

Total Validation



Total packaging validation
with a difference



The need for validation is an integral part of the medical device industry. At Nelipak[®] Healthcare Packaging we understand the demands put on businesses by the work involved in validating both devices and equipment.

As no two products are the same, the test protocol will be tailor-made for your package at our fully equipped ISO 11607 compliant test lab.

Nelipak Services:

- Medical Packaging
- Sealing Machines
- Validation
- Product Development
- High Performance Applications
- Transport Totes
- Medical Rigid
- Robot Handling Trays
- Total Packaging Solutions



Total Validation

Packaging & process validation

Nelipak® offers a comprehensive range of services specifically providing support to your package testing and validation requirements. In addition to providing high quality testing and analysis, our team of experts has experience in problem solving and offering advice on all aspects of packaging design and regulation.

Our dedicated validation team will advise you on applicable standards and test methods. The test protocol will be tailor-made for you. The work will be carried out at our in-house validation centre. We will not only provide the test data, but we will interpret the data and provide conclusions, which can then be used as part of a submission to your notifying body.

Our validation centre carries out packaging testing in accordance with ISO11607 and the relevant ASTM, ISTA and ISO norms, including:

- Transportation simulation
- Packaging integrity testing
- Environmental conditioning
- Visual inspection
- Customer specific testing
- Shelf-life testing
- Sealing Validation
- Seal strength testing
- Dye penetration testing
- Process validation

BENEFITS

- Fully equipped ISO 11607 compliant test lab
- Testing to relevant ISTA or ASTM norms
- Nelipak® can advise on the testing protocol including:
 - Bracketing strategy
 - Sample size advice / justification
 - Advice on test sample build & traceability
 - Analyse test result / data and draw conclusions
- Create test reports
- Process validation of production processes
- Tooling validation
- Sealing IQ, OQ, PQ validation

DIVERSE CAPABILITIES

- Design, development and manufacturing
- Lidding material stock - printed / unprinted
- Cartons - printed product shippers
- Die cards - HDPE mounting cards
- Tray / blister sealing machines
- Contract packing - assembly / packing
- Material supply

NELIPAK® IN ACTION

A major pharmaceutical company with a product which had been on the market for a number of years came to Nelipak with a validation need. Following an audit by their notified body, it came to light that no packaging or process validation work had been carried out.

Nelipak advised on sample-size selection and devised a test plan within the applicable norms and standards. Working within tight time-lines Nelipak carried out a programme of testing.

On completion of the testing the data was analyzed by Nelipak. The client was presented with data and conclusions which allowed them to complete the required documentation within the deadline from their notified body.



LID STOCK PEEL TEST

Contact the Nelipak® Product teams at:

Nelipak® Corporate Head Office

21 Amflex Drive, Cranston
RI, 02921 USA

P +1 401 946 2699

E info@nelipak.com

Americas Offices

Whitehall, PA
P +1 610 261 2100

Phoenix, AZ

P +1 602 269 7648

Liberty, NC

P +1 336 622 2100

Caribbean Offices

Humacao, PR

P +1 787 285 2100

Heredia, CR

P +506 22 393 856

Europe Offices

Venray, the Netherlands

P +31 478 529 000

Galway, Ireland

P +353 91 757 152



www.nelipak.com