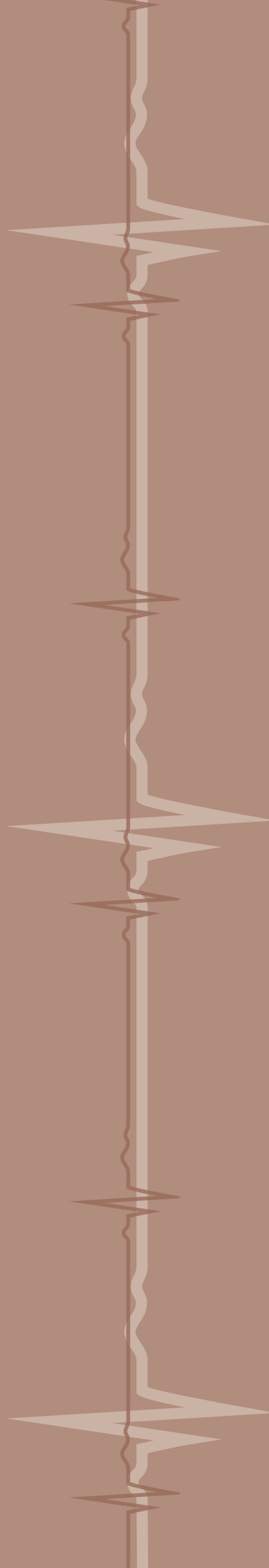
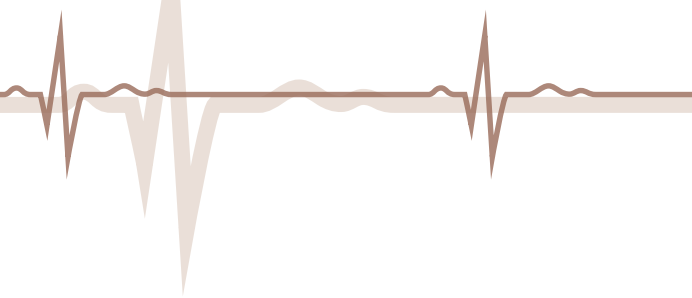




Your Partner for Medical Device
Testing and Transport Simulation

paaconsult
MEDITEC





Tensile Test



Climatic Conditioning



Integrity Test



Burst Test



Visual Inspection



Accuracy



Gravimetry



Workshops

paconsult Meditec – Your partner for Packaging and Medical Device Testing

From the first test specification to final documentation;
with tests of paconsult you can be sure that you will offer a high-quality and durable product.
To ensure this, the aim of our services is to recognize potential vulnerabilities in each test phase.
We support you throughout the entire life cycle of your product and packaging.

paconsult Meditec – everything from one source

- Creation of test strategies and worst-case analysis
- Developing and realizing the test setup
- Provision of external services
- Creation of test plans and final reports
- Custom validation in accordance with ISO 11607-1 and ISO plans 11607-2
- Process validation, shelf-life validation, transport validation for sterilized medical devices
- In-house training and seminars
- Transport and packaging testing for non-sterilized medical devices
- Physical testing of active and non-active medical devices
- Breadth of experience
- Wide range of experience, reliability, timely processing and highly professional competence



*„Your image – benefiting
from each product“*

Convince yourself of our experience –

Whether durability tests, transport simulation or mechanical functional testing -
we perform product, material and packaging tests according to national and international standards, and your internal quality standards.



„Sterile Products by validated Packaging”

Packaging Validation according to ISO 11607

In accordance with ISO 11607, we perform packaging validations for processing, shelf life and transport stability of sterilized medical devices.

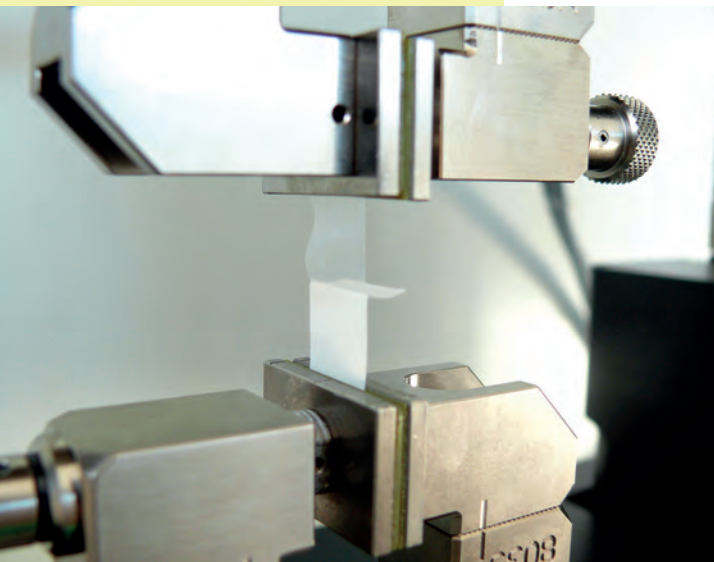
For validation of the packaging process we offer individual solutions for the implementation of the Operation Qualification (OQ) and Performance Qualification (PQ) in accordance with ISO 11607-2 and support you in the definition and implementation of revalidation.

We perform complete shelf-life and transport validations according to ISO 11607-1 and support you in the definition of product families and worst-case analysis.



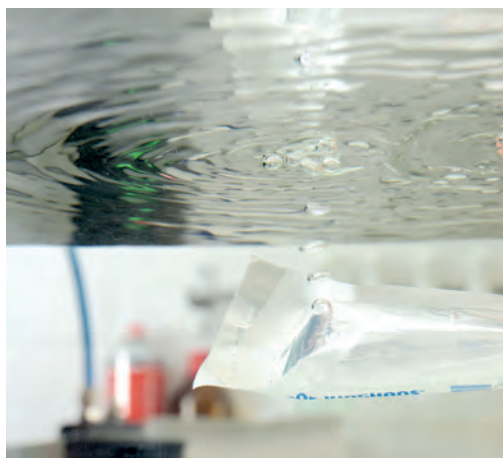
*Climatic Lab for Material Testing
(23 °C / 50 %rH)*

Seal Strength Testing



*Sterile Barrier:
Pouches and Blister*

Integrity Testing:
Bubble Test and
Dye Test



Packaging- and Material Testing

TEST SYSTEMS

Integrity Testing

- Dye Penetration (ASTM F1929, ASTM F3039)
- Bubble Test (ASTM F2096, ASTM D3078)
- Visual Inspection (ASTM F 1886)
- Leakage Test (ASTM D4991)

Seal Strength Testing

- Tensile and Peel Test (ASTM F88 und EN 868)
- Burst Test (ASTM F1140)

Shelf-life Studies und Accelerated Aging

- according to (ASTM F1980)

Transport Simulation Tests

- according to (ASTM D4169)
- according to ISTA 1, 2 & 3 Series

Packaging Material Testing

- Tensile test on foil material (ASTM D882, ISO 527)
- Air Permeance (ISO 5636, ISO 11607-I Annex C)
- Print and Labeling (ASTM F2252)



Conditioning and Aging Tests

Transport Simulation

TO MAKE SURE YOUR PRODUCT ARRIVES ABSOLUTELY SAFELY

- Packaging Design
- Product Safety and Stability
- Marketing Authorization

In transport, handling and storage processes, not least an optimized packaging system ensures product safety, maintenance of sterility and cost savings.

Whether your product is shipped by parcel service, carrier or air freight, in our laboratories, we are able to simulate common shipping stress.

With the selection of appropriate standards for packaging and product tests, you can identify possible vulnerabilities, preventive during product development or analyzing after completion. This enables you to deduce optimization measures and to guarantee the safe distribution of your product.

Our ISTA (International Safe Transit Association) certified laboratory in Hamburg will be pleased to support you with their „Know How“.



Medical Devices

PHYSICAL AND MECHANICAL TESTS

Your product will be tested in accordance with international and national standards and internal specifications:

Flow measurement, tensile- and compression testing, bending and kink behaviour, gravimetric measurements, dimensional accuracy and visual inspection.

For special medical devices, new methods for mechanical functional testing can be developed and validated.



Drop and Vibration Testing

Experience and Expertise for a wide range of standards for testing of medical devices, for example:

- ISO 8536-4** Infusion equipment for medical use –
Part 4: Infusion sets for single use, gravity feed
- EN 1615** Enteral feeding catheters and enteral giving sets for single use and their
connectors – Design and testing
- DIN 13097-4** Hypodermic needles –
Part 4: Point geometry, requirements and testing
- ISO 9626** Stainless steel needle tubing for the manufacture of medical devices
- ISO 1135-4** Transfusion equipment for medical use –
Part 4: Transfusion sets for single use
- ISO 3826-1** Plastics collapsible containers for human blood and blood components –
Part 1: Conventional containers
- ISO 10555-1** Intravascular catheters – Sterile and single-use catheters –
Part 1: General requirements
- ISO 7864** Sterile hypodermic needles for single use
- ISO 7886-1** Sterile hypodermic syringes for single use –
Part 1: Syringes for manual use



Medical Devices:
Surgical Instruments,
Infusion Sets and much
more...





For further info please contact:



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Comprehensive Solutions in Process Automation and Technology