gke develops and produces cleaning and sterilization monitoring and documentation materials.

Cleaning and sterilization processes are used to reprocess medical devices. Washer/disinfectors and sterilizers are regarded as medical devices. The indicators used for monitoring and documentation are no medical devices. Therefore, biological and chemical indicators are not allowed to carry a CE-mark according to the new Medical Device Regulation (MDR)

The following background information is taken from the “Guide to the implementation of directives based on the New Approach and the Global Approach” published by the European Commission. This document is available on the **gke** homepage www.gke.eu under „Downloads / Laws / Regulations“.

Standards of security relevant areas

Among the technical standards the standards in the security relevant area have an exceptional position: Their application is mandatory. Other standards “only” determine the state of the art. If the product has been tested for standard conformity, the CE-mark has to be put on the product and the declaration of conformity has to be presented to surveillance authorities.

Mostly the manufacturer or his authorized person can check and confirm conformity of class I medical devices. Exceptions are complex medical devices or sterilizers (class II a, II b or III): A notified body to check conformity with the standards has to be involved.

Which products have to carry a CE-mark?

All products concerning the scope of one or more of the EU-guidelines regarding product security, have to carry a CE-mark. There are more than 20 EU-guidelines concerning product security, e.g. for

- Low voltage devices
- Simple pressure reservoirs
- Toys
- Building products
- Electro-magnetic compatibility *[98/13/EG]* (13) *6.11.1992*
- Machines
- Personal protective equipment
- Non-automatic scales
- Gas consumption appliances
- Hot water boiler
- Explosive materials for civil purposes
- Medical devices
- Explosive areas
- Pleasure crafts
- Elevators
- Cooling and freezing devices
- Pressure devices
- In-vitro diagnostics
- Radio installations and telecommunication equipment for end users, etc.

With the CE-mark the manufacturer or importer documents that the marked product conforms to the requirements of the harmonized guidelines or standards, which have to be applied, and is allowed to market. The CE-mark also may only be applied, if the product belongs to one or more of these harmonized guidelines and it is proven that the requirements are fulfilled.

A product belonging to the scope of one of these guidelines must not be marketed or used without CE-mark. Also the marketing of a product with a CE-mark must not be obstructed as long as there is no reasonable suspicion that the CE-mark has been applied unjustifiably.

Products which don't belong to one of these guidelines – this is the case with monitoring and documentation materials for sterilization processes – must not carry a CE-mark.

Responsibility

The CE-mark has to be applied by the manufacturer or his EU-representative. Usually the CE-mark is applied on the product itself or on the attached label. If type and consistence of the product don't allow any attachment, the CE-mark is put on the package and on the documents inside. It must be well visible, readable and fixed durably. A minimum font size of 5 mm is required.