

## TS-FA-10 Instructions for the biological monitoring of formaldehyde gas sterilization processes

### Area of application:

The test system contains the biological indicator SIMICON FA according to ISO 11138-5. It is designed for the biological validation and routine monitoring of formaldehyde gas sterilization.

### Testing procedure:

1. Remove the process challenge devices from the carton.  
Do not open the paper-foil bags!
2. One of the biological indicators serves as growth and transport control.  
Do not sterilize this control indicator.
3. Number the process challenge devices and place them in sterilization packagings (one-, two- or threefold) you habitually use.  
Distribute these in representative spots among a typical load.
4. Check the temperature - time setting (i.e. 60 °C) and the sterilizing agent.
5. Start the sterilization process.
6. Fill in the test report.  
Mark the distribution of the process challenge devices in the sterilizer on the test report.
7. At the end of the sterilization process and the minimum outgasing period, remove the process challenge devices from the sterilizer.  
Do not open the paper-foil bags.  
Together with transport control and test report send them to SIMICON GMBH.  
**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.