

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

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## Introduction to Steam Sterilisation - Medistri

### 🚀 Introduction to Steam Sterilization

#### 👉 What is Steam Sterilisation?

Steam Sterilisation Technology is a simple yet very effective decontamination method. Sterilisation is achieved by exposing products to saturated steam at high temperatures (121°C to 134°C). The device's exposure time to steam would be anywhere between 3 to 15 minutes, depending on the generated heat.

#### 👉 How does Steam Sterilisation work at Medistri?

Steam sterilisation works by placing products in a steam autoclave and exposing the products to pressurised steam at high temperatures in order to destroy viable microorganisms. By modifying temperature factors, pressure factors and humidity conditions, we can reach the balance point between the liquid and gas phase of the water. This allows for the creation of saturated steam which will immediately induce condensation on the surface of the product to sterilise.

#### What is the Steam Sterilisation Validation process?

Medistri offers complete validation of your products for steam sterilisation according to ISO 17665. The validation integrates physical and microbiological qualification processes. Our experts aggregate all data, outline findings and recommend risk management proposals in a transparent, detailed and precise manner.

#### 👉 What are the benefits of Steam Sterilisation at Medistri?

- 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.
- The process components of steam sterilisation provide the benefit of being non-toxic which reduces the bio-compatibility complexities.

#### 👉 Who uses Steam Sterilisation?

At Medistri, Steam sterilisation is used regularly for the sterilization of pharmaceutical vials & syringes.

#### 👉 What are the regulatory requirements for Steam Sterilisation?

ISO 17665 specifies 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

✅ Medistri is fully qualified to perform Steam Sterilisation according to ISO 17665, ANSI & AAMI guidelines.

For effective Steam Sterilisation it is critical that the steam covers all surfaces of the device. To ensure optimal conditions, our autoclaves have built in meters that display temperature and pressure conditions with respect to time. Biological indicator devices and Indicator tape which changes colour are also used to gauge the performance of the autoclave.

🎯 To learn more about our Steam Sterilisation Services, visit our website [www.medistri.swiss](http://www.medistri.swiss) or contact our team directly at [contact@medistri.swiss](mailto:contact@medistri.swiss).

#### - The Medistri Team

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#Pharmaceutical #MedicalDevices #MedTech #BioTechnology  
#SterilizationServices #LaboratoryServices  
#SteamSterilisation  
#SterilisationValidation

Medistri's Contract Steam Sterilisation Services :  
<https://www.medistri.swiss/servicesubpage/steam-sterilisation-services>