
gke Steri-Record[®] Direct inoculation syringe to test sterility inside complex instruments



Application

This inoculation syringe 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. **gke** offers *G. stearothermophilus* and *B. atrophaeus* suspensions. 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 aseptically quantitative microbiological incubation and evaluation is necessary. This whole validation procedure shall be carried out from an experienced laboratory.

Product Description

The precision syringe is available with a needle of 20 cm lengths. The syringe is used to inject 100 µl of suspension.

The suspension is available separately. 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. 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	Application
228-111	I-SYRINGE	100 µl precision syringe with needle of 20 cm lengths	Used with suspension to check the sterility inside complex hollow instruments

10 ml Suspension in 40% Ethanol

Art.-No.	Product Code	Germ	Population CFU/ml	Sterilization process
228-107	B-S-F-V-SUS-10-7	<i>G. stearothermophilus</i>	10 ⁷	Steam, Formaldehyde, Hydrogen peroxide
228-108	B-S-F-V-SUS-10-8		10 ⁸	
226-107	B-E-H-SUS-10-7	<i>B. atrophaeus</i>	10 ⁷	Ethylene oxide, Dry heat
226-108	B-E-H-SUS-10-8		10 ⁸	
226-109	B-E-H-SUS-10-9		10 ⁹	

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