

DIRECTIONS FOR USE



for GKE Steri-Record® biological indicators

1. Spore Strips and Spore Discs

Art.-No.*	Product Code	Quantity	Pop.	Sterilization process	Content	Biological indicator	Incubation temperature
221-601	B-E-H-SS-10-6	100	10 ⁶	Ethylene oxide, Dry heat	Spore strips	<i>B. atrophaeus</i>	33-37°C
221-605		500					
221-610		1.000					
221-611	B-E-H-SD-10-6	110			Spore discs		
221-612		100					
223-501	B-S-SS-10-5	100	10 ⁵	Steam, Formaldehyde**	Spore strips on filter paper	<i>Geob. Stearothermophilus</i>	55-60°C
223-505		500					
223-510		1.000					
223-601	B-S-SS-10-6	100	10 ⁶				
223-605		500					
223-610		1.000					
332-601	B-V-P-SS-10-6	100	10 ⁶	Hydrogen peroxide / Plasma	Spore strips on PET carrier		
332-604		40			Spore strips on glass fiber carrier		
332-602	B-V-G-SS-10-6	100			Spore strips on tyvek carrier		
332-605		40			Spore strips on stainless steel carrier		
332-603	B-V-T-SS-10-6	100			Spore discs on PET carrier		
332-606		40					
332-607	B-V-ST-SS-10-6	100			Spore discs on tyvek carrier		
332-608		40					
332-612	B-V-P-DIS-SP-10-6	100					
332-614		110					
332-616	B-V-G-DIS-SP-10-6	100					
332-611		110					
332-618	B-V-T-DIS-SP-10-6	100					
332-613		110					
332-617	B-V-ST-DIS-SP-10-6	100					
332-615		110					

2. Growth medium, diameter: 16,1 mm (accessories to incubate biological indicators)

Art.-No.*	Product Code	Quantity/ pack	Growth media additive	Colour change of media after sterilization and incubation		Biological indicator	Sterilization process tested
				Sterile	Non-sterile		
221-010	B-E-H-CM	10	pH-indicator	Green	Yellow- orange	<i>B. atrophaeus</i>	Ethylene oxide, Dry heat
221-100		100					
223-010	B-S-V-CM	10		Purple	Yellow-green	<i>G. stearothermophilus</i>	Steam, Hydrogen peroxide
223-100		100					

(*) 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 table.

(**) The D-value for steam is specified in the certificate, not the D-value for formaldehyde (LTSF). The D-value for LTSF can be determined at extra cost (Art.no. 223-998).

Application

The GKE Steri-Record® biological indicators (spore strips and discs) are used for validation and monitoring of sterilization and decontamination processes. For evaluation, a microbiological laboratory is required. GKE offers specific growth media with a pH-indicator. The growth medium has been developed to incubate *G. stearothermophilus* and *B. atrophaeus* biological indicators to easily monitor growth. During the growth of the bacteria the pH-value of the medium is changing the colour allowing a quicker evaluation of biological indicators.

Product Description

Spore Strips:

The GKE Steri-Record® biological spore strips consist of a contaminated carrier of 6 x 38 mm in a glassine packaging that protects the spore strip from re-contamination after sterilization. For steam, ethylene oxide and formaldehyde filter paper is used as a carrier while hydrogen peroxide (H₂O₂/plasma) strips uses different carrier materials. The spore strips for hydrogen peroxide sterilization processes are individually packaged or alternatively packaged together. The glassine packaging has to be opened in a micro-biological laboratory where the indicator strip is aseptically transferred into the GKE Steri-Record® growth medium.

Spore Discs:

The spore discs (diameter 7 mm) consist of *B. atrophaeus* or *G. stearothermophilus* spores that are immobilized on different carriers. The spore discs are packaged together or individually in a blister box.

Growth Medium:

The European Pharmacopeia (EP) requires an incubation time of 7 days since alive but damaged spores need a longer time for growth. The GKE growth medium is optimized so that an incubation time of 7 days is not necessary. Currently a new standard will be published to measure the reduced incubation time (RIT). The growth speed heavily depends on the growth medium used. The incubation times mentioned in our directions for use can only be assured if the GKE growth medium is used.

The glass tube with the length of 7,6 cm and an inner diameter of 16,1 mm, contains 8 ml sterile CASO bouillon optimized for a quick *G. stearothermophilus* and *B. atrophaeus* bacteria growth. The medium contains different pH-indicators for a quicker readout. The medium volume has been optimized for spore strips of 6 x 38 mm.

Performance Characteristics

All GKE biological indicators are produced in accordance to the EN ISO 11138-1 standard and the current European and United States Pharmacopoeia (EP*+USP). Population and D-value are measured and certified for each batch documented in the enclosed certificate.

For hydrogen peroxide a standard does not yet exist since no appropriate resistometers/test sterilizers are available to measure D-values. Therefore, most manufacturers have their own test procedures that are not comparable. GKE has developed a test method for hydrogen peroxide in liquid H₂O₂ solution. This test method has been presented to the Standard committee and will be published later and has the advantage that resistances can be compared throughout the world.

For information on carrying out the population determination, please refer to GKE Technical Information TI 730-067 EN. The TI is available on the GKE website:

<https://www.gke.eu/en/technical-information.html>

Handling Information

1. Use of

1.1. Spore Strips:

A minimum of two GKE Steri-Record® spore strips indicators shall be used to monitor each sterilizer cycle. Place them in the most difficult location in the sterilizer chamber. Alternatively, the spore strips can also be used in process challenge devices (PCD). For this specific use the spore strips have to be taken out of the package and put into the PCD. Place the PCD in the lower section of the sterilizer close to a door. After sterilization, the strips must not be removed and the closed PCD shall be opened aseptically in a microbiological lab.

1.2. Spore Discs:

To decontaminate isolators and rooms/chambers hydrogen peroxide processes can be used. For monitoring spore discs are positioned at the most critical areas, e.g. on apparatuses/devices.

2. a) After sterilization or decontamination, aseptically transfer the spore strip or disc into sterile tryptic broth. Preferentially use GKE growth medium, containing a pH-indicator for fast and easy evaluation.

b) After LTSF sterilization processes, prior to incubation, inactivate remaining FO residues on the strips according to EN ISO 11138-5.

3. It is recommended to run a vitality test. Use an unsterilized control strip to guarantee the vitality of the strips and to check quality of the media. For the negative control incubate the culture medium without spore strip to exclude contamination of the media or tube. Growth of the vitality test should be evident in 2 days latest. The tube without spore strip shall not change colour.
4. Incubate sterilized spore strips for a maximum of 7 days at 55-60°C for *G. stearothermophilus* and 33-37°C for *B. atrophaeus*.
5. Observe all tubes for growth daily.
6. Record results.
7. If a positive result is observed, repeat the test procedures, placing several indicators throughout the sterilizer. If a positive result is observed again, the sterilizer has to be examined for malfunction.
8. After a repair, repeat the test with several indicators and proceed only to use the sterilizer if all tests show a negative result.

Safety Precautions

Standard growth medium for steam sterilization processes should only be used in accordance with GKE Technical Information TI 730-041 when evaluating biological indicators for testing NTDF (low temperature steam formaldehyde) as this could lead to false negative results (see EN ISO 11138-5).

Storage and Disposal

1. For longer periods store all spore strips in the original package between 5-30°C with a humidity of 5-80% RH away from sterilizing agents. Store the growth medium in a dark place between 5-30°C.
2. Biological indicators should not be used after expiry date.
3. Dispose biological indicators with normal waste. Sterilize biological indicators before disposal.

For further technical details please contact your local dealer or the GKE application laboratory. We will assist you with any technical questions. Also visit our website www.gke.eu for more information.

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(*) If *B. atrophaeus* biological indicators are used to test ethylene oxide sterilization processes according to EP an additional D-value determination at 30°C is necessary. This certificate (art.no. 221-999) is available at extra cost.