

European Standard

EN 13060 • Small water steam sterilizers

Small steam sterilizers are used for materials and equipment which are likely to come into contact with blood or body fluids. They are widely used for hygiene and infection control in general medical practices, dentistry, veterinary, facilities for beauty therapists, tattooists and body-piercers.

The European Standard EN 13060 was enforced in June 2004.

It is THE technical reference par excellence and raises the performance level of small steam sterilizers up to medical grade, ensuring the prevention of cross infection.

It includes fundamental sterilization concepts such as:

- Description of the types of load and the relevant types of cycle (B, S, and N).
- Proper steam penetration into the load and adequate air removal.
- Critical parameters: temperature, pressure and time.
- Test methods and validation of sterilization processes.

Load type classification

The very specific loads used within the above mentioned fields of application call for different performance requirements of the sterilization cycles. The Norm specifies different types of load and the corresponding test methods: unwrapped solid products, full porous load, small porous load and porous items, hollow loads, bagged, single and double wrapped products.



Cycle type classification



N cycle: exclusively for **N**aked solid products.
No transportation, no storage, for immediate use only.

S cycle: only for **S**pecific products as specified by the manufacturer (cycle table). It is essential that this cycle is used only for the types of load it was designed for.

B cycle: Provides medical grade sterilization as per a **B**ig sterilizer. It will process **all** types of load specified in the Standard.

Important

It is the user's responsibility to ensure that the cycle selected is suitable for the types of load to be sterilized.
Not all sterilizers / cycles are appropriate for all types of load.

Lisa[®]



The Concept: Totally Class B

W&H are aware that a sterilizer should be user-friendly and always give reliable and consistent results.

Since **ONLY** the Class B cycle provides safe sterilization of all types of load, the Lisa sterilizers were designed to provide exclusively **Class B** cycles, no Class S or N.

This means that all cycles have the same profile which always includes fractioned pre-vacuum and complete pulsed vacuum drying.



No specific training on the load type selection required for the user.

The selected cycle is **always correct** for the types of load to be sterilized.

Totally safe sterilization

releasing the user's responsibility!



➤ Conformity - Non conformity?

How can professionals be sure that the sterilizer they are to purchase is in full compliance with the new European Norm EN 13060:2004? ... By asking for the following documentation:

➤ **Declaration of conformity**

The Norm EN 13060:2004 **MUST** be mentioned.

➤ **Works test**

It is the final validation test to be performed on **every** sterilizer before it is released for use. It guarantees to the user that all cycles are suitable for the types of load they were designed for.

➤ **Detailed cycle table providing:**

- The types of cycle available: B, S or N.
- The types of load each cycle is and is not designed for.
- The maximum load mass for both solid and porous loads.



STERILIZATION

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