

	Technical Information	730-092-EN		V05
	Process indicators of type 1 according to EN ISO 11140-1	Created	06.10.2008	JM
		Changed	02.09.2021	KP
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Packs containing sterile goods have to be marked clearly, if they have passed a sterilization process, to distinguish sterile from untreated (unsterile) packs. These packs are commonly labeled outside with a chemical type 1 indicator according to EN ISO 11140-1 changing colour during sterilization. These so-called process indicators indicate, if the pack has been exposed to a sterilization process or not. They cannot be used to release sterile goods because they are located outside of the pack and therefore do not provide any information about what happens inside. It is just logistic information for the material flow.

It is a wrong widespread assumption that any chemical indicator changing its colour in a sterilization process fulfills the standard requirements for type 1 indicators.

EN ISO 11140-1 contains requirements for type 1 indicators which have to be fulfilled by all process indicators. Amongst others these are the following points:

1. The indicator has to be suitable for the type of sterilization process and has to be clearly marked accordingly. Type 1 indicators for steam sterilization processes have to be marked with

STEAM pictogram

For indicators used in other sterilization processes there are also clearly defined symbols, e.g.

FORM, H₂O₂, EO, etc.

for Formaldehyde, Hydrogen Peroxide („Plasma“) or Ethylene Oxide sterilization processes. An indicator without this symbol is not conforming to the standard.

2. It has to be documented that the indicator is in conformity with the corresponding type according to EN ISO 11140-1. However, not all indicators have enough space on the carrier to print this information. Therefore it is also accepted according to the standard to print this information inside of the direction for use or on the outside label of the box. The GKE documentation labels and batch monitoring and Bowie-Dick test strips have the documentation on the outside labels.
3. The standard requires that the starting and the end colour have to be printed or described in words on the indicator clearly.
4. The colour change from the starting to the end colour must occur within a defined time. So e.g. during steam sterilization a colour change at 121°C must not occur before 3 minutes, but must be finished after a maximum of 10 minutes. The test, if these time frames are kept, must be made in a test sterilizer, a so-called resistometer according to EN ISO 18472.

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5. The colour change may only occur in the intended sterilization process. Process indicators of type 1 for steam sterilization processes must show a colour change in steam (see point 4), but must not change to the end colour e.g. in dry heat at 140°C even after 30 minutes.
6. The indicator colour must be protected against bleeding, so that the colour change can be judged clearly and it is secured that no indicator substance gets in contact with the sterile goods.
7. Self-adhesive products, e.g. labels with a printed process indicator, must adhere safely on the surface of the package and must not fall off during sterilization. Adhesion labels used in office applications, e.g. address labels, are not suitable to be used for steam sterilization, because these materials lose their adhesive strength when they are exposed to steam (134°C) and can fall off.

GKE offers a range of process indicators which fulfill all standard requirements. The indicator characteristics and the correct colour change characteristics as well as the adhesion properties necessary for the different sterilization processes have been tested in the GKE application laboratory in test sterilizers according to EN ISO 18472 which are suitable for the individual sterilization process.