

Declaration of Conformity

GKE Steri-Record® Indicators according EN ISO 11140-1 to monitor sterilization processes

Art. No.	Product Code	Pack size	Sterilization process	Indicator type according EN ISO 11140-1	
Multi-variable Indicators					
211-403	C-S-P-4-SV1	3,200	Steam	Type 4	
212-360	C-E-P-4-SV3		EO		
212-364		400	LTSF		
213-221	C-F-P	400			
214-221	C-V-P-SV9	400	H ₂ O ₂		
214-223		3,200			
214-241	C-V-P-SV7	400			
214-243	C-V-P-SV6	3,200			
214-251		400			
214-253	3,200				
214-261	C-V-P-SV8	400			
214-263		3,200			
Integrating indicators					
211-221	C-S-P-5-SV1	100		Steam	Type 5
211-224		400			
211-226		3,200			
211-230		C-S-P-5-78x48-SA-SV1	1,000		
212-224	C-E-P-5	400	EO		
212-226		3,200			
Emulating indicators					
211-241	C-S-P-6-SV1	2,000	Steam	Type 6	
211-242		500			
211-243		250			
211-238	C-S-P-6-SV2	2,000			
211-240		250			

(*) 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 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 types are available in the above table. The indicators listed above are tested in a resistometer according EN ISO 18472.

According to EN ISO 11140-1, 5.9 the indicators do not release any particles or toxic substances in quantities to cause a health hazard. The colour of the indicators remains constant after the sterilization process has passed successfully and does not fade back to the colour before sterilization for at least 5 years under the condition the indicator is not stored in contact with oxidation agents like H₂O₂ or other chemicals.

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, 2023-03-08


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

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

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