

Declaration of Conformity

GKE Bowie-Dick-Simulation (BDS) and Hollow load Test

Art. No.*	GKE description	Content		Product description	Indicator according to EN ISO 11140-1 type 2 with the following reference
		PCD	Indicator strips		
211-150	C-S-BDS-EUH-RCPCD-KIT	1	100	Compact-PCD®	BDS-Test according to EN 285 and hollow-test according to EN 867-5, validated with the method in EN ISO 11140-4
211-151	C-S-BDS-EUH-RCPCD	1	-		
211-111	C-S-BDS-SV1	-	100	Refill pack for all Bowie-Dick-Simulation Tests	Indicator strips for above-mentioned PCDs
211-112		-	250		
211-115		-	500		

(*) 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 indicator systems type 2 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 GKE BDS-Bowie-Dick-Simulation-Tests above have been tested from a test laboratory accredited according to EN ISO 17025 and are in conformity with the European Standards EN 285 and EN ISO 11140-4. Also both tests overfulfil the requirements of the hollow-test according to EN 867-5 "Hollow Load". Both tests are indicator systems according to EN ISO 11140-1, type 2 and tested in a resistometer according EN ISO 18472.

The PCDs do not release any particles or toxic substances.

Note 1: The trans-atmospheric cycle B2 and the super atmospheric cycle B3 of the above-mentioned norm are unable to remove air from complex hollow instruments and these instruments with those cycles could lead to an incomplete sterilization process and should be avoided by the user due to obvious risks. As the GKE Bowie-Dick-Simulation tests have been designed especially to test the more complex and modern minimal invasive surgical (MIS) instrumentation in use today, the test cycles B2 and B3 already fail in the pass cycle, therefore fail cycles are not tested.

Note 2: The indicator systems may be used for all temperature ranges from 115 to 145°C. Therefore no specific temperature is indicated. The Bowie-Dick-Test cycle as described in EN 285 (134°C – 3.5 min, 125°C -15 min) are suitable for the GKE Bowie-Dick-Simulation-Tests, however the GKE Bowie-Dick- Simulation-Test can be used in temperatures of 115 – 145 °C. In comparison to the standard- Bowie- Dick- Test porous load test according to EN 285 or other porous simulation tests, longer sterilization-times than 3 min. do not change the sensitivity of the GKE Bowie-Dick-Simulation-Tests.

Above mentioned products are tested in an independent accredited laboratory to proof conformity with above Standards. Test reports are available on request.

The test-results are only valid if the original GKE Steri-Record® indicator strips with the original GKE Steri-Record® Process challenge device according to the instructions for use are applied.

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, 2021-06-08



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