

Bioindicators for steam sterilization – Sporotest-D

Product information

Field of application:	Biological indicator for use in validation and monitoring of moist heat sterilization processes (steam sterilization)
Conformity:	The Sporotest-D bioindicator fulfils the requirements of DIN EN ISO 11138-1 and -3
Specifications:	Test microorganism: Geobacillus stearothermophilus ATCC 7953 Colony count (nominal): $> 10^5$ CFU Resistance (D-value): ≥ 1.5 min Germ carrier: filter paper Primary packaging: sterilisable package with chemo-indicator Shelf life: 24 months from date of manufacture
Resistance determination:	The D-value is determined by exposure in the resistometer in accordance with DIN EN ISO 11138-1 (Spearman-Karber method).
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 bioindicators are distributed evenly inside the sterilizer, preferably in items that are hard to sterilize (do not remove the indicator strips from the packaging!). 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>The bioindicators are also suitable for use in test bodies.</p> <p>In order to verify the microbiocidal effect on the test germs, the bioindicators are transferred into 10 ml Soybean Casein digest Broth and incubated for 7 days at 55 - 60°C.</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>