Declaration of Conformity

GKE Steri-Record® Dental Batch Monitoring System (Dental-BMS)

C-S-BMS-Dental-OCPCD-KIT
Art. No.: 211-281

Indicator system according to EN ISO 11140-1 type 2, consisting of a process challenge device and an indicator to proof the air removal and steam penetration of dental instruments in steam sterilization processes

The above-mentioned chemical indicator systems type 2 are manufactured according to the corresponding standards and therefore conform in general with the standard requirements, which are not changing from batch to batch. In contrast to biological indicators with batch-related modifications, an individual batch-related certificate does not make sense because the specifications of chemical indicators and chemical indicator systems do not change batch by batch.

This Dental-BMS is used to monitor air removal and steam penetration of dental instruments in steam sterilization processes to prove sterility of a full instrument load. It has been tested with an equivalence test using the dental instruments shown as the reference load configuration. The validation report is available on request. The tests have been carried out from an accredited test laboratory on the test method basis of DIN 58921.

The inside of hand pieces are the most difficult part of an instrument to be sterilized. The successful sterilization of hand pieces does not only depend on the efficiency of the sterilizer program but also on the construction of the hand piece. There are instruments on the market which cannot be sterilized with the most efficient steam sterilization processes due to inappropriate construction preventing steam penetration in sealed areas resulting in non-sterility. Therefore only instruments should be used which are sold by the manufacturer with a validated reprocessing method according EN ISO 17664.

The Dental-BMS is used to assure that the sterilization program is able to sterilize dental instruments.

The Dental-BMS monitors the efficacy of the penetration characteristics of sterilization processes. During the sterilization process the main physical parameters, pressure and temperature, are usually recorded. The GKE Steri-Record® batch monitoring system in addition monitors air removal, potential leaks and the content of non-condensable gases to assure the total penetration of steam into the packs and into hollow devices and therefore sterility at the worst-case location inside the instruments.

The Dental-BMS has been validated to guarantee sterility in dental loads, if the minimum sterilization process conditions of 134 °C – 3 minutes or 121°C – 15 minutes are achieved. All bars of the chemical indicator in the PCD must change its colour from yellow to black. If some bars of the chemical indicator remain yellow or if the color changes only to beige-brown after a longer sterilization period, non-condensable gases are present inside of the PCD with the consequence of a potential malfunction in part of the process.

The BMS consists of an external plastic case with an internal stainless steel tube closed at one end with a capsule holding the chemical indicator. The results of the test system are only valid, if the PCD is used together with the original GKE Steri-Record® indicator strips. Using other indicator strips changes the sensitivity of the test system, so that these results cannot be used to secure the sterilization process.

To prevent leakage, the washer in the capsule should be exchanged precautionary after approximately 500 cycles.

This document certifies that the above performance criteria and the GKE test requirements for quality control are met. The continuous quality is guaranteed by our quality management system according to EN ISO 13485*.

Waldems, 2021-06-23

Dipl.-Ing. Dr. Ulrich Kaiser
R & D-Manager

* This certificate is available on the GKE homepage www.gke.eu.

751-009-EN V08