Declaration of Conformity

gke Steri-Record® Batch Monitoring System for ethylene oxide sterilization processes

Art. No.	*gke* Description	Content
212-250	C-E-PM-HPCD-KIT	1 Helix-PCD according EN 1422 + 200 indicator strips according EN ISO 11140-1
200-028	C-E-PM-HPCD	1 Helix-PCD according EN 1422 for chemical indicators or spore strips
300-028	B-E-PM-HPCD	1 Helix-PCD according EN 1422 for SCBI
212-202	C-E-PM	250 chemical indicator strips according EN ISO 11140-1
221-6XX	B-E-H-SS-10-6	100, 500 or 1.000 spore strips B. atrophaeus 10^6
326-6XX	B-E-MBP-10-6	50 or 100 Mini-Bio-Plus SCBI B. atrophaeus 10^6

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 as a type test for ethylene oxide sterilizers according to EN 1422 using differential-pressure-cycles for air removal and ethylene oxide gas penetration. It can't be used for ethylene oxide sterilization processes without differential pressure processes. The standard EN 1422 uses biological indicators, the *gke-Steri-Record*®-batch monitoring system can use biological indicator strips or self-contained biological indicators or chemical indicators. The colour change of the chemical indicator from blue to green is indicative for ethylene oxide gas penetration into the test device.

Instruments and recorders of those sterilizers register pressure and temperature over time. The sufficient air removal, ethylene oxide penetration and necessary gas concentration cannot be monitored with physical recording. The *gke-Steri-Record*®-batch monitoring system checks the air removal and ethylene oxide gas penetration in hollow and packaged goods.

Ethylene oxide 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 11138-2. 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 existing process conditions.

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

The test results are only guaranteed, if original *gke* indicators 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, 2014-07-21

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