

NEW

Activation Control Self-Contained Biological Indicator (AC-SCBI®)

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 new **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. a plastic vial and lid containing:
 - a crushable colourless medium glass ampoule with TSB
 - an inoculated spore disc with a population of 10^5 or 10^6 CFU/ampoule
 - a pH-indicator (outside of the 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. a 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 Pharmacopeia (USP) and European Pharmacopeia (EP).

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.

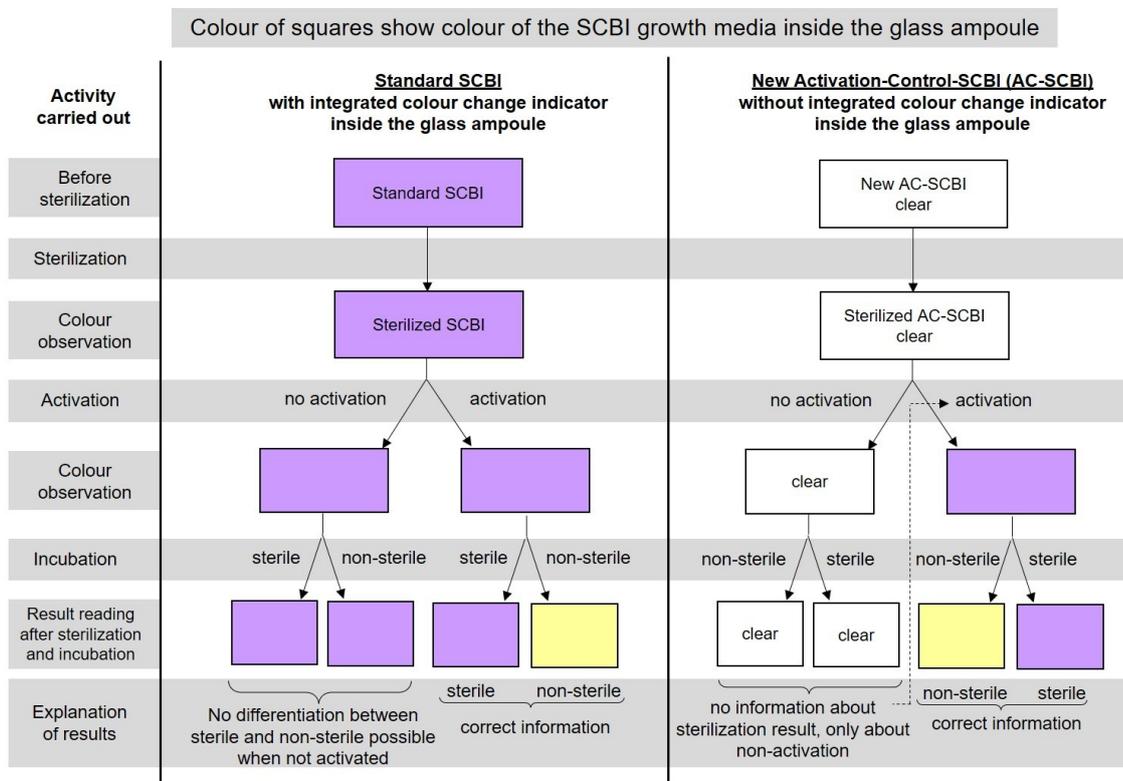
Patent Pending.

Benefits

- Activation control prevents mistakes of wrong interpretation result.
- Easy distinction between activated and non-activated SCBI.
- No external microbiological laboratory required.
- Simple handling and traceability of test results.
- The combination of AC-SCBI® and Bio-C-PCD® allows correct testing of hollow lumen instruments.
- The AC-SCBI can be easily removed and evaluated immediately on completion of each cycle without having to open any packs or containers when used in a Bio-C-PCD®.

Operational Description

The following diagram shows the new AC-SCBI® with activation control function compared to a standard SCBI without activation control function



Order Information

Art. No.	Quantity	Product Code	Population	Application
324-595	50	B-S-AC-MBP-10-5	10 ⁵	Steam
324-590	100			
324-695*	50	B-S-AC-MBP-10-6	10 ⁶	
324-690*	100			
326-595*	50	B-E-AC-MBP-10-6		Ethylene Oxide
327-595*	50	B-V-AC-MBP-10-6		Hydrogen Peroxide

* available on request

Incubators and accessories are also available. See separate datasheet.