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Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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Steam Sterilisation Technology - Medistri

🚀 Steam Sterilisation Technology

Steam sterilisation is a widely used non-toxic sterilisation technology that works by exposing your products to pressurised steam at high temperatures in order to destroy viable microorganisms. Medistri's Steam Sterilisation Infrastructure is fully certified for Medical Device Sterilisation in accordance with ISO 17665.

Steam sterilisation technology exposes your products with saturated steam under pressure. Steam enhances the ability of heat to kill microorganisms by reducing the time and temperature required to denature or coagulate proteins in the microorganisms. Steam sterilisation cycles generally have three phases including conditioning, exposure and exhaust. Steam sterilisation is a simple but very effective method of decontamination.

The 3 phases of a standard Steam Sterilisation cycle are:

1. **Pre-Conditioning:** During this phase, the air is removed from the chamber and the load is humidified by means of alternating vacuum and pressure pulses.
2. **Exposure:** During this phase, the chamber temperature is raised to and held at the pre-validated sterilising temperatures for the per-validated exposure duration.
3. **Post-Conditioning:** During this phase, dry loads are cooled and dried or liquid loads are cooled. The chamber is brought to atmospheric levels.

Steam sterilisation is important because it is a highly effective method of deactivating microorganisms through the total elimination of germs, providing a sterile product for later use. It is widely used and dependable because it is nontoxic, inexpensive, rapidly microbicidal, sporicidal, and rapidly heats and penetrates fabrics.

Some of the advantages of Steam Sterilization are:

✔️ It's fast. Cycles length can range between 1 and 3 hours.
✔️ There's decreased Biocompatibility complexities.
✔️ It's suitable for Clinics, Hospitals & Private Practices.
✔️ It's suitable for batches smaller than 400L.
✔️ It's suitable for R&D stages of product development.

Products are sterilised by being exposed to saturated steam at high temperatures (121°C to 134°C). The exposure time of the device to steam is between 3 and 15 minutes, depending on the heat generated.

For effective steam sterilisation, it is essential that the steam covers all surfaces of the device. To ensure optimal conditions, our autoclaves are equipped with built-in meters that display temperature and pressure conditions over time. Biological indicators and a colour indicator are also used to assess the performance of the autoclave.

ISO 17665 specifies the various requirements for the development, validation and routine control of a steam sterilisation process for medical devices. The procedures that are covered by ISO 17665-1:2006 for steam sterilization include, but are not limited to:

- Saturated steam exhaust systems.
- Saturated air/steam exhaust systems.
- Air/steam mixtures.
- Water vaporization.
- Water immersion.

This standard was last reviewed and confirmed in 2016. Therefore this version remains current. ISO 17665-1:2006 includes requirements for the following:

- Quality management system elements such as documentation, management responsibility, product realization, measurement, analysis and improvement.
- Sterilizing agent characterization including the sterilizing agent, microbicidal effectiveness, materials effects, and environmental consideration.
- Process and equipment characterization including the process and equipment.
- Product definition.
- Process definition.
- Validation.

Our team focuses on designing custom cycles after studying all the critical parameters of your products to deliver high sterility assurance levels without influencing the validity of the products. Medistri also prepares the validation protocol, performs all the required sterilisation cycles, and carries out all the tests to generate a complete final report.

🎯 To learn more about Medistri's Steam Sterilization, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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