

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

Packaging Validation Services

The Complete Range of Tests

Packaging Validation stems from the need to ensure the quality of products across the many steps in your distribution cycle: from shipping to storage. It is an increasingly common requirement for many product categories, including a strong emphasis on the packaging quality requirements for the medical and pharmaceutical industries.

Test for Strength & Integrity.

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

- Environmental Conditioning.
- Transport Simulation (or also known as Transit Testing) .
- Integrity Testing (or also known as Sterile Barrier Integrity Testing).

Medistri's most popular packaging validation tests.

Environmental Conditioning.

Sterile Barrier System Integrity Testing.

- Accelerated Ageing Tests
- Real-Time Ageing Tests
- Visual Inspection Tests
- Dye Migration Tests
- Bubble Emission Tests
- Seal Tensile Strength Test
- Peel Strength Test
- Burst Test

Transport Simulation Testing.

- Atmospheric Preconditioning
- Atmospheric Conditioning
- Mechanical Handling Test
- Compression Test
- Concentrated Impact Test
- Free Fall Drop Test
- Fork Handling Test
- Low-Pressure Test
- Loose Load Vibration Test
- Fixed or Random Vibration Test
- Incline Impact Test
- Rotational Drop test

For Pharmaceuticals & Medical Devices

Medistri can validate your packaging according to **ISTA 2A, ISTA 3A, ASTM D7386, ASTM D4169 and more**. To fully validate your packaging system or simply test one particular characteristic of your sterile barrier integrity system, Medistri's in-house laboratory is highly experienced to bring together the right testing plan to test the packaging's performance for medical & biopharmaceutical products.

- Predict the performance of your packaging during your distribution cycle.
- Identify cost savings potentials in your packaging.
- Compare packaging designs using technical results.
- Meet your regulatory requirements & objectives.
- Minimise risks of product-damage & infections.
- Increase customer satisfaction.

ASTM Standards.

ASTM, the American Society for Testing and Materials is an international standards organisation that develops and publishes quality standards. The ASTM guidelines are an agreement between the consumers, producers, government bodies and scientists from over 140 countries on the implementation of quality & testing requirements of packaging.

ISTA Standards.

International Safe Transport Association is an organisation devoted to understanding the expectations of secure transport services. It is the key source of research protocols for packaging validation that has been evolving methodology since 1948.

Accelerated Aging Tests.

The Accelerate Aging test simulates real-time aging using elevated environmental conditions to artificially speed up the aging process. This test enables manufacturers to get their product to market faster with accurate data.

According to ISO 11607-1.

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

- **Sterile barrier system:** "The minimum packaging that prevents the entry of microorganisms and allows the sterile presentation of the product in the place of use".
- **Protective packaging:** "A material configuration designed to prevent damage to the sterile barrier system and its contents from the time they are assembled until they are used".
- **Packaging:** "A combination of the sterile barrier system and the protective packaging".

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

The New Stack of Fully Integrated Services.

Validation Infrastructure

Sterilisation Validation

Cleaning Validation

Process Validation

Disinfection Validation

Packaging Validation

Transport Simulation

Sterile Barrier Integrity Testing

Aging Tests

Laboratory Infrastructure

Chemistry

Biocompatibility & Toxicology

Sterility Assurance

Extractable's & Leachable's

Manufacturing Infrastructure

Product Assembly

Custom Packaging Solutions

Quality Control & CE Marking

Labelling & Distribution

Sterilisation Infrastructure

Steam Sterilisation

EO Sterilisation

Medistri is continually innovating its **in-house** range of services. We're expanding our infrastructure to offer a completely integrated stack of services for healthcare companies. Organisations of every size — from startups to large enterprises use our suit of services to start, grow & optimise their business.

Within our site located at the heart of Switzerland, we **combines all its technical infrastructure together** and places quality at the heart of its day-to-day operations. Allowing you to simplify your supply chain management, focus on growth & maintain excellence.



Swissmedic
& FDA Registered