

Declaration of Conformity

GKE Steri-Record® self-contained biological indicators

Art. no.*	Product code	Quantity/ pack	Popu- lation	Sterilization process	Biological indicator spores	Conform with EN ISO 11138-1			
324-501	B-S-MBP-10-5	10	10 ⁵	Steam	<i>G. stearo- thermophilus</i>	EN ISO 11138-3			
324-505		50							
324-510		100							
324-521	B-S-MBP-I-10-5-SV5**	10							
324-525	Instant-MBP-121-SCBI (121-124 °C)	50							
324-551	B-S-MBP-I-10-5-SV4**	10							
324-555	Instant-MBP-134-SCBI (132-137 °C)	50							
324-550	100								
324-591	B-S-AC-MBP-10-5	10							
324-595	Activation Control SCBI	50							
324-590	100								
324-581	B-S-AC-MBP-I-10-5	10							
324-585	Activation Control 134°C	50							
324-580	Instant-SCBI (132-137 °C)	100							
324-601	B-S-MBP-10-6	10					10 ⁶	Formalde- hyde	<i>B. atrophaeus</i>
324-605		50							
324-610		100							
324-651	B-S-MBP-I-10-6-SV4**	10							
324-655	Instant-MBP-134-SCBI (132-137 °C)	50							
324-650	100								
324-691	B-S-AC-MBP-10-6	10							
324-695	Activation Control SCBI	50							
624-690	100								
325-601	B-F-MBP-10-6	10	Hydrogen peroxide	no standard existing					
325-605		50							
327-601	B-V-G-MBP-10-6 (Glass fiber carrier)	10							
327-605		50							
327-610		100							
337-601	B-V-T-MBP-10-6 (Tyvek carrier)	10							
337-605		50							
347-601	B-V-ST-MBP-10-6 (Stainless steel carrier)	10							
347-605		50							
357-601	B-V-P-MBP-10-6 (PET carrier)	10							
357-605		50							
326-605	B-E-MBP-10-6	50				Ethylene oxide	<i>B. atrophaeus</i>	EN ISO 11138-2	
326-610		100							

* 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.

** Additional type 5 chemical indicator according to EN ISO 11140-1 that changes its colour from yellow to black to indicate a pass.

All self-contained biological indicators (SCBI) are produced according to the United States and European Pharmacopeia (USP + EP) and meet the requirements of the International Standard EN ISO 11138 series. These regulations fulfill the GMP-rules for medical devices. All GKE biological indicators are tested for conformity by an accredited test laboratory.

All biological indicators are non-pathogenic and do not harm.

This document certifies that the above performance criteria and the GKE test requirements for quality assurance are met. The continuous quality of our products is assured by our quality management system according to EN ISO 13485***.

Waldems, 2023-03-21



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

* This certificate is available on the GKE homepage

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