

## Tattoo-BMS Batch Monitoring System to monitor tattoo instruments



### Application

The GKE Steri-Record® Tattoo-BMS is used for routine monitoring of Tattoo loads in steam sterilization processes in each cycle to detect insufficient air removal, leaks and/or non condensable gases (NCG) in steam.

The European Medical Device Directive (MDD) requires from manufacturers bringing medical devices to the market that they are checked by a test laboratory according to EN ISO 17664. This test should ensure that a medical device can be reprocessed reproducibly (cleaned, disinfected and sterilized) with the methods described in the directions for use of the manufacturer. It is recommended that users should request detailed reprocessing information from the manufacturer to ensure that instruments can be reprocessed properly.

### Product Description

This GKE Steri-Record® Tattoo-BMS is a type 2 indicator according to EN ISO 11140-1 consisting of a "specific test load" (Process Challenge Device = PCD) with a specifically selected external case containing an internal stainless steel tube connected with a stainless steel capsule holding the "indicator" (indicator strip) inside. The oval cross section of the PCD with a flat height of 2,5 cm allows the PCD to be placed horizontally in a table-top sterilizer.

### Performance Characteristics

The Tattoo-BMS is validated using the "equivalence test" method according to the German Standard Draft DIN 58921 simulating a typical Tattoo instrument load configuration (as shown in the picture above). Hollow Tattoo instruments have the most difficult steam

penetration characteristics in that load. The "equivalence test" is carried out in a laboratory accredited according to the standard EN ISO 17025. A test report is available on request.

The GKE Steri-Record® Tattoo-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.

### Operation Description

If all four bars of the chemical indicator turn from yellow 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, no air removal and no steam penetration



## Benefits

- The GKE Steri-Record® Tattoo BMS is the first Batch-Monitoring-System tailored to monitor Tattoo loads in steam sterilization processes.
- The use of this Tattoo-BMS allows the monitoring of sterility inside of Tattoo instruments not provided by recording pressure, temperature and steam quality in the chamber and/or using exposed indicator strips.
- The batch can be released without opening the pack to check the internal packaging indicator.
- All information relevant to release the load is supplied on completion of the process so that the person authorized can release the batch.
- Cost effective. Only one indicator strip is required for each sterilization process instead of one in each pack.
- Easy interpretation of the results due to precise colour change.
- The graduated colour change of the indicator bars informs about the magnitude of air removal and steam penetration into the PCD.
- Environmentally friendly, no unnecessary waste.
- GKE self-adhesive labels simplify recording with the GKE Steri-Record® documentation system.
- The indicator colour chemistry is a non-reversible chemical reaction. The indicator strip can be documented proof for several years without changing back to its original colour.
- 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 innovative design and rationalized production provide a sensitive and cost effective test, where the PCD can be used for 5.000-10.000 cycles. Its specifications remain constant over the lifetime of the device.
- The Compact-PCD® can be used for a large number of cycles. All important parts are made of stainless steel or thermal resistant polymers. Seals are replaced easily.
- Continuous reproducibility of the results over the lifetime of the PCD if seals are replaced precautiously.
- All GKE chemical indicators are protected from bleeding by a polymer binder and surface coating and can be disposed with normal garbage.
- Assurance that only sterile released packs are used.

## Order Information

Each start-up kit contains one Compact-PCD® and 100 integrating indicator strips. Test devices are available separately as well. The indicator strips are available as refill packs without test devices containing a seal ring for the screw cap.

Art. No.	Quantity	Product Code	Content	Application
211-271	1 + 100	<b>C-S-BMS-Tattoo-OCPCD-KIT</b>	Compact-PCD® Tattoo BMS <u>oval</u> cross section (colour: black), integrating indicator strips	Monitoring tattoo loads in steam sterilization processes
200-071	1	<b>C-S-BMS-Tattoo-OCPCD</b>	Compact-PCD® Tattoo BMS <u>oval</u> cross section (colour: black)	
211-251	100	<b>C-S-PM-SV1</b>	Refill pack integrating indicator strips, + 1 sealing kit	for all GKE BMS and PMS to be used in standard cycles
211-252	250			
211-255	500			

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