

## Declaration of Conformity

***gke*-Steri-Record® self-contained biological indicators according to EN ISO 11138 series and their use in special PCDs (class 2 indicators according to EN ISO 11140-1)**

***gke* Steri-Record® Self-contained Mini-Bio-Plus Biological Indicators (SCBI)**

Art.-No.*	Product code	Quantity/pack	Pop.	Sterilization process	Colour of cap	Colour change of				Incubation temperature	Biological indicator spores
						Indicators on label		growth media in SCBIs after sterilization and incubation			
						before	after	sterile	unsterile		
324-501	B-S-MBP-10-5	10	10 <sup>5</sup>	Steam 132-137°C	Light blue	Blue	Brown	Purple	Yellow-green	55-60°C	<i>G. Stearothermophilus</i>
324-505		50									
324-510		100									
324-551		10									
324-555		50									
324-550	Instant-MBP-SCBI	100									
324-601	B-S-MBP-10-6	10	10 <sup>5</sup>	Steam 132-137°C	Dark blue	Blue	Brown	Purple	Yellow-green	55-60°C	<i>G. Stearothermophilus</i>
324-605		50									
324-610		100									
324-651		10									
324-655		50									
324-650	Instant-MBP-SCBI	100									
325-601	B-F-MBP-10-6	10	10 <sup>5</sup>	Formaldehyde	Yellow	Yellow					
325-605		50									
327-601	B-V-MBP-10-6	10	50	Hydrogen peroxide	White	Purple	Pink				
327-605		50									
326-605	B-E-MBP-10-6	50	100	Ethylene oxide	Red	Blue	Green	Green	Yellow-orange	33-37°C	<i>B. Atrophaeus</i>
326-610		100									

***gke* Steri-Record® Bio-Compact-Process Challenge Devices (Bio-C-PCD®)**

Art. no.*	Product code	Bio-C-PCD® version	Sterilant penetration characteristics			
300-011	B-PM-OCPCD-1	oval	minimal requirements regarding penetration characteristics			
300-016	B-PM-RCPCD-1	round				
300-012	B-PM-OCPCD-2	oval	low requirements regarding penetration characteristics			
300-017	B-PM-RCPCD-2	round				
300-013	B-PM-OCPCD-3	oval	less than	hollow load test according to EN 867-5 and draft EN ISO 11140-6		
300-018	B-PM-RCPCD-3	round				
300-014	B-PM-OCPCD-4	oval	equal to			
300-019	B-PM-RCPCD-4	round	more than			
300-015	B-PM-RCPCD-5					

\* Notice: 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 in the above table. All articles with the same 6-digit number have the same specifications.

\*\* Additional Class 5 chemical indicator according to EN ISO 11140-1 that changes its colour from yellow to black to indicate a pass.

All *gke*-Steri-Record®-Bio-C-PCD®s consist of a process challenge device (PCD) with a capsule hosting a self-contained biological indicator (SCBI) inside.

All Bio-C-PCD®s consist of an external plastic case with an internal stainless steel tube, available in round and oval design. 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.

The Bio-C-PCD®s with SCBIs inside are used to monitor the efficacy and penetration characteristics of the sterilization processes listed in the table.

If during the sterilization process the main physical and chemical parameters are present, the SCBI is inactivated under the condition that air removal, potential leaks and the presence of non-condensable gases are not present in the process to assure the total penetration in packs and into hollow devices. Therefore sterility at the worst case penetration conditions in the process is achieved. The PCD 300-014 is calibrated according EN 867-5 using the test method described inside.

The PCDs can be used in small and large sterilizers for solid instruments, porous loads and complex minimal invasive instrumentation. During validation the correct Bio-C-PCD®-system should be selected according to the requirements of the load. Afterwards the selected Bio-C-PCD®-system can be used for routine monitoring.

The test devices do not release any particles or toxic substances.

The test results are only valid, if original *gke* Steri-Record®-Mini-Bio-Plus SCBI with original *gke*-Steri-Record® Bio-C-PCD®s are used together 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 of our products is assured by our quality management system according to EN ISO 13485\*\*\*.



Waldems-Esch, 2012-12-12

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\*\*\* This certificate is available on the *gke*-homepage [www.gke.eu](http://www.gke.eu).

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