CLEANING
STERILIZATION

GKE Stearo-Ampoules
for 121 and 134°C
liquid and waste sterilization

Application

GKE Steri-Record® stearo-ampoules are used for sterilization monitoring of liquids and solid sterile goods in liquids, e.g. eye lenses. They are suitable for all thermal processes, such as steam sterilization, liquid sterilization, sterilization with microwaves and their mixed forms, with the exception of dry heat.

They are particularly suitable for waste sterilization and can be used in in 121°C and 134°C programs. If waste is sterilized in PP foil bags, about 1 l of water should be added to the bag the ampoule, fixed with a string and immersed in the water.

At the end of the sterilization process the stearo-ampoule is taken out and incubated at 55-60°C. Unless all germs have been inactivated by the sterilization process, they will growth in the growth media and produce acids that cause the pH indicator to turn from purple to yellow-green.

Product Description

The glass ampoule contains a TSB nutrient solution with pH indicator.

- Two sizes available (1.5 ml | 0.2 ml)
- Two populations available (10^5 | 10^6 CFU/amp)

Ampoules are shipped in special cooled packaging, otherwise growth may occur during transporation, see technical information 730-179.

Performance Characteristics

The stearo-ampoules are manufactured according to the standard EN ISO 11138-1 + -3 as well as the USP and EP guidelines. Population and D-value are tested with each production batch according to the standard and documented in an enclosed certificate.

Benefits

- Applicable in both 121°C and 134°C processes.
- Manufactured in Germany.
- Stearo ampoules are manufactured according to the current EN ISO standards as well as the European and American Pharmacopoeia.
- Each batch contains a certificate showing the analysis data of the population and the D-value under precisely defined sterilization conditions.
- Guaranteed shelf life of 12 months after production.
- Permanent quality monitoring of each batch until the expiry date.
- Mini ampoules available to perform sterility testing within small sterile packages (e.g. ophthalmic lenses).
- Rapid incubation by optimizing the nutrient solution with pH indicator. Suitalbe incubator available from GKE.
- No negative control necessary (details, see Technical Information TI 155).
- Choice of two types of cooled shipping packages.
- Consistent quality according to quality management system EN ISO 13485.

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Order Information

Art. No.	Quantity	Product Code	Dimension	Population	Description
225-550	50	B-S-AMP-10-5	11 x 44 mm	10^5 KBE	Standard Stearo-Ampoule
225-650		B-S-AMP-10-6		10^6 KBE	
235-510	100	B-S-MAMP-10-5	5 x 25 mm	10^5 KBE	Mini Stearo-Ampoule
235-610		B-S-MAMP-10-6		10^6 KBE	

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