

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

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ISTA Packaging Standards - Medistri

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Packaging Validation lets you measure & certify the strength of your packaging when it is faced with unknown distribution, logistical & environmental stressors.

Although validating your packaging is a regulatory requirement in the medical device & pharmaceutical industries, the process offers several advantages:

- Examine your packaging risk potential against controlled environments.
- Optimise the costs of your packaging for optimal results.
- Improve your packaging performance.
- Reduce end-user complaints.
- Reduce damage products.
- Maintain the same quality standard across multiple distribution markets and environments.
- Reduce costs of packaging modifications & redesigns.
- Increase end-user satisfaction.

✓ To guarantee the safe delivery of your packaging's content, ISTA creates internationally recognised and cross-industry respected test procedures based on leading research and the latest current global transport data. The organization provides the final validation of package revisions through its packaged-product performance test procedures. For medical device manufacturers, the ISTA packaging validation procedures/testing standards are in compliance with the ISO 11607.

👉 ISO 11607-1 specifies the requirements related to the compliance of the packaging for sterilized medical devices, including materials, sterile barrier systems and packaging systems.

The International Safe Transit Association (ISTA) is a member-based nonprofit organization that gives organizations the tools they need to reduce product damage along the whole supply chain and maximize resource use through efficient package design.

Packaging Validation for medical devices & pharmaceutical goods is segmented into three categories:

1. Environmental Conditioning.
2. Transport Simulation (also known as Transit Testing).
3. Integrity Testing (also known as Sterile Barrier Integrity Testing).

✓ Once you've performed the first two test categories, we finish the packaging validation process with Sterile Barrier Integrity Testing in our laboratory. This last series of tests allows you to ensure that your packaging's sterile barrier has not been compromised during the previous tests.

At Medistri, you can validate your packaging according to ISTA 2A, ISTA 3A, ASTM D7386, ASTM D4169. Should you fully validate your packaging system or should you simply test one particular characteristic of your sterile barrier system, Medistri laboratory is accredited and highly experienced for the most common test method provided in ISO 11607-1.

🌐 To learn more about Medistri's Packaging Standards, visit on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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