

## TS-EO-10

### Instructions for the biological monitoring of ethylene-oxide gas sterilization processes

#### Area of application:

The test system contains the biological indicator SIMICON EO according to ISO 11138-2. It is designed for the biological validation and routine monitoring of ethylene-oxide gas sterilization processes.

#### Testing procedure:

1. Remove the process challenge devices from the carton.  
Do not open the paper-foil bags!
2. One indicator serves as growth and transport control.  
Do not sterilize this control indicator.
3. Number the pouches and place them in sterilization containers or packagings (one-, two- or threefold) you habitually use.  
Distribute these in representative spots among a typical load.
4. Check temperature and time settings (i.e. 55 °C) and the sterilizing agent.
5. Start the sterilization process.
6. Fill in the test report and sketch the position of the PCDs in the sterilizer on the drawing. Indicate what kind of sterilization packaging you used.
7. At the end of the sterilization process and the minimum outgassing period remove the pouches with the PCDs from the sterilizer. Do not open the pouches.  
Send the pouches with transport control and test report 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.