

# Medical Devices Packaging Validation



## What Is Packaging Validation for Medical Devices?

**Packaging validation** is an important step in our [medical device testing](#) which ensures the safety and durability of the packaging for medical devices. Packaging validation includes **sterilisation control, sealing testing**, as well as intense testing of the **robustness of packaging**. Our packaging validation ensures that **storage and transportation packaging** comply with regulatory standards.

Applus+ Laboratories offers packaging validation as part of our **batch release testing services**. This is to make sure that medical devices are well packaged and can withstand differing storage and transportation conditions. We offer packaging validation along with:

- [Biocompatibility testing](#)
- Cleaning validation
- Material and Chemical Characterisation
- Stability validation

## What Packaging Validation Services Do We Offer?

We offer **comprehensive packaging validation services** to test packaging solutions. These services are major test methods according to **NF EN ISO 11607-1 standard** and are critical for the certification of packaging for medical devices.

### Visual Inspection of Seals According to ASTM F1886

We provide visual inspection of seals according to ASTM 1886 standard. This involves the **close examination of seals** in order to spot any potential sealing defects that might be visible to the naked eye at a **distance of 30 to 45 cm**. In order to pass, a seal must

not exhibit any defects such as holes, inclusions, channels, or pores that could affect its integrity. The seal should not show any signs of **delamination** or **detachment of the paper**.

## Manual Peeling and Seal Strength Tests

We conduct rigorous testing methods for evaluating the manual peeling and seal strength of medical packaging materials. We perform these tests **according to the NF EN 868-5 standard**.

- **Seal Peelability NF EN 868-5 Annex E**  
Seal peelability testing involves a visual inspection of the seal for **imperfections** or **inadequate coverage**. This also includes observing that there is **no paper cleavage outside the sealing area** which needs to be **at least 6 mm**.
- **Strength of Sealings NF EN 868-5 Annex D**  
Sealing strength assessments are performed with a resistance test using a **tensile machine**. A **punch knife** and **press** are used to cut perpendicularly to the weld from the pouches. For steam sterilisation processes, the acceptance criterion is that **the value must not be less than 1.5 N/15mm**. For other sterilisation processes, the value must not be less than 1.2 N/15mm.

## Integrity Testing by Dye Penetration ASTM F1929 / ASTM F3039

We perform **dye penetration tests** on both porous and non-porous packaging materials in order to detect leaks. This involves **introducing coloured solution** within the packaging to visibly signal where there might be **holes or cracks** in the sealing that emit leaks. The sealing should not allow for any passage of liquid.

## Integrity Testing by Bubble Test ASTM F2096

We conduct this method to validate that the packaging is **perfectly leak-tight**, both at the welds and at the faces of the materials. This integrity testing consists of detecting any leaks in sterile barrier systems by applying pressure inside the packaging.

## Natural and Accelerated Ageing Tests

We provide **crucial natural and accelerated aging tests** to determine the lifespan and expiry dates of medical devices. These dates are typically 2 to 3 to 5 years and we test both the accelerated and natural tests **simultaneously according to the ASTM F1980 standard** to validate the packaging's integrity post-aging. **This process uses Arrhenius' law** to establish time/temperature equivalence. Passing this test can greatly speed up a manufacturer's time to market.

## Transport Tests Simulation

We **perform transport test simulation** is a critical validation process used to ensure that medical packaging can **withstand being transported**. We mainly test according to two standards: the ASTM D4169 standard and the [International Safety Transport Association \(ISTA\) programme](#).

First, we define the **test sequence representative of the distribution circuit**, then we apply the various mechanical stresses associated with transport: climatic environment, drop, compression, vibration, altitude. At the end of the tests, a **full validation of the packaging is performed** to validate its integrity and the maintenance of sterility. The medical devices are returned to the customer for verification of the devices after transport tests.

## What Are the Advantages of Packaging Validation?

Packaging validation is essential for making sure the packaging material for your medical devices is secure and **conforms to regulatory requirements**. Packaging validation has important advantages for clients since means that your product is **fully certified and able to enter the marketplace**. These advantages include the following:

- **Performance and Reliability**  
Our packaging validation ensures the **integrity of your medical device's packaging** under various environmental and logistical conditions throughout its lifecycle. This is critically important to ensure that when patients receive the product, it **functions exactly as intended**, without any issues caused by packaging faults.
- **Patient Safety**  
Effective packaging validation tests the packaging's ability to **prevent contamination and physical damage**, thereby protecting the medical device from failures that **could pose a safety hazard** to patients. Particular attention is given to the strength of the seals and barrier properties to **eliminate risks of leaks and contamination penetration**.
- **Compliance with Regulatory Requirements**  
By adhering to strict regulatory standards, our packaging validation process not only ensures compliance with legislation but also **enhances consumer confidence**. Demonstrating that product packaging can effectively protect it throughout its lifecycle bolsters consumer confidence in its safety and efficacy.
- **Risk Minimisation**  
Packaging validation identifies risks such as **packaging degradation, breaches in sterile barriers**, and the **potential for physical damage** during transport. By identifying these issues, necessary adjustments can be made to enhance packaging robustness, ensuring that the product withstands the rigours of transportation and storage without **compromising safety or performance**.
- **Market Access**  
Adhering to international packaging standards broadens the market access of your



product. Certified reliable packaging allows for the **safe transportation and storage of your medical device** in various regions, thereby expanding your global presence and market potential.

## Why Choose Applus+ Laboratories for Packaging Validation?

Choosing Applus+ Laboratories for your package validation aligns you with a **distinguished leader in medical device testing**. Our services, compliant with ASTM and ISO standards, are specifically crafted to guarantee the structural integrity and safety of your medical device packaging.

At Applus+ Laboratories, we offer packaging validation testing combined with **exceptional client service**, making us the ideal partner for your packaging needs. We support the full spectrum of your project, from development to market entry:

- Our team delivers **development testing and insightful recommendations** for enhancing packaging designs, ensuring your packaging meets high-quality standards.
- We conduct thorough **lifecycle testing of packaging** to ensure it preserves product integrity across various conditions and over time.
- We provide **qualification services** for both your product and its packaging, performing detailed evaluations to ensure your packaging solutions are **robust and effective**.
- Our **Contract Manufacturing Organisation (CMO) services** also include comprehensive support for packaging operations.

With operations **across multiple countries**, Applus+ Laboratories brings our leading-edge packaging validation testing services to clients worldwide, ensuring accessibility to superior testing solutions wherever you are located.

Choose Applus+ Laboratories as your trusted advisor and partner in medical device packaging testing. Our commitment to **providing high-quality services** and **expert guidance** is designed to streamline your path to market while navigating the complexities of packaging validation with confidence and precision.