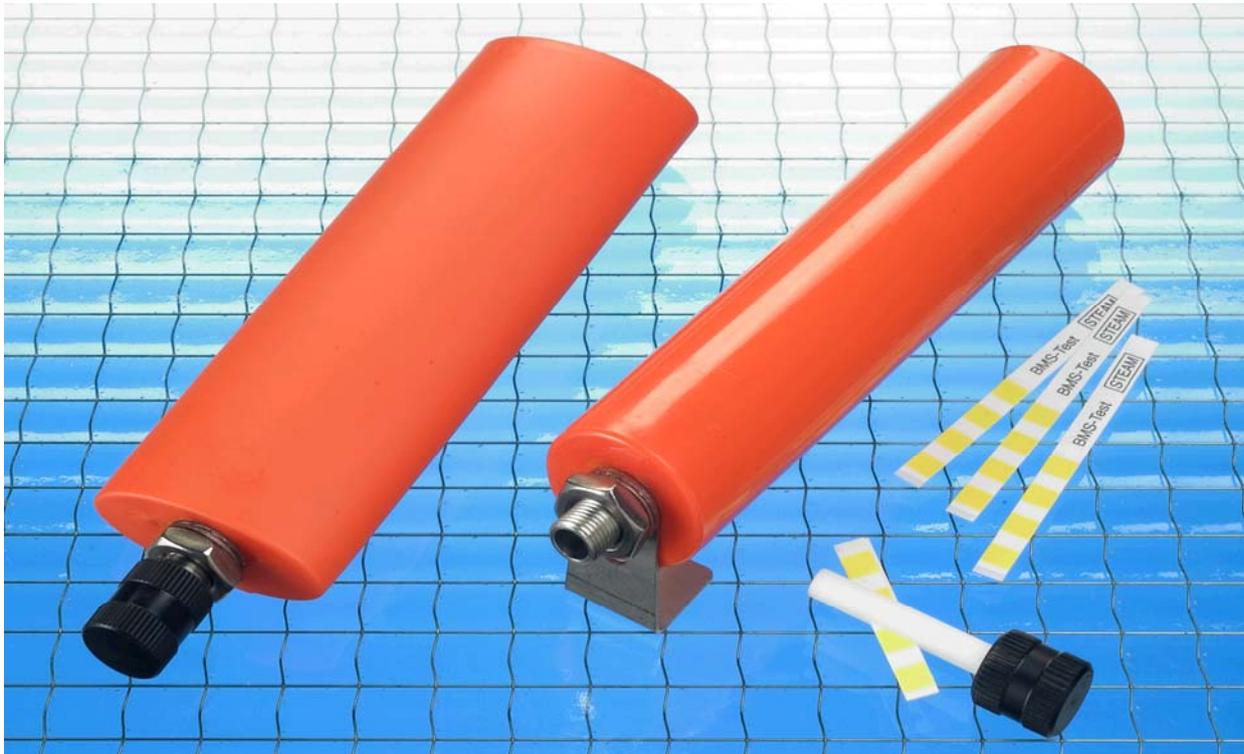


# *gke* Steri-Record<sup>®</sup> Batch Monitoring System (BMS)

for complex hollow and solid instruments and porous loads  
for steam sterilization processes

STEAM



## Application

The *gke* Steri-Record<sup>®</sup> 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. Monitoring temperature and pressure alone does not provide sufficient information to ensure steam penetration. This BMS simulates the penetration requirements of complex hollow minimal invasive surgical (MIS) instruments, tubes, solid instruments and porous loads.

## Product description

The *gke* Steri-Record<sup>®</sup> Compact-PCD<sup>®</sup> (process challenge device) consists of an external plastic casing with an internal stainless steel tube and capsule holding the indicator. Two PCDs with the same performance characteristics are available\*:

- Compact-PCD<sup>®</sup> 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<sup>®</sup> 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.

\* The performance characteristics are identical in the test cycles required by the standard. There can be small differences if using cycles that differ from the test cycles.

## Performance characteristics

The *gke* BMS is a class 2 indicator according to EN ISO 11140-1, consisting of a „specific test load“ (Process Challenge Device = PCD) and “indicator system” (indicator strip). The BMS is a hollow load test according to EN 867-5. This standard will be modified into the new standard EN ISO 11140-6 and is covered by EN 285 (large sterilizers) and EN ISO 13060 (small sterilizers type B) and fulfils the requirements in terms of air removal and steam penetration. This test has been validated by an accredited laboratory according to EN ISO 17025 (a test report is available on request).

## Operation description

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

1. 134°C, 3,5 min or 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. This result ensures air removal and steam penetration into the whole load under the condition that the PCD is representing the load configuration.

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

Colour change of standard indicator strips

## Benefits

- Indicator strips for standard and prion sterilization cycles are available.
- Only the use of a BMS allows the 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 strip is required for each sterilization process instead of one in each pack.
- All information relevant to release the process is supplied on completion of the process so that the authorized person can release the batch without opening the pack for the internal packaging indicator.
- Easy interpretation of the results due to precise colour change.
- Continuous reproducibility of the results.
- Environmentally friendly, no unnecessary waste.

- The graduated colour change of the indicator bars informs about the magnitude of air removal and steam penetration inside the sterilizer and non-condensable gases in steam.
- The indicator colour chemistry is a non-reversible chemical reaction and remains colour-fast over time.
- All *gke* chemical indicators are protected from bleeding by a polymer binder and surface coating and can be disposed off with normal garbage.
- *gke* self-adhesive labels simplify recording with the *gke Steri-Record*<sup>®</sup> documentation system.
- Selection between two Compact-PCD<sup>®</sup> versions - ideal handling for each chamber size and load.
- The screw-cap consists of a highly thermal resistant material and stainless steel sandwich-construction that protects hands from high temperatures. The indicator may be easily removed and evaluated on completion of each cycle.
- The Compact-PCD<sup>®</sup> can be used for a large 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<sup>®</sup> and 100 integrating indicator strips for standard steam sterilization processes as well as a documentation sheet to be copied before daily use. 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 sealing kit for the screw cap.

Art.-No.	Product code	Quantity	Content	Stated Value	Application	
211-263	Chemo-D-CH-1-C-HA	1 + 100	Compact-PCD <sup>®</sup> <u>round</u> cross section (colour: orange), integrating indicator strips	134°C, 3.5 min 121°C, 15 min	Monitoring complex hollow and solid instruments and porous loads in steam sterilization processes according to EN 867-5 hollow load test	
211-264	Chemo-D-CH-1-OC-HA		Compact-PCD <sup>®</sup> <u>oval</u> cross section (colour: orange), integrating indicator strips			
200-021	Chemo-D-CH-PCD-C-HA	1	Compact-PCD <sup>®</sup> <u>round</u> cross section (colour: orange)	-		
200-026	Chemo-D-CH-PCD-OC-HA		Compact-PCD <sup>®</sup> <u>oval</u> cross section (colour: orange)			
211-252	Chemo-D-CH-2,5	250	Refill pack integrating indicator strips, + 1 sealing kit	134°C, 3.5 min 121°C, 15 min		Indicator strips for all <i>gke</i> BMS to be used in standard cycles
211-255	Chemo-D-CH-5	500				
211-211	Chemo-D-CH-PP-1	100		134°C, 18 min	Indicator strips for all <i>gke</i> BMS to be used in prion cycles	
211-212	Chemo-D-CH-PP-2,5	250				
211-215	Chemo-D-CH-PP-5	500				

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