Declaration of Conformity

gke *Steri-Record*® Batch Monitoring System for formaldehyde sterilization processes

Art. No.	*gke*-Description	Content	Application
213-260	C-F-PM-HPCD-KIT	1 Helix-PCD + 200 indicator strips	Formaldehyde sterilization processes
213-203	C-F-PM	250 indicator strips	

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 and the above table. All articles with the same 6-digit number have the same specifications.

This batch monitoring test is designed for formaldehyde sterilization processes with differential-pressure-cycles for air removal and steam formaldehyde penetration. It can't be used for formaldehyde sterilization processes without differential pressure cycles.

Instruments and recorders of those sterilizers register pressure and temperature over time. The sufficient air removal, formaldehyde penetration and necessary gas concentration cannot be monitored with physical recording. The *gke-Steri-Record*®-batch monitoring system checks air removal and formaldehyde gas penetration in hollow and packaged goods. The test device has been designed according to EN 14180 and EN 867-5 Hollow load. This standard uses biological indicators, the *gke-Steri-Record*®-batch monitoring system uses formaldehyde sensitive chemical indicators. The colour change of the indicator from yellow to brown is required for formaldehyde gas penetration into the test device.

Formaldehyde sterilization processes are not standardized and vary from manufacturer to manufacturer and sterilizer type. The chemical colour change kinetics have been validated according to biological indicators of EN ISO 11138 part 5. This validation however depends on the individual sterilization process. Therefore a validation of the batch control with biological indicators is required once to check the system under actual process conditions.

If the *gke-Steri-Record*®-batch monitoring system is more difficult to penetrate than any device in the load, the load can be released when the indicator inside the test device has turned to brown.

The test results are only valid, if original *gke*-indicator-strips and test devices are used according to the directions for use.

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, 2013-02-22

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

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