

TS-HL-6 Instructions for the biological monitoring of dry heat sterilization processes

Area of Application:

The test system contains the biological indicator SIMICON DH/HL according to ISO 11138-4. It is designed for the biological validation and routine monitoring of dry heat sterilization processes.

Testing procedure:

1. Remove the cards with the biological indicators from the envelope.
Don't open any of the indicator pouches.
2. The biological indicator in the PE-bag serves as growth and transport control.
Do not process this control indicator!
3. Place the cards with the biological indicators in the sterilizer as follows:
LOWER LEVEL: card with 3 biological indicators
UPPER LEVEL: card with 2 biological indicators
If you are using a sterilizing container, put the cards in the container.
4. Check the temperature and time settings of the sterilizer!
WHO recommendation calls for: 180 °C - 30 min.
Generally these conditions are met if the sterilization time of 30 min is preceded by a 30 min heating-up time.
The overall sterilization time should therefore amount to approximately 60 min.
5. Start the sterilization process.
6. Fill in the test report.
Note: Make sure to enter all data concerning sterilizer, testing conditions as well as packaging.
7. At the end of the sterilization process remove the biological indicators from the machine.
Send the biological indicators with transport control and test report to SIMICON GMBH in the envelope provided.
Note: Don't forget to add your address, telephone and fax number on the test report.
8. As soon as the biological assessment has been completed, SIMICON will return the test report including test results to you.