

***gke* Steri-Record® Direct inoculation kit**
to test sterility inside complex instruments using steam,
formaldehyde, hydrogen peroxide sterilization processes

STEAM
FORM
VH2O2



Application

This test is used for direct inoculation to test critical areas inside of complex hollow instruments at the most difficult penetration location, to test sterility, where usual biological indicators cannot be inserted. The inoculation and the sterility test procedure afterwards is the only possibility to check sterilization inside of complex instruments and sealed areas. The test can be used for all types of steam, formaldehyde or hydrogen peroxide sterilization processes with the enclosed *G. Stearothermophilus* suspension. In addition the same procedure can be used for ethylene oxide and dry heat sterilization processes if *B. atrophaeus* suspension is purchased separately. All types of instruments may be tested.

This procedure cannot be used for routine monitoring but only for validation. For routine monitoring of complex instruments, batch monitoring systems (BMS) are recommended.

To check the efficacy of the sterilization procedure, the correct inoculation with a defined population at the worst-case location is necessary. It is important to validate quantitative recovery. Before sterilization. After sterilization the aseptic quantitative microbiological incubation and evaluation is necessary. This whole validation procedure shall be carried out from an experienced laboratory.

Product Description

One test kit contains 2x 1,5 ml of *G. stearothermophilus* suspension in 40% Ethanol, a precision syringe and a needle of 20 cm lengths. The syringe is used to inject 100 µl of suspension. Other suspensions can be used as well described in the table above. All suspensions are accompanied by a certificate containing population, D- and z-value.

Performance characteristics

All *gke* biological indicators meet the *gke* quality control specifications and performance parameters published in the current European and United States Pharmacopoeia and the EN ISO 11138-1 to 5 standards. The above indicated specifications are tested in regular periods until the expiry date is reached. The continuous quality is guaranteed by the *gke* quality management system according to EN ISO 13485:2003. Population and D-value information are mentioned in the certificate of each pack.

Benefits

- Only direct inoculation allows to check sterility inside complex instruments.
- The test can be carried out by all microbiological laboratories.
- Supports the test requirements of the validation standards EN ISO 14937, 17665-1, EN 15242, EN ISO 11135-1 and ISO 20857.
- Easy handling.
- Use of standardized microbiological suspensions.
- Kill kinetics can be measured with all sterilization processes.
- All types of instruments can be tested.

Order information





Art.-No.	Product Code	Content	Sterilization Process
228-110	Direct inoculation kit	<ul style="list-style-type: none">• 2x 1,5 ml suspension of <i>G. stearothermophilus</i> 10⁷ CFU/ml in 40% Ethanol.• 100 µl precision syringe• 1 needle of 20 cm lengths• Directions for Use• Certificate	Steam, Formaldehyde, Hydrogen peroxide

Refill pack

10 ml Suspension 10⁷ in 40% Ethanol

Art.-No.	Product Code	Germ	Population	Sterilization Process
228-107	Bio-DFW-Sus-10-7	<i>G. stearothermophilus</i>	10 ⁷ CFU/ml	Steam, Formaldehyde, Hydrogen peroxide
226-107	Bio-EH-Sus-10-7	<i>B. atrophaeus</i>		Ethylene oxide, Dry heat

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