

	<b>Technical Information</b>	<b>730-116-EN</b>		<b>V05</b>
	<b>Immediate release of GKE Steri-Record® Instant-Mini-Bio-Plus SCBI for 121 and 134°C sterilization processes without incubation</b>	Created	15.05.2013	UK
		Changed	31.08.2021	KP
		Checked	31.08.2021	UK
		Released	31.08.2021	UK
<b>File no.: 3.3</b>				

Quite often we get a feedback from our customers why steam sterilization processes can be released without incubating the biological indicators inside of the Instant-Mini-Bio-Plus SCBIs, since the information about the result of a sterilization process of biological indicators requires some time of incubation.

The GKE Steri-Record® Instant-SCBI contains in addition to the biological indicator a class 5 chemical indicator according to EN ISO 11140-1. According to this standard this chemical indicator provides at least the same sterility information as a biological indicator after 7 days incubation according to EN ISO 11138-1 and -3 with a probability of 100 %.

At the end of the sterilization process the load is released with the result of the colour change of the chemical indicator. Afterwards the biological indicator shall be incubated as all other biological indicators.

A valid question may be raised, if the load is already released with the chemical indicator, why the biological indicator incubation is required in addition and the result of the biological indicator is not yet available. This is a good question. In most European countries steam sterilization monitoring with biological indicators has been replaced using chemical indicators class 5 or 6 only, since the probability of a class 5 chemical indicator according to standards is as good or even better than the result provided by a biological indicator. Therefore biological indicators are not anymore used in most Western European countries for steam sterilization processes.

The incubation of an Instant-SCBI is recommended under the condition, if local authorities still require monitoring with biological indicators.

If the chemical indicator of the Instant-SCBI is showing a pass, it is 100 % guaranteed that the biological indicator later on will show a pass as well. If the opposite occurs, that the chemical indicator shows a fail, it may happen after incubating the biological indicator that it may show a pass, since the pass criteria of chemical indicators are harder to achieve than for biological indicators. The CI inside the Instant-SCBI for 134°C shows only a pass after 134°C, 3.5 min plateau time while the biological indicator is already killed within 1 min latest and will already show a pass. When the sterilization plateau time is for example 134°C, 2 min, the biological indicator is killed showing a pass, while the chemical indicator is still showing a fail.

Therefore using a GKE Steri-Record® Instant-SCBI the release with the chemical indicator is more safe than just using a biological indicator alone according EN ISO 11138-1 and -3. A test report from an accredited laboratory according EN ISO 17025 showing those results is available on demand.

GKE offers two different Instant-SCBIs to monitor steam sterilization processes, one for 121-124°C (Art. no. 324-521, -525) and a second one for 132 -137°C (art. no. 324-551, -555, -550; 324-651, -655, -650). It is mandatory to use always the correct temperature version to monitor your process. Using the wrong version will lead to wrong results.

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All GKE Steri-Record® SCBIs have an additional advantage: They are designed with a minimal internal SCBI volume, so they can be used in a special Bio-C-PCD designed by GKE, to simulate a hollow load test according to EN 867-5 (new: EN ISO 11140-6). There is currently no other SCBI on the world market which offers this opportunity. (Also see our Technical Information TI 730-113.)