

## Package Shipping Validation



Shipping validation is mandatory for medical devices that are CE marked. MET's testing protocols follow ISO 11607-1:2006 *Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems*

Testing is usually applied to complete shipping cartons of products. The shipping simulation processes subjects the package to the rigours of transport and handling.

In the basic test we report on carton performance. The internal packaging can also be subject to our integrity and seal strength testing. Finally, the products themselves can be tested to assess their resistance to shipping.

We offer a choice of ASTM or ISTA testing protocols and variety of pre-conditioning regimes, which can be mixed:

Conditions	Temperature	Relative Humidity
Tropical	+38°C	85%
Desert	+50°C	low
Frozen	-20°C	low
Ambient/wet	+23°C	85%

### Testing protocols (Typical)

Shipping simulation to ASTM D4169-05 *Standard Practice for Performance Testing of Shipping Containers and Systems*.

- **Air transport** – long haul.
- **Initial manual handling** – ASTM D332-1, sch. A: Drop on each side from 15 inches – visual inspection.
- **Vehicle stacking** - ASTM 642-00, sch. C: Calculate stacking load, compress – visual inspection.
- **Loose load vibration** – ASTM D 999-01, schedule F: Vibrate at 40Hz for 40 minutes, turning twice – visual inspection
- **Vehicle vibration** – ASTM D 4782-01, sch. E: Vibrate at 2-200Hz at RMS 0.52G for 180 mins, turning twice – visual inspection.
- **Final manual handling** – ASTM D 5725-98, sch. A: Drop each side from 15" and the base from 30" x 2 – visual inspection.