

# Instructions for Use

## Chemical Indicator Type 2 PCD Indicator Systems according to EN ISO 11140-1 for Hydrogen Peroxide sterilization processes

Art.-No.	Quantity [pc]	Product Code	Description	SV/Dosage
214-201	250	C-E-PM	To be used inside a process challenge device	50 °C, 2.6 mg/l H <sub>2</sub> O <sub>2</sub> , 2 min

### Application

The GKE H<sub>2</sub>O<sub>2</sub> chemical indicators is placed into an appropriate process challenge device (PCD) are used to monitor sterilization processes with vaporized hydrogen peroxide. The type 2 indicator system consists of a PCD and an indicator inside. It should represent the worst-case penetration condition of load configuration and is used for routine monitoring. The indicator system is positioned outside the load in the sterilizer.

### Product Description

Each indicator strip contains 4 indicator bars which are printed on a self-adhesive plastic carrier for documentation. The chemical substances of the indicator are protected against bleeding by a polymer binder coating and therefore, do not release substances. They are non-toxic.









### Performance characteristics

The indicator system design is in accordance with EN ISO 11140-1 Type 2. Since there is currently no international standardization for H<sub>2</sub>O<sub>2</sub> testing, the indicator is measured in a special test sterilizer developed by GKE.

### Handling Information

1. Open the cap and make sure the seal ring in the cap is in good condition.
2. Take out an indicator strip from the sheet and fold it that the indicator bars are inside the folding and place it in the white holder with the fold toward the screw cap of the PCD.
3. Insert the white indicator holder into the PCD and tighten the cap.
4. Place the test device in the worst-case position outside of the load. The PCD does not require to be put into a pack, pouch or container.
5. Run the sterilization program.
6. On completion of the cycle remove the test device carefully. After cooling down, remove the indicator strip and check the result:
  - If all four bars have turned into the final colour the sterilization process has been successful.
  - If one or more bars remain red or have not turned to the final colour completely this indicates inadequate

penetration of the sterilant (hydrogen peroxide) during the process. In this case do not release the batch.

Starting color			
			
BMS-Test <b>VH2O2</b>			
Final color			
			
BMS-Test <b>VH2O2</b>			

7. The person authorized will decide whether to release the batch or to re-sterilize the load.
8. The indicator is self-adhesive and can be adhered onto the GKE documentation sheet with date, sterilizer and batch number and the signature of the person authorized to do so.

If type 2 indicator systems cannot be used, package monitoring indicators must be placed in the worst-case position in each pack being sterilized.

### Storage and Disposal

1. Always store indicators in the closed foil bag and in the Store all indicators in the original package and away from sterilizer or sterilizing agent. Ideally, keep in a separate room.
2. Store indicators always between 5-30 °C or 41 - 86°F and a humidity of 5 - 80% RH.
3. The vapour of chemicals, especially hydrogen peroxide, may change the indicator before or after sterilization. Therefore, do not store them together with other chemicals.
4. The indicators should not be used after expiry date. They may be disposed with normal waste.

For further technical details please contact your local dealer or GKE directly. We will assist you with any technical questions. Visit our website [www.gke-healthcare.com](http://www.gke-healthcare.com) for more information.

760-009 ED V04 07-2024