Steam sterilisation processes must be monitored for each batch. A batch monitoring system monitors the steam penetration, which the steriliser itself cannot measure. Therefore, this requirement is included e.g. in the RKI-KRINKO recommendation for the preparation of medical devices* and in the validation standard for steam sterilisation processes EN ISO 17665-1.

A batch monitoring system must be selected so that it is more difficult to sterilize than the actual worst-case load. There are therefore various different batch monitoring systems, see the quotation from the RKI-KRINKO recommendation (p. 1274) ***"PCDs were developed to show a specific difficulty of steam penetration in a sterilisation process. […] There is no universal PCD that is suitable for all types of processes and all purposes".***

Batch monitoring systems consist of a Process Challenge Device (PCD) and corresponding indicator strips. The test sensitivity results from the interaction of the individual components, e.g. the material, the indicator chemistry, the geometry of the indicator and the indicator capsule, etc.. Even the smallest differences can significantly change the sensitivity of the test system.

For this reason it is not possible to combine components from different manufacturers. The result would be a completely new test whose properties are completely unknown and whose test results would therefore be completely worthless.

The GKE *Steri-Record*® Process Challenge Devices (PCDs) are entirely developed by the GKE R&D department and are manufactured in accordance to the corresponding standards (the Bowie-Dick-Simulation test according to EN 285 and EN ISO 11140-4 and the batch monitoring system according to EN 867-5, new EN ISO 11140-6).

Our manufacturing process is controlled by a certified quality management system according to EN ISO 13485.

The sensitivity of all PCD systems is guaranteed when used together with the GKE indicators only. Using chemical indicators from other brands will influence the sensitivity of our calibrated products dramatically.

If third party indicators are used inside GKE PCD:

1. **Net capsule volume**
   The effective capsule volume is the capsule volume of the empty PCD minus the volume of the indicator. The volume of the indicator is determined by the porosity and dimensions of the indicator carrier and is varying quite dramatically just using another paper material thus changing the net capsule volume up to 50%. The capsule volume extremely influences the sensitivity of the PCD.

2. **Absorption of humidity from the indicator carrier**

Indicator carriers consist of several materials, like paper, adhesive and silicon backing material. Those materials have chemically active functions like OH-groups and absorb smaller or bigger amounts of humidity. Therefore the humidity left in the capsule volume is heavily influenced by that material. The amount of humidity left is important for the colour change characteristics and therefore for the total sensitivity of the type 2 indicator system.

3. Indicator colour

There are several different types of chemical compositions used to produce chemical indicators to monitor steam sterilization processes. The specifications written in the International Standard EN ISO 11140 series for type 1, 4, 5 and 6 are standards for indictor strips being placed in the sterilization chamber or packs but have no descriptions for the special PCD use, where air removal and steam penetration are tested.

There are large differences in humidity response between the different indicators and therefore different reactions will occur.

4. Position of the indicator inside the capsule

In order to achieve a reproducible response and best sensitivity results it is important to always place the indicator itself at the worst-case area inside the capsule of the PCD. Some indicators are positioned outside of the worst-case position. Therefore they cannot detect non-condensable gases in the worst case places. Other indicators are positioned differently depending in which way the indicator is inserted.

5. Non-condensable gases

When reacting with steam some indicators create CO_2 thus creating a non-condensable gas by itself which is also influencing the total sensitivity of the PCD system.

Because of the high variation of the different indicators on the market GKE cannot guarantee any function of the GKE PCD systems, if indicators of brands other than GKE are used.

* = Hygiene requirements for the reprocessing of medical devices
Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)