Directions for Use

STEAM

GKE Steri-Record® Mini-Bio-Plus Activation Control SCBI (AC-SCBI®)

Art.-No.*	Product code	Quantity/ pack	Pop.	Colour of SCBI cap	Sterilization process	Colour change of Outside Type 1 Indicator on label		Colour of liquid growth media			Incubation temperature
						before Sterilization	after Sterilization	before activation sterilization and incubation	after activation, sterilization and incubation: sterile	after activation, sterilization and incubation: non-sterile	
324-591	B-S-AC-MBP-10-5	10	10^5	Light blue	Steam	Blue	Brown	Colourless	Purple	Yellow-green	55-60°C
324-595		50									
324-590		100									
324-691	B-S-AC-MBP-10-6	10	10^6	Dark blue							
324-695		50									
324-690		100									

(*) To all article numbers a 3-digit alpha code is added. 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 on the above table.

Application

Self-contained biological indicators (SCBI) are used to monitor the sterilization process efficacy allowing safe incubation and evaluation by the user without a microbiological laboratory. SCBIs contain a glass vial with growth medium. This glass vial has to be crushed after sterilization in order to get the spores in contact with growth medium.

This is called "ACTIVATION".

There is a common handling error to forget activation before incubation. This is particularly dangerous because it is impossible to discover this error visually. Non-activated and activated SCBIs nearly look alike.

The **GKE Activation Control SCBI** (AC-SCBI®) is the first SCBI worldwide where non-activated and activated SCBIs are distinguishable by colour!

Standard GKE SCBI contains growth medium with a purple pH indicator in the glass vial while GKE AC-SCBI® contains a glass vial with colourless growth medium, which only becomes coloured if being activated! Therefore, activation becomes visible. No more risk to forget activation or not being able to differentiate activated and non-activated SCBIs.
SCBI and AC-SCBI® are typically used inside a GKE Steri-Record® Process Challenge Device (Bio-C-PCD®) which is designed to represent the most demanding load to be sterilized. Different PCDs with different penetration sensitivities are available.

Product Description

The GKE Steri-Record® AC-SCBI® consists of:

1. plastic vial and lid containing:
   - crushable colourless medium glass ampoule with TSB
   - inoculated spore disc with a population of 10^5 or 10^6 CFU/ampoule
   - pH-indicator (outside of glass ampoule).
   - After activation the pH-indicator mixes with the growth medium indicated by a colour change and getting in contact with the BI disc enabling growth.
2. type 1 chemical indicator according to EN ISO 11140-1 outside on the label of the vial to check if the SCBI has been in a sterilization process.

Performance Characteristics

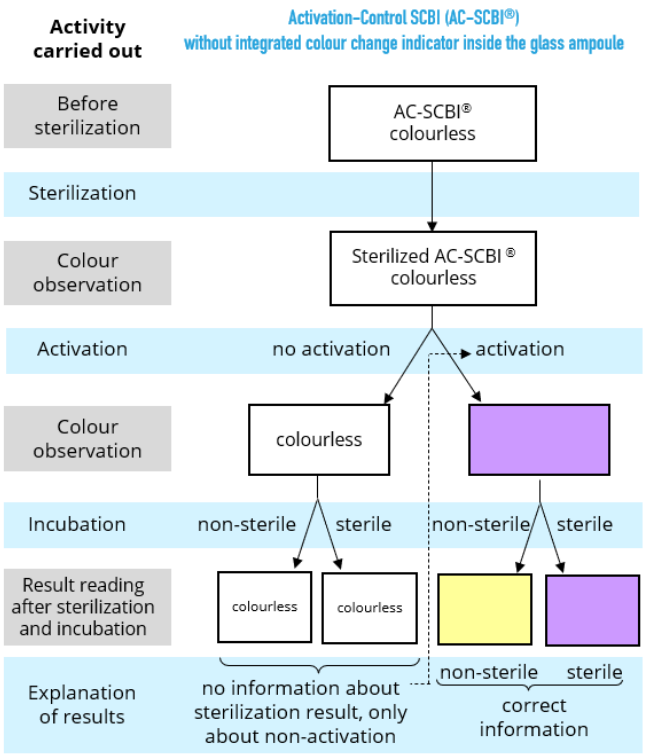
The GKE Steri-Record® AC-SCBI® complies with the standard EN ISO 11138 series for biological indicators and meets the performance characteristics published in the current United States and European Pharmacopeia.

The D-Value for each sterilization process that is tested under defined sterilization test conditions and is described in the certificate included in each package.

Patent Pending.

Handling Information

1. Place the AC-SCBI outside of the load inside a self-made or commercial PCD representing the worst-load configuration, e.g., in a GKE Bio-C-PCD® and run the sterilization process.
2. After sterilization remove the SCBI from the package or Bio-C-PCD®. Cool SCBIs down at room temperature for 15 min.
3. Check the chemical type 1 indicator on the label for proper colour change (blue → brown). If there is no colour change, the vial has been exchanged by accident or sterilization process did not occur. The chemical indicator is a process indicator, unable to determine a successful sterilization process.
4. **Activation of the AC-SCBI®:**
   Use the crusher in the middle of the aluminium block of the GKE incubator by inserting the SCBI and push it in sideward's direction to 2nd hole until the interior glass ampoule is broken. Do not crush the glass ampoule until the vial is at room temperature because the hot glass ampoule may burst the plastic vial. **After being activated, the liquid growth medium will change colour to purple.** If no GKE incubator is used, activate the SCBI with the crusher (art. no. 224-002). The spore plate inside the SCBI must be moistened by the liquid. If the SCBI is not activated, the growth medium remains colourless.
5. Vitality Test: After sterilization additionally mark, activate and incubate a non-sterilized SCBI of each SCBI batch.
6. Incubate the sterilized AC-SCBI®s together with the non-sterilized AC-SCBI with the cap upwards at 55-60 °C according to EN ISO 11138-1. Based on the GKE performance test results, a reduced incubation period of 24 hours is sufficient for GKE-Steam-SCBIs. The test report is available on request.
7. Observation of growth: After 12 hours observe the colour change of the liquid growth media in the plastic vial hourly. The vitality test should have already changed to yellow-green. If no colour change occurs after 24 hours the sterilization process has been successful. Any change in colour of the vials coming out from the sterilizer is indicative for alive organisms demonstrating non-successful sterilization processes. An incubation time beyond the mentioned incubation time is not necessary and does not increase the probability of sterility. If the vials are incubated longer than mentioned above, the liquid could dry out. The colour of the remaining crystals is still observable. If required, the incubation time can be extended by using para film to close the cap before incubation. This procedure is not necessary for routine operation. It is advised to incubate the vials no more than 5 days. Storage of the vial for documentation purposes does not make sense.
8. The previously marked vitality test shall change colour demonstrating growth after one day incubation time latest. If this test does not show colour change of the growth media liquid to yellow-green, the incubator has not been switched on or the SCBI batch has a malfunction. In this case the sterilization has to be repeated with a new biological indicator batch.
9. If any sterilized test vial shows a colour change, stop the tested sterilization process and repeat the test with a larger quantity of Mini-Bio-Plus vials. If the sterilization process fails again, the sterilization process was not successful. Then check the sterilizer for malfunctions. After repair check the sterilization process again with Mini-Bio-Plus SCBI.



10. Keep record of the results on the GKE documentation sheet (see documentation information) with time, date and batch number of the sterilization cycle, time and date of the incubation start and incubation duration with a result. Include name and signature of the responsible person. The label on the SCBI itself can be removed and used for documentation.

Documentation Information

According to MDR, the release must be documented in a way that compliance with all necessary release conditions can be proven. This requirement can be implemented by e.g., archiving the program data and the test results.

Documentation sheets for SCBIs and Instant-SCBIs are available for download:
https://www.gke.eu/en/documentation-system-video.html

To link batch monitoring and sterilized goods, GKE offers a documentation system with a hand labelling device. The documentation label contains the date of production, expiry date, lot and content number as well as the user's initials. Those labels are placed on all sterile goods and also onto the documentation sheet. After using the sterile goods in the operating room, the labels are removed and are placed onto the patient documentation sheet (all labels are double self-adhesive). This easy process offers a cost-effective documentation system for all sterilized goods used on a patient in the operation room. In case of a nosocomial infection the result of the used sterile instruments can be traced back. This procedure fulfils the requirements of quality standard EN ISO 13485 for batch-oriented documentation.

Storage and Disposal

1. For longer periods store all Mini-Bio-Plus AC-SCBI® in the original package between 5-30°C with a humidity of 5-80% RH and avoid exposure to light.
2. The vapour of chemicals especially hydrogen peroxide may change the chemical indicator on the label before or after sterilization. Therefore, do not store them together with other chemicals.
3. Sterilized vials may be disposed with normal waste.

Safety Precautions

1. The indicators shall not be used after expiry date.
2. Do not activate the SCBI by crushing the inner glass ampoule until the vial is at room temperature! The hot glass ampoule inside may burst the plastic vial and may leak during incubation.
3. Mini-Bio-Plus SCBI must not be used in dry heat sterilization processes. The glass ampoules explode and the plastic vial will melt.
4. Bio-C-PCD® and AC-SCBI® are closely adjusted to achieve the required sensitivity of the type 2 indicator system. If the test device is used with other SCBIs or PCDs, GKE cannot guarantee proper results.
5. SCBIs are not able to check liquid sterilization processes. GKE Stearo-Ampoules should be used for this application.

For further technical details please contact your local dealer or the GKE application laboratory. We will assist you with any technical questions. Also visit our website www.gke.eu for more information.

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