

Declaration of Conformity

GKE Steri-Record® Batch Monitoring Systems (BMS) including Refill Packs for Steam Sterilization Processes

Art.-No. *	GKE Product Name	Content		Product Description of the Process Challenge Device (PCD)	Indicator according EN ISO 11140-1 type 2 using the following reference for equivalence
		PCD	Indicator strips		
211-253	C-S-PM-SHL-RCPCD-KIT	1	100	Compact PCD (C-PCD), round version	lower requirements than EN ISO 11140-6
200-020	PM-SHL-RCPCD	1	-		
211-254	C-S-PM-SHL-OCPCD-KIT	1	100	Compact PCD (C- PCD), oval version	
200-024	PM-SHL-OCPCD	1	-		
200-150	PM-HPCD-2-150	1	-	Helix-PCD	according EN ISO 11140-6 for routine monitoring** and according EN 285 for operational qualification
211-263	C-S-PM-HL-RCPCD-KIT	1	100	Compact PCD, (C- PCD), round version	
200-021	PM-HL-RCPCD	1	-		
211-264	C-S-PM-HL-OCPCD-KIT	1	100	Compact PCD (C- PCD), oval version	
200-026	PM-HL-OCPCD	1	-		
200-029	PM-HDH-RCPCD	1	-	Compact-PCD, round version, red	higher requirements than EN ISO 11140-6**
200-030	PM-VHDH-RCPCD	1	-	Compact-PCD, round version, brown	much higher requirements than EN ISO 11140-6**
211-251	C-S-PM-SV1	-	100	Indicator refill packs for all BMS above, SV = 134°C; 3 min and 121°C; 15 min	Indicator strips for above mentioned test devices
211-252		-	250		
211-255		-	500		
211-211	C-S-PM-SV2	-	100	Indicator refill pack for BMS using the prion program SV = 134°C; 18 min	
211-212		-	250		
211-215		-	500		

(*) On all GKE packages, an additional letter code has been added to the 6-digit article number. The additional letter code refers to the language and/or customized version. It is only added on the outside label, the inside of the pack is identical to the article numbers and the above table. All articles with the same 6-digit number have the same specifications.

** Test reports are available on request.

All GKE Steri-Record® batch monitoring systems (BMS) are indicator systems according to EN ISO 11140-1 type 2, consisting of a process challenge device (PCD) with a capsule hosting a chemical indicator inside and tested in a resistometer according EN ISO 18472. The indicator systems are used to monitor the temperature and time integral as well as the efficacy of the penetration characteristics of steam in a sterilization process.

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.

The Compact-PCD®s consist of an external plastic case with an internal stainless-steel tube holding the indicator, available in round and oval design. The PCDs can be used in small and large sterilizers for solid instruments, porous loads and complex minimal invasive instrumentation. All BMS can be used for routine batch monitoring in steam sterilization processes. During process validation the information should be provided which BMS should be used for routine monitoring. Both versions meet the same specification. GKE guarantees a life span of more than 10.000 cycles under the condition the PCD is used according to the directions for use.

During the sterilization process the main physical parameters, pressure and temperature, can be monitored and are usually recorded by the sterilizers. The GKE Steri-Record®-batch monitoring systems in addition monitor air removal, potential leaks and the presence of non-condensable gases in steam to assure the total penetration of steam into packs and into hollow devices and therefore sterility at the worst cases inside the process. The PCDs have been calibrated, using 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 change colour from yellow to black. If some bars of the chemical indicator remain yellow or if the colour changes only to yellow-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 sterilization times may be increased up to 10 minutes at 134 °C or 30 minutes at 121 °C. For 134°C, 18 min (prion program) we recommend to use the specific indicator strip (refill pack art. no. 211-211; -212; -215, see above).

Above GKE Steri-Record® batch monitoring systems can't be used for sterilization processes which achieve the air removal with single vacuum, gravity displacement, steam flashing or overpressure air removal cycles. Depending on the load configuration and packaging an individual validation for those processes is necessary to select a PCD accordingly for batch monitoring purposes.

According to EN ISO 11140-1, 5.9 the PCD and indicators do not release any particles or toxic substances in quantities to cause a health hazard. The colour of the indicators remains constant after the sterilization process has passed successfully and does not fade back to the colour before sterilization for at least 5 years under the condition the indicator is not stored in contact with oxidation agents like H2O2 or other chemicals.

The test results are only valid if original GKE Steri-Record® indicator strips with original GKE Steri-Record® test devices (PCD's) are used and the instructions for use are applied.

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



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

Waldems, 2024-01-25

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

751-006-EN V14