Introduction – No validation standard

Hydrogen peroxide (H_2O_2) sterilization processes(*) are used in many health care facilities to sterilize medical devices. The processing of medical devices has to be carried out with validated procedures according to the European medical device directive (MDD).

The requirement for a standard validation is not available since there is no special validation standard available for hydrogen peroxide sterilization processes. Therefore the general validation standard EN ISO 14937 has to be used.

Requirements to validate the process:

To validate a sterilization process and to establish a standard, the following requirements have to be fulfilled:

A resistometer (test sterilizer) is necessary

A special test sterilizer, a so-called resistometer, is necessary to find out and test all critical variables. Such a resistometer is currently not available on the market for hydrogen peroxide sterilization processes.

Hydrogen peroxide is an extreme reactive chemical, which is explosive as a pure component and used as rocket fuel. Therefore, the material is mixed with water to be used without explosion risk. Water reduces the reactivity but unfortunately also reduces the sterilization efficacy.

During sterilization the germs are inactivated with the reaction of hydrogen peroxide. At the same time water is generated.

Water is inhibiting the sterilization efficiency, but injected with hydrogen peroxide into the chamber and additionally produced during sterilization. The quantity of water is increasing during sterilization and reducing the sterilization speed.

A test sterilizer requires that all critical variables temperature, time, water and H_2O_2 concentration remain constant and can be selected.

GKE has developed a test sterilizer to fulfil all the required criteria above and will provide D-value determinations of biological indicators on their biological indicator certificates.

(*) In many hydrogen peroxide sterilization processes at heat-up and at the end of the program plasma is set off to eliminate the existing hydrogen peroxide. The sterilization is also often called plasma sterilization. However, plasma is not the sterilization agent.

A reference germ (biological indicator) is necessary

A reference germ (biological indicator) must have a higher resistance than pathogenic germs listed in the standard EN ISO 14937.

Currently for testing hydrogen peroxide sterilization processes *Geobacillus stearothermophilus* is used which is also used in steam sterilization processes. This biological indicator is used because there is no other one tested in a resistometer.

Furthermore the resistance of a germ depends not only on the germ itself but also on the material that is used for the carrier. The identical germ has a completely different resistance depending on the carrier material, e.g. Tyvek or glass fibre, cellulose, stainless steel or aluminium. The influence of the carrier material on the resistance is less intensive in other sterilization processes rather than in hydrogen peroxide sterilization processes. This observation is not only relevant for biological indicators but also for the instruments to be sterilized themselves.

Today's practise according to the validation standard EN ISO 14937

Hydrogen peroxide sterilization processes cannot be validated since two main requirements (missing resistometer and reference germ, see above) cannot be fulfilled. These processes can only be approximately evaluated according to the general standard for validation of sterilization processes EN ISO 14937.

The instruments have to be inoculated with biological indicator suspension and after sterilization they have to be tested in a microbiological laboratory for growth. Only this method allows the conclusion if a specified instrument can be sterilized in this process or not.

The most difficult positions of the instrument (e.g. inside of hollow instruments) have to be inoculated. Measurements/studies show that the penetration of hydrogen peroxide in long hollow devices with narrow diameters is limited and the sterilization of complex instruments may be difficult.

The sterilization complexity does not only depend on the geometry of the instrument but also on the material. It is not possible to infer from one instrument to another. Each instrument has different dimensions and consists of other materials. The test with spore suspension has to be carried out for each instrument.

Summary

The hydrogen peroxide sterilization process can effectively sterilize surfaces. However, there is always an uncertainty about the influence of the materials used and also about the penetration characteristics of the sterilization agent inside packages and hollow devices.

As long as it is not possible to carry out a process validation, most questions cannot be answered. As a consequence each instrument has to be individually inoculated and tested if the instrument and its material can be sterilized in a defined process.