



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

From the Blog

Steam Sterilization at Medistri

September 8th 2025

Sterilization refers to the process of removing, killing, or deactivating all forms of life (microorganisms such as fungi, bacteria, spores, and unicellular eukaryotic organisms) and other biological agents. Steam sterilization is a widely used method for items that can withstand moisture, high temperature, and pressure. Its primary purpose is to inactivate microorganisms, ensuring a sterile product for safe use.

To guarantee consistent results, manufacturers must comply with established standards such as ISO 17665. This standard specifies the requirements for the development, validation, and routine control of a moist heat sterilization process for medical devices. Validation involves both physical and microbiological qualification processes that confirm the method's effectiveness.

Physical Qualification Processes

Physical qualifications verify that the sterilizer is functioning properly and consistently. Examples include:

- **Bowie-Dick Test:** Checks steam penetration and air removal using a chemical indicator test pack.
- **Empty Chamber Heat Distribution Studies:** Establishes temperature uniformity in the sterilizer chamber and identifies the "coolest point," measured with calibrated data loggers.
- **Loaded Chamber Heat Distribution & Penetration Studies:** Confirms heat distribution and penetration in a defined loading pattern with calibrated probes.

Microbiological Qualification Processes

To complement these physical assessments, microbiological qualifications provide further assurance that resistant microorganisms are effectively inactivated. The use of biological indicators offers a direct measurement of process lethality and confirms that the required sterility assurance level has been achieved.

Laboratory Support

Medistri's in-house laboratory provides specialized microbiology services to support steam sterilization validation, including:

- Endotoxin/LAL testing
- Sterility testing

Our team compiles all results and delivers risk management recommendations in a clear and accurate manner, ensuring every step of the validation is thoroughly documented.

Partner with Medistri

Work with Medistri's team to identify the most challenging sterilization locations and specific complexities of your products. Using precise data, our experts determine the optimal placement for biological indicators, enabling complete monitoring of the validation process.

🌐 To learn more about Medistri's Steam Sterilization at Medistri, visit our website [here](#) or contact our team directly at contact@medistri.com.

— The Medistri Team

#Medistri



Medistri's Expertise

At Medistri, qualification and validation procedures are part of routine operations. These include daily control of sterilizers and periodic requalification to ensure reliable performance. Our experts work closely with your team throughout the process and deliver a comprehensive validation report. The report details process analysis, test results, and recommendations, ensuring full transparency and traceability.

Medistri offers complete validation of products for steam sterilization in line with ISO 17665. Depending on the product and process, validation activities may include:

- Equipment calibration
- Chamber and load mapping
- Biological indicator placement and monitoring
- Heat penetration studies with microbiological challenge
- Routine control and requalification of sterilization infrastructure

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1. What is steam sterilization and when is it used?

Steam sterilization is a process that uses moisture, high temperature, and pressure to inactivate microorganisms. It is commonly applied to products that can withstand these conditions, ensuring they are sterile and safe for use.

2. Why is validation necessary in steam sterilization?

Validation demonstrates that the sterilization process consistently achieves the required sterility assurance level. It ensures compliance with standards such as ISO 17665, which specifies the requirements for developing, validating, and routinely controlling moist heat sterilization processes for medical devices.

3. What are physical qualification processes in steam sterilization?

Physical qualifications confirm that the sterilizer is functioning properly. Examples include Bowie-Dick tests to check steam penetration, empty chamber studies to measure heat distribution, and loaded chamber studies to assess temperature uniformity in defined product loads.

4. What role do microbiological qualifications play?

Microbiological qualifications provide direct evidence that resistant microorganisms are effectively inactivated. Using biological indicators, the lethality of the process is measured to ensure the required sterility assurance level is achieved.

5. How does Medistri support steam sterilization validation?

Medistri integrates both physical and microbiological assessments with laboratory services such as endotoxin/LAL testing and sterility testing. Our experts compile results, provide risk management recommendations, and deliver comprehensive validation reports, ensuring full transparency and regulatory compliance.

