

Declaration of Conformity

gke Steri Record[®] Indicators to monitor sterilization processes

are available from *gke* as the following product variations:

<u>BDS introduction packs</u> 211-110 C-S-BDS-EU-HPCD-KIT 211-150 C-S-BDS-EUH-RCPCD-KIT 211-120 C-S-BDS-EU-RCPCD-KIT 211-130 C-S-BDS-USA-RCPCD-KIT			Class 2
<u>Indicator refill pack for all <i>gke</i> BDS-Tests</u> 211-111, -112, -115 C-S-BDS-SV1 pack of 100, 250 or 500 indicator strips			
<u>Batch monitoring introduction packs</u> 211-260 C-S-PM-HL-HPCD-KIT 211-263 C-S-PM-HL-RCPCD-KIT 211-264 C-S-PM-HL-OCPCD-KIT 211-253 C-S-PM-SHL-RCPCD-KIT 211-254 C-S-PM-SHL-OCPCD-KIT			
<u>Indicator refill pack for all <i>gke</i> batch monitoring systems for</u> 211-252, -255 C-S-PM-SV1 (Steam) pack of 250 or 500 indicator strips 212-202 C-E-PM (EO) pack of 250 indicator strips 213-203 C-F-PM (FO) pack of 250 indicator strips 214-203 C-V-PM (H ₂ O ₂) pack of 250 indicator strips			
<u>Package monitoring multi-variable indicators</u> 211-403 C-S-P-4-SV1 (Steam) pack of 3200 labels 212-360 C-E-P-4-SV3 (EO) pack of 3200 labels			Class 4
<u>Package monitoring integrating indicators</u> 211-224; -225, -226 C-S-P-5-SV1 (Steam) pack of 400, 800 or 3200 labels 211-230, -235 C-S-P-5-78x48-SA-SV1 (Steam) pack of 1.000 or 500 endless labels 211-220, -222 C-S-P-5-58x35-SV1 (Steam) pack of 1.000 or 200 endless labels 212-206 C-E-P-5-58x35-W-SV3 (EO) pack of 200 labels 213-206 C-F-P-5-58x35-W-SV4 (FO) pack of 200 labels 214-206 C-V-P-5-58x35-W (H ₂ O ₂) pack of 200 labels			Class 5
<u>Package monitoring emulating indicators for steam sterilization processes</u> 211-241 - 243 C-S-P-6-SV1 pack of 2000, 500 or 250 indicators (121°C, 15 or 134°C, 3 min) 211-238 - 240 C-S-P-6-SV2 pack of 2000, 500 or 250 indicators (134°C, 18 min, prion program)			Class 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 in the above table. All articles with the same 6-digit number have the same specifications.

We hereby declare under our sole responsibility that above mentioned integrating indicators have been tested in the *gke* application laboratory and are in conformity with the European and ISO standard EN ISO 11140-1 for steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes. The corresponding indicator classes are available in the above table.

The indicators do not release any particles or toxic substances. The colour of the indicators remains constant after sterilization and does not fade back to the colour before sterilization.

The above mentioned products manufactured by *gke*-GmbH are produced in accordance with the requirements of the Medical Device Directive 93/42/EEC and the Medical Device Regulation 2002:618.

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



Waldems-Esch, 2012-02-28

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

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

751-019-EN V10