

## for GKE Steri-Record<sup>®</sup> Type 2 Indicator Systems according to EN ISO 11140-1 in hydrogen peroxide sterilization processes



A type 2 indicator system is a combination of a process challenge device (PCD) where a chemical indicator is placed inside to check the hydrogen peroxide penetration conditions.

## **Start Conditions**



All indicator bars have a red/purple starting colour.

If the indicator has already slightly changed before sterilization, it is an indication of wrong storage or expired indicators. These indicators should not be used anymore.

## **Pass Conditions**

The batch can be released when all four colour bars of the indicator have turned to yellow (see image) and all other critical process variables and their parameters such as temperature, dosage and sterilization time correspond to the specifications.

Hydrogen peroxide sterilization processes are not standardized and have different process conditions, therefore the indicator may come out with slightly different contrast shades under pass conditions.



All colour segments are yellow

## **Fail conditions**

The example shown below demonstrates insufficient hydrogen peroxide penetration which may be due to various reasons. If one of the results shown below is found after sterilization, the respective batch must not be released and requires reprocessing.



Insufficient hydrogen peroxide penetration all colour segments are orange-yellow or even red

A failure of the indicator system is not a conclusive proof that the fault is necessarily associated to the sterilizer itself (insufficient air removal or leakages), but may well be due to external causes such as insufficient hydrogen peroxide supply or heavy loads. Therefore, repeat sterilization.



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