

gke Steri-Record[®] Stearo Ampoules for liquid and waste sterilization

STEAM

Application

The **gke Steri-Record[®]** Stearo Ampoules can be used for sterilization monitoring of liquids in glass bottles or solid materials. All thermal processes such as steam sterilization, liquid sterilization, microwaves or mixtures of those, except dry heat sterilization, can be monitored from 110 - 134°C with corresponding sterilization times. They are especially suitable for waste sterilization.

The F_{Bio} -value of the ampoule should be adapted to the F_0 -value of the sterilization process.

Place the ampoule in an area which is considered to be most difficult to sterilize: directly in fluids or in the center of packs.

If waste in PP plastic bags is sterilized, about 1 l water should be filled into the bag and the ampoule, connected with a string, should be positioned in the water.

Product description

The ampoule contains 1.5 ml or 0.2 ml of growth medium with a pH indicator and different populations of *Geobacillus stearothermophilus* spores which are used for monitoring steam sterilization processes. After finishing the sterilization process, the glass ampoules are incubated. If not all spores were inactivated during the sterilization process, the germs replicate and produce acids. The resulting drop of the pH value results in a color change of the liquid.

Performance characteristics

The Stearo Ampoules are produced in accordance to the EN ISO 11138-1 + 3 standards and the current European and United States Pharmacopoeia (EP+USP). Population and D-value are measured and certified for each batch. This is also documented in the certificate.

The continuous quality is guaranteed by the **gke** quality management system according to EN ISO 13485.

Benefits

- Stearo Ampoules are produced according to the actually EN ISO standards and the European and United States Pharmacopoeia.
- Each batch contains a certificate which represents a data analysis of population and D-value under exactly defined conditions of sterilization.
- Guaranteed stability of 12 months of production.
- Continuous quality monitoring of each batch according to the quality criteria according to EN ISO 13485.
- Mini ampoules available to test sterility inside of small packs (e.g. eye lenses)
- Rapid incubation by optimization of growth medium with a pH indicator.
- No negative control necessary (details see technical information TI 155)



Incubator

gke offers a special incubator for the ampoules to monitor the colour change without taking out the ampoules.

More information is available at the backside or order a data sheet or ask for a quotation.

Order information

Art.-No.*	Product code	Population per ampoule	Quantity/ Box	Dimensions	Result of the sterilization process	
					sterile	unsterile
					Colour change of ampoule after sterilization and incubation	
225-550	B-S-AMP-10-5	10 ⁵ CFU	50	11x44mm	Purple	Yellow-green
225-650	B-S-AMP-10-6	10 ⁶ CFU				
235-510	B-S-MAMP-10-5	10 ⁵ CFU	100	5x25 mm		
235-610	B-S-MAMP-10-6	10 ⁶ CFU				

Incubators** (Aluminum block has to be ordered separately)

Art.-No.*	Product Code	Description of incubator and aluminium block
610-110	I-57	Incubation temperature: 37°C fixed
610-111	I-V	Variable temperature selection
610-112	I-V-T	Variable temperature selection and programming of the incubation time
610-114	I-AB-AMP	Aluminum block for gke Steri-Record® Standard Stearo ampoules

* 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 tables.

** For details see separate data sheet.

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