

	<b>Technical Information</b>	<b>730-125-EN</b>		<b>V03</b>
	<b>Information about the use of GKE Steri-Record® Self-contained biological indicators (SCBIs) for hydrogen peroxide sterilization processes</b>	Created	28.07.2014	UK
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There is no special standard for the validation and routine monitoring of hydrogen peroxide sterilization processes except the general one, EN ISO 14937, which is valid for all sterilization processes.

According to this standard it is not only important to test the sterilizer but to test that the goods are coming out sterile. Therefore to adjust a biological indicator to a sterilizer (V Pro, Sterrad, etc.) only, does not make any sense from a technology point of view. This is still an old-fashioned approach in the USA which cannot be supported anymore.

GKE uses the same biological indicator (*Geob. Stearothermophilus*, ATCC 7953) as Advanced Sterilization Products (ASP), which is a subsidiary of Fortive, with the same population. A standardized D-value is required in the general standard for all biological indicators EN ISO 11138-1, however a test procedure has not been published. Therefore each manufacturer is using his own test method. Currently a new standard is under development (EN ISO 11138-6, but not finished).

If the indicator is positioned at the most difficult penetration location of a load, GKE can guarantee that the goods coming out are sterile. The positioning of biological indicators is absolutely not mentioned in the United States and most important for the result of a sterilization process.