

<i>gke</i> – Technical Information	TI 730-114-EN	
Batch Monitoring - The user's liability – no matter who made an incorrect recommendation	Version 01	
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The sterilization processing of medical devices has to be carried out with validated methods according to the European Medical Device Directive (MDD). A validated process has to be efficient (approved by a validation procedure) and shall not unnoticeable change during daily operation. The requirement for reproducible results applies to all validated processes in all industrial areas, as well in health care. Therefore, a validated process always includes routine monitoring to be able to detect any changes of the process parameters.

Routine monitoring is required in the validation standard (EN ISO 17665-1) for steam sterilization processes. The standard describes tests that have to be carried out during validation and afterwards for routine monitoring (user's side) to guarantee that the process does not change without being detected.

User of steam sterilization processes have to monitor the compliance with critical parameters in each cycle according to EN ISO 17665-1. The critical parameters pressure and temperature over time are monitored by modern sterilizers with built-in sensors. In addition EN ISO 17665-1 requires a steam penetration test for every batch which is another critical variable in sterilization processes. Steam penetration varies depending on the load configuration. Sterilization of complex hollow devices is more demanding regarding air removal and steam penetration than the sterilization of solid instruments or porous loads.

Physical data (pressure, temperature) are monitored by the sterilizer itself allowing no conclusion about steam penetration. A sterilizer is not able to "know" which goods are placed inside. Therefore, a release of the batch cannot be made with the data provided by the sterilizer alone. According to the above mentioned standard the verification of sufficient steam penetration has to be carried out in each batch by using a batch monitoring system that consists of a process challenge device and appropriate indicator strips. The test has to be selected so that it is more challenging in terms of air removal and steam penetration than the most difficult load.

Minimal requirements for routine monitoring and documentation are precisely described in above-mentioned standard and in the MDD and have to be executed by the operator of a sterilization process. If a user abandons such required tests – maybe by recommendations of a third party – liability still remains with the operator. From a legal point of view a third party advice will not transfer the liability to the advisor even if he has made incorrect recommendations.