

Declaration of Conformity

GKE Steri-Record® Autoclave tape

with chemical process indicator type 1 according to EN ISO 11140-1
to monitor sterilization processes

Art. No.*	Description	Roll		Rolls/unit	Sterilization process	Colour change
		length	width			
211-351	C-S-L-1-AT	50 m	19 mm	12	Steam	green → black
211-352				48		
212-351	C-E-L-1-AT	50 m	19 mm	12	Ethylene oxide	brown → purple
212-352				48		
214-351	C-V-L-1-AT	25 m	24 mm	4	Hydrogen peroxide	purple → pink

(*) 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.

The above-mentioned chemical indicators are manufactured according to the corresponding standards and therefore conform in general with the standard requirements, which are not changing from batch to batch. In contrast to biological indicators with batch-related modifications, an individual batch-related certificate does not make sense because the specifications of chemical indicators and chemical indicator systems do not change batch by batch.

We hereby declare under our sole responsibility, that the above-mentioned process indicators have been tested in the GKE application laboratory using a resistometer according to EN ISO 18472 (certificate available on request) and are in conformity with the European and International Standard EN ISO 11140-1 type 1.

The indicator and the adhesive of the steam autoclave tape do not contain any Lead and the adhesive does not damage the packaging materials when used under normal process conditions.

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, 2021-08-23



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

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