

# Declaration of Conformity

## for the *gke Steri-Record*<sup>®</sup> – Documentation System

The *gke Steri-Record*<sup>®</sup> – Documentation System consists of one of the hand labeler devices below

Art. No.	Description	Version	Application
240-840	D-G-A	alphanumeric	for all <i>gke Steri-Record</i> <sup>®</sup>
240-850	D-G-N	numeric	3-line documentation labels

in combination with double self-adhesive labels and a documentation page stored in the sterile supply department. The hand labeler device is manufactured of various plastic and stainless steel materials where self-adhesive labels, an ink roll and a printing head with rubber letters are implemented.

Labels contain a class 1 chemical indicator according to EN ISO 11140-1 and are used to mark the packages in sterilizers. Labels for different sterilization processes are available:

Art. No.	Description	No. of rolls/pack	Application (Sterilization processes)
240-871 – 874	C-S-L-1-DA-G,-B,-R,-Y	12	Steam
240-883	C-S-L-1-DA-R	4	
242-875	C-E-L-1-DA-P	12	Ethylene oxide
242-885		2	
243-873	C-F-L-1-DA-R	12	Formaldehyde
243-883		2	
244-871	C-V-L-1-DA-G	12	Hydrogen peroxide
244-881		2	

The hand labeler is exclusive part of *gke Steri-Record*<sup>®</sup> documentation system and for correct application it should be used only in combination with all above mentioned *gke Steri-Record*<sup>®</sup> double self-adhesive documentation labels.

The *gke* documentation system allows the complete tracing of the sterile products from a sterile supply department to the patient and back to the documentation page. The documentation system fulfils the requirements of relevant standards and the European Medical Devices Directive (MDD) and is suitable for a quality management system (QMS) according EN-ISO 13485.

The hand labeler is from USA origin. All labels are produced by *gke* and are therefore from German origin. Both products are no medical devices and do not require a CE-mark.

We hereby declare under our sole responsibility, that all above mentioned process indicators have been tested in the *gke* application laboratory and are in conformity with the European and International Standard EN ISO 11140-1 class 1. The chemical indicator strips have an expiry date of 3 years after production. The expiry date is printed on the package.

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-Esch, 2011-07-05

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