

gke Steri-Record[®] Batch Monitoring System

for complex and solid instruments and porous goods

for steam sterilization processes

STEAM



Application

The **gke Steri-Record[®]** batch monitoring systems (BMS) are used for routine monitoring in steam sterilization processes in each cycle to detect insufficient air removal, leaks and/or non condensable gases (NCG) in steam. The BMS is designed to monitor steam penetration at the most difficult positions inside of the sterilization load. Monitoring temperature and pressure alone does not provide sufficient information to ensure steam penetration. This type of BMS simulates the penetration requirements of complex hollow minimal invasive surgical (MIS) instruments and tubes, solid instruments and porous loads.

Product description

The **gke Steri-Record[®] Compact-PCD[®]** consists of an external plastic casing with an internal stainless steel tube and capsule holding the indicator. Two BMS versions with the same performance characteristics are available:

- Compact-PCD[®] with a round cross section and a stainless steel bracket. It can be put vertically on a loading rack or placed horizontally on the bracket.
- Compact-PCD[®] with an oval cross section which can be placed horizontally on the flat side of the PCD. This type of construction with a flat height of 2,5 cm allows the PCD to be used in table-top sterilizers.

Both versions are re-usable and can be used for a considerable number of sterilization cycles.

Performance Characteristics

This **gke Steri-Record[®]** BMS is a type 2 indicator according EN ISO 11140-1, consisting of a „specific test load“ (Process Challenge Device = PCD) and “indicator” (indicator strip). The BMS is a hollow load test according to EN 867-5. The **gke** BMS has been validated from a laboratory accredited according to the standard EN ISO 17025. A test report is available on request.

Operation Description

Two indicator strips can be selected according to the program used and are available with different stated values:

1. 134°C, 3 min / 121°C, 15 min; standard cycle
2. 134°C, 18 min; prion cycle

If all four bars of the chemical indicator turn from yellow (standard cycle) /pink (prion cycle) to black it is an indication of sufficient steam penetration inside the PCD.

	Sufficient temperature, time and steam penetration
	Insufficient air removal and steam penetration
	Temperature achieved, but no air removal and no steam penetration
	Insufficient temperature, no air removal and no steam penetration

This result ensures air removal and steam penetration into the whole load under the condition that the PCD is representing the load configuration.

Benefits

- Indicator strips for standard and prion sterilization cycles are available.
- Monitoring of sterility inside of complex hollow instruments, tubes and porous goods not provided by recording pressure, temperature and steam quality in the chamber and/or using exposed indicator strips.
- Cost effective due to multiple use. Only one indicator strips is required for each sterilization process instead of one in each pack.
- Easy interpretation of the results due to precise colour change.
- Reproducibility of the results for a long period of time.
- All information relevant to the process is supplied on completion of the process so that the authorized person can release the batch without opening the packs.
- The indicator colour chemistry is a non reversible chemical reaction and remains colour-fast over time if they are not stored with other chemicals.

- Environmentally friendly, no unnecessary waste.
- The graduated colour change of the indicator bars informs about the kind and magnitude of air removal and steam penetration inside the sterilizer and non-condensable gases in steam.
- **gke** self-adhesive labels simplify recording with the **gke Steri-Record[®]** documentation system.
- All **gke** chemical indicators are protected from bleeding by a polymer binder and surface coating can be disposed with normal garbage.
- The screw cap consists of a highly thermal resistant material and stainless steel sandwich construction that protects hands from high temperatures. The chemical indicator may be easily removed and evaluated on completion of each cycle.
- The Compact-PCD[®] can be used for a considerable number of cycles. All important parts are made of stainless steel or thermal resistant polymers.

Order information

Each start-up kit contains a Compact-PCD[®] and 100 integrating indicator strips for standard steam sterilization processes. All test devices are also available separately. The indicator strips are available as refill packs for standard and prion steam sterilization processes and also contain a seal ring for the screw cap.

Art.-No.	Product Code	Content		Stated Value	Application	
211-263	C-S-PM-HL-RCPCD-KIT	1 + 100	Compact-PCD [®] <u>round</u> (colour: orange), integrating indicator strips	134°C, 3 min 121°C, 15 min	Batch Monitoring System for complex instruments, Hollow load test according to EN 867-5	
211-264	C-S-PM-HL-OCPCD-KIT		Compact-PCD [®] <u>oval</u> (colour: orange), integrating indicator strips			
200-021	PM-HL-RCPCD	1	Compact-PCD [®] <u>round</u> (colour: orange)	-		
200-026	PM-HL-OCPCD		Compact-PCD [®] <u>oval</u> (colour: orange)			
211-252	C-S-PM-SV1	250	Refill pack integrating indicator strips, + 1 seal ring	134°C, 3 min 121°C, 15 min		Indicator strips for all gke BMS to be used in standard cycles
211-255		500				
211-211	C-S-PM-SV2	100		134°C, 18 min	Indicator strips for all gke BMS to be used in prion cycles	
211-212		250				
211-215		500				

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700-006 EN V05 08/2018

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