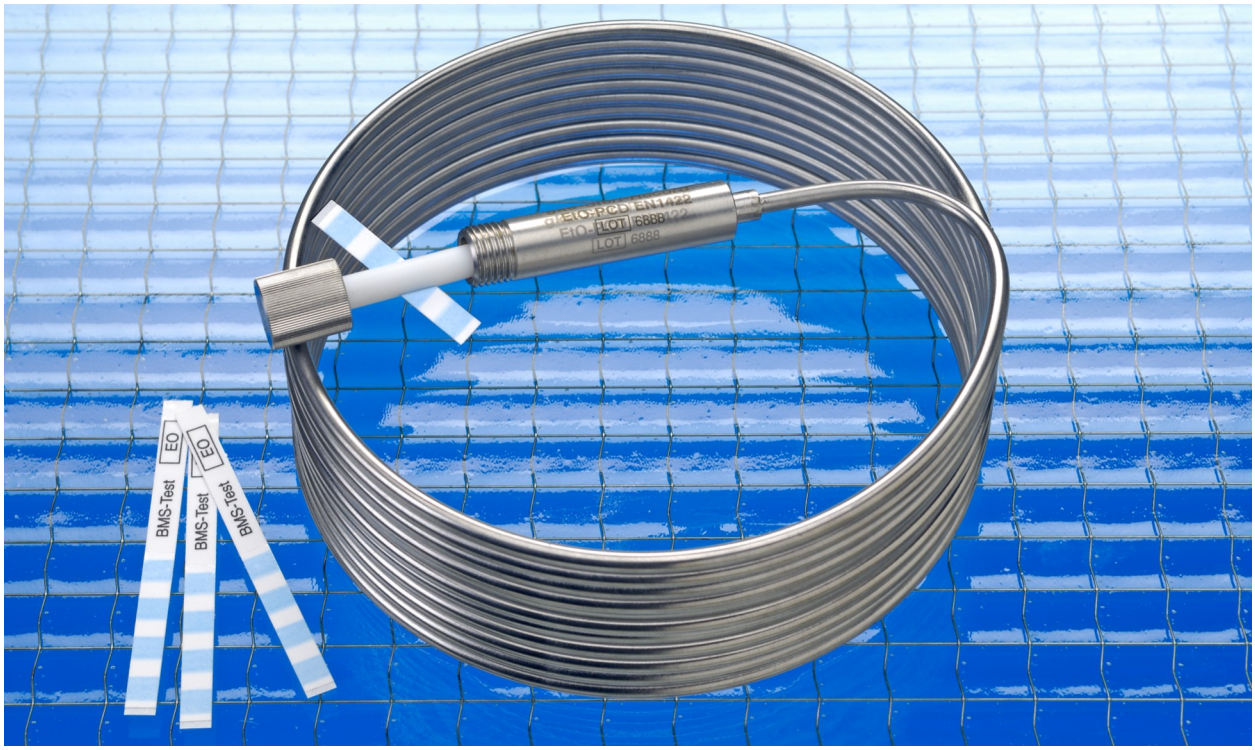
gke Steri-Record ® Type Test for ethylene oxide sterilization processes according to EN 1422

EO



Type Test according to EN 1422 , annex F

Application

Ethylene oxide sterilization processes in the market differ in temperature, pressure, EO concentration and inertgas mixtures, i.e. CO_2. Therefore the monitoring system should be validated with biological indicators before chemical indicators are used.

For routine monitoring chemical indicators can be used with the advantage that they can be also checked immediately after the sterilization process has finished.

The indicator system has been tested at 55°C under the following sterilization conditions:

EO/l [mg]	Pressure [bar]	CO_2 [%]	EO [%]	Time [min]
500	1,7	85	15	90
600	5,5	94	6	60
250	1,7	94	6	180
1200	5,5	85	15	30
600	0,5	0	100	60

During the sterilization process it is absolutely necessary to monitor the relative humidity, which should not be below 60%. The ideal relative humidity during sterilization is between 70% and 90%. A successful test confirms that the sterilizer meets the requirements of EN 1422 concerning air removal and ethylene oxide penetration.

Product Description

The Process Challenge Device (PCD) for ethylene oxide sterilization processes has been developed according to the standard EN 1422. It consists of a 4.55 m long stainless steel tube of 3 mm diameter connected with a capsule holding the indicator strip sealing one end.

Performance Characteristics

The PCD complies with a type test described in the European standard EN 1422, annex F, for air removal and ethylene oxide penetration.

The combination of a PCD and a biological or chemical indicator is a class 2 indicator according to EN ISO 11140-1 consisting of a “specific test load” (PCD) and “indicator system” (indicator strip). The chemical indicators have the performance characteristics of a class 5 indicator but a combination with a PCD is a class 2 indicator.

Sterilization programs are not standardized. Therefore a validation with biological indicators (*B. atrophaeus* 10^6) according to EN ISO 11138-1 + 2 is required before chemical indicators may be used for routine monitoring.

The validation of the load configuration (PQ = Performance Qualification) according to EN ISO 11135-1 ensures that the sterilization process meets the requirements to sterilize the load configuration.

Operation Description

If all four bars of the chemical indicator turn from blue to green it is an indication of sufficient EO-gas penetration inside the PCD. This result ensures air removal and EO-gas penetration into the whole load as the PCD is representing the load configuration.

Sufficient air removal and ethylene oxide penetration

Insufficient air removal and ethylene oxide penetration

No air removal and ethylene oxide penetration

Benefits

- The use of this EO BMS allows the monitoring of sterility inside hollow instruments, tubes and porous goods not provided by recording pressure, temperature and EO concentration in the chamber and/or using exposed indicator strips.
- The batch can be released without opening the pack to check the internal packing indicator.
- All information relevant to release the load is supplied on completion of the process so that the person authorized can release the batch.
- Cost effective. Only one indicator strip is required for each sterilization process instead of one in each pack.
- Easy interpretation of the results due to precise colour change.
- The graduated colour change of the indicator bars shows the level of the penetration into the PCD.
- The indicator colour chemistry is a non-reversible chemical reaction. The indicator strip can be documented proof for several years without changing back to its original colour.
- Environmentally friendly, no unnecessary waste.
- ***gke*** self-adhesive labels simplify recording with the ***gke*** *Steri-Record*® documentation system.
- The test device can be used for an unlimited-number of cycles. All important parts are made of stainless steel.
- Continuous reproducibility of the results over the lifetime of the PCD.
- All ***gke*** chemical indicators are protected from bleeding by a polymer binder and surface coating and can be disposed with normal garbage.
- For validation biological indicators are available according to EN ISO 11138-1 + 2
- Assurance that only sterile released packs are used.

Order Information

Art.-No.*	Product code	Quantity	Content	Application
200-028	C-E-PM-HPCD	1	Stainless steel helix test device according to EN 1422	Monitoring EO sterilization processes
212-202	C-E-PM	250	Chemical integrating indicator strips, 1 seal ring	for all EO sterilization processes
221-601	B-E-H-SS-10-6	100	*B. atrophaeus* spore strips on paper carrier, 10^6	

*All article numbers are supplemented with a three digit letter code providing the language, customized- or sample version.

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