

Providing Sterilisation & Laboratory Services
for the world's most innovative healthcare
companies.

Contract Sterilisation Services

Steam Sterilisation

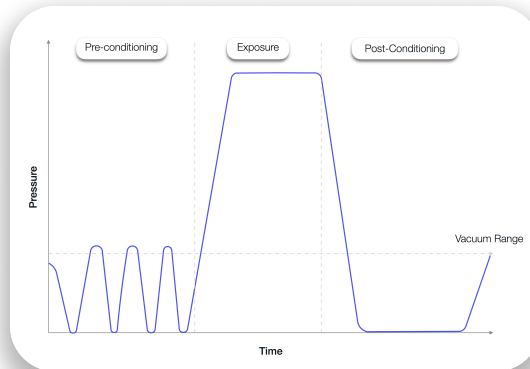
Steam Sterilisation technology exposes your products with saturated steam under pressure. Steam enhances the ability of heat to kill microorganisms by reducing the time and temperature required to denature or coagulate proteins in the microorganisms. Steam sterilisation cycles generally have three phases including conditioning, exposure and exhaust. Medical devices that have contact with sterile body tissues or fluids are considered critical items. These items should be sterile when used because any microbial contamination could result in a disease transmission.

Use Medistri's Steam Sterilisation infrastructure to sterilise your products.

- Ready-to-use pharmaceutical packaging systems.
- Surgical instruments.
- Biopsy forceps.
- Implanted medical devices.
- Syringes.
- Container-closure systems.
- Cartridges.

The 3 phases of a standard Steam Sterilisation cycle:

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



There are four parameters of steam sterilization: steam, pressure, temperature, and time. Steam sterilization is generally carried out at:

- **Temperatures:** Between 121°C (250°F) and 134°C (273°F).
- **Pressure:** Under 15–30 psi (1.0–2.0 bar).
- **Duration:** Between 15 and 60 min, depending upon the material and the type of organism to be inactivated.



At Medistri, companies of every size, from startups & university projects to Fortune 500 companies, use our Steam sterilisation infrastructure throughout the different stages of their product development.

Advantages

- ✓ Fast. Cycles length can range between 1 and 3 hours.
- ✓ Decreased Biocompatibility complexities.
- ✓ Suitable for Clinics, Hospitals & Private Practices.
- ✓ Suitable for batches smaller than 400L.
- ✓ Suitable for R&D stages of product development.

Disadvantages

- ✗ Strong mechanical & thermal stress on the product and its packaging.
- ✗ Limited to specific packaging designs and variations.
- ✗ Not suitable for industrial volumes 400L.



According to ISO 17665

ISO 17665 & EN 285 specify the requirements for the development, validation and routine control of a moist heat sterilization process for medical devices. Moist heat sterilisation processes covered by ISO 17665-1:2006 include but are not limited to:

- Saturated steam venting systems.
- Saturated steam active air removal systems.
- Air steam mixtures.
- Water spray.
- Water immersion.