

Bioindicators for steam sterilization of solutions – Steri-Test-L

Product information

Field of application:	Biological indicator for use in validation and monitoring of steam sterilization of solutions
Conformity:	The Sporotest-L bioindicator fulfils the requirements of DIN EN ISO 11138-1 and -3
Specifications:	Test microorganism: Geobacillus stearothermophilus ATCC 7953 Colony count (nominal): 10^6 CFU Resistance (D-value): ≥ 1.5 min (relating to filter carton as germ carrier) Germ carrier: 1 ml NaCl 0.9% Primary packaging: glass vials Shelf life: 3 months from date of manufacture
Storage:	For transport and storage, temperatures should be kept below 30°C and relative humidity between 30 and 65%. Do not expose bioindicators to direct sunlight.
Disposal:	Unused bioindicators or bioindicators whose shelf life has expired are disposed of by steam sterilization at 121°C – 15 min or 134°C – 5 min without additional packaging
Instructions for use:	<p>The test vials are inserted into the filled bottles intended for sterilization, which are distributed evenly in the interior of the sterilizer. The distribution pattern is indicated in form of a sketch-map in the test report.</p> <p>The control indicator (red sticker) included in delivery serves as growth test and for verifying storage and transport conditions. This indicator must not be included in sterilization.</p> <p>After completion of the sterilization process, the bioindicators are removed and sent to the microbiological test laboratory together with the control indicator and the completed test report.</p> <p>In order to verify the microbiocidal effect on the test germs, the germ suspension is extracted from the test vial using a sterile syringe, transferred into 10 ml Soybean Casein digest Broth and cultivated for 7 days at 55°C \pm 2K.</p> <p>The sterilization process fulfils the microbiological requirements if no growth of Geobacillus stearothermophilus ATCC 7953 can be detected in any of the samples. The control indicator must show distinct growth of the test germ after 24 hours of cultivating.</p>