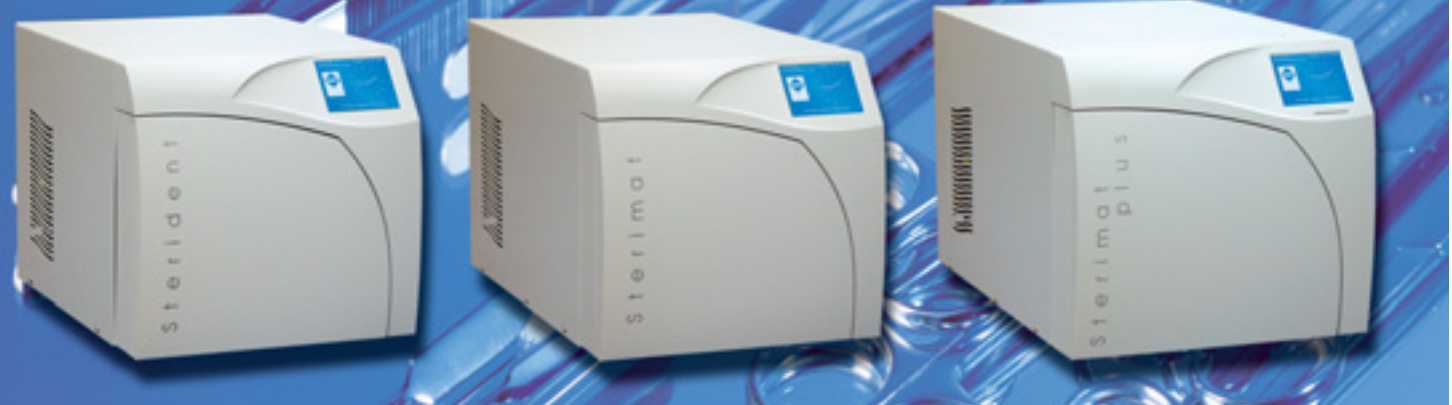







**Do buy without compromises!**

# New standard
# New requirements
# New generation of small steam sterilizers




### STERIDENT (15 l)
- utilization especially at stomatological workplaces

### STERIMAT (20 l)
- wide range of utilization at medical workplaces

### STERIMAT PLUS (25 l)
- utilization especially at surgical workplaces

## Small steam sterilizers – STERIDENT, STERIMAT, STERIMAT PLUS

- meet, without exception, requirements of EU technical and legislative regulations, the conformity mark CE0123 is a guaranty that the products are in compliance with the EU legislative
- offer a design with four patents that is protected by the industrial pattern (patented system of steam regulation and generation, patented system of unique hardware, patented system of door closing, patented compound function of pump)

CLASS B CE 0123

## Ask for information about other products


Hot-air sterilizer **STERICELL** 22, 55, 111, 222 and 404 l

Steam sterilizer **UNISTERI** 70 l

Steam sterilizer **STERIVAP HP** 140–1 275 l

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