DDL Inc. is an ISO 9001:2000 registered resource for product, packaging and material testing services. We serve the medical device, chemical electronics, aerospace, packaging and automotive industries. Founded in 1990, our three strategically located testing facilities offer a wide range of test services, including:

- Accelerated Aging
- Material Evaluation
- Shipping/Distribution Simulation
- Package Integrity Testing
- Product and Material Testing
- Package Design and Prototyping

Our single source, totally integrated approach enables globally recognized corporations to maximize product performance, reliability and safety while seamlessly achieving regulatory compliance.

DDL’s mission is to provide our customers with the highest quality of testing services and engineering consulting services, at prices consistent with industry norms. Our testing services are delivered with integrity and a high degree of professionalism. We strive to be creative and experienced problem solvers in meeting our customers’ needs. Our primary goal is to exceed our customers’ expectations for the product, material and package testing services that we provide.

DDL provides product, material and package testing services that adhere to all applicable governmental and industrial standards for quality. We monitor the quality of the products and services we purchase from our suppliers to ensure adherence to the same high standards to which we hold ourselves.

DDL conducts its business in a manner consistent with community expectations regarding all issues of legality, ethics and environmental awareness. DDL’s relationships with its customers, employees, suppliers, and neighbors will be conducted on an ethical and honest basis. We strive to be a trusted and respected member of the business community. In addition, DDL, Inc. strives to provide our employees with a stimulating environment for their professional growth and development.
By applying decades of collective experience in test development and analysis, DDL’s professional team of packaging and product testing engineers has creatively resolved a broad spectrum of project challenges. For products seeking initial validation, we provide critical insight to identify and resolve potential design flaws before the final testing process is initiated.

Our approach to testing projects requiring a strategic third-party analysis involves a detailed investigation and review process. With this technique, we uncover potentially damaging and costly inconsistencies or oversights in testing and reporting methodologies that may have occurred at the point of origin. A protocol is then developed to ensure compliance measures are never compromised.

A COMMITMENT TO PROJECT DEADLINES

The critical package testing process is often the final step in the lengthy journey to bring products to market. Winning the battle over stressfully tight time constraints poses a difficult challenge for companies attempting to meet looming project and first to market deadlines.

At DDL we alleviate time concerns by initially providing a clear, comprehensive project quotation within four hours of your request. And, we offer an unmatched commitment to timelines and budgetary parameters. While the majority of testing protocols are completed within one week from receipt of samples, we also offer Priority One emergency expedition of your project to meet market critical product debut demands.

COMPREHENSIVE DOCUMENTATION

DDL’s clear, precise and detailed approach to protocol development and implementation allows us to generate a comprehensive, fully documented test methodology and results report, ready for direct submission to the FDA or other regulatory agencies. You then have the option of receiving a copy of this extensive analysis, or a succinct one-page overview, based on your desired level of involvement.

FEDERAL REGULATION COMPLIANCE

At DDL we invite you to eliminate the uncertainty of meeting challenging FDA, OE and ISO 11607 compliance mandates by transferring this responsibility to DDL’s proven and trusted industry experts. Serving active roles on all major technical committees for medical device packaging, DDL project engineers are made instantly aware of all forthcoming industry regulations. This enables us to immediately and correctly apply new standards to your particular project scenario, providing your company with ultimate security that your products will perform safely, efficiently and effectively.
Gain the Most Value for Your Testing Dollar

Today, more than ever, it is extremely important for packages containing medical devices or substances to maintain sterility or a reliable cold chain through appropriate package design.

For this reason, it is important to work with a packaging testing provider that not only tests and reports on packaging integrity, but also commits to consult with you in terms of how you can improve your packaging integrity and strength.

As tested and proven package testing professionals, DDL engineers believe that consulting services should be a value added service that comes with all package testing projects.

The Right Packaging Advice

Core DDL services include package testing and detailed reports of package pass/fail integrity status. To augment this service, DDL offers Pack-Advice counsel to package engineers actively engaged in a package testing initiative.

Advice can range from recommending methods that can improve your package sterility and strength, detailing alternative packing processes or materials and even addressing package manufacturing vendor selection.

Exceed Quality Standards

DDL is dedicated to conducting a preliminary analysis of your package testing requirements to ensure that your packaging meets and exceeds quality standards such as:

- ISO 11607 (CE Mark)
- the FDA Modernization Act, which calls for the safety and effectiveness of medical devices.

CHOOSING A TESTING PROVIDER

Assure Depth of Service

Tested and proven, DDL offers one of the broadest range of testing services within the package testing industry. Industry-leading package testing engineers at DDL are proud to offer the highest quality package testing and consulting services, including:

- Accelerated Aging
- Distribution Simulation
- Compression
- Environmental
- Shock
- Package, Strength & Integrity
- Vibration
Understand the testing provider’s point of interest
When searching for a pharmaceutical package testing expert, be sure that the company's testing is unbiased. The best way to assure this is to find a package testing vendor that remains independent from package manufacturers.
Because DDL maintains strict ethical standards, we are committed to conducting unbiased pharmaceutical package testing. Unlike other package testing labs that sell both testing and packaging, DDL will never recommend or urge you to buy a specific brand of packaging. Because of this policy, DDL can remain focused on high-quality and valid pharmaceutical package testing.

The Quick Test
When choosing a testing provider, call for a detailed quote. Take note of the response time and the way the quote is delivered. These are often indicators of future project performance, willingness to consult and even a clear understanding of your testing needs. Another way to determine validation expertise is by posing detailed questions regarding how a vendor would develop a statistically relevant sample.
DDL Inc. is your single source for medical device testing and validation for products, materials and packaging, as well as specific tests which may be required.

DDL has been a leader and innovator in the medical device testing industry since 1990. We offer single-source solutions to medical device development engineers, QA and regulatory affairs professionals who are concerned that their devices meet all regulatory agency requirements and the highest level of industry standards.

MEDICAL DEVICE PACKAGE TESTING

Medical device manufacturers are required to obtain 510(K) approval on each medical device package. DDL performs a variety of testing services to ensure the integrity of the medical device packaging is compliant with ISO Standards, such as ISO 11607.

Tested and proven, DDL offers one of the broadest range of testing services within the package testing industry. Industry-leading package testing engineers at DDL are proud to offer the highest quality package testing and consulting services, including:

- Accelerated Aging
- Distribution Simulation
- Shock
- Vibration
- Compression
- Environmental
- Package, Strength & Integrity

ISO 11607

ISO 11607 is the foremost guidance document for validating packaging for terminally sterilized medical devices. Packaging must comply with ISO 11607 to ensure that the enclosed medical device is kept sterile throughout all the elements and hazards generated by the manufacturing, shipping and storage environments.

The ISO 11607-01 standard has recently been revised to incorporate the provisions of the EN 868-1 standard. As a result, the new ISO 11607-01 is compromised of two parts:

- Part 1 - Materials & Designs
- Part 2 - Processes

Medical device manufacturers and package testing professionals should take note of the revisions to the ISO 11607 standard, as the revisions could mean the difference between pass or fail when it comes to package testing and validation.
Medical Device Testing

MEDICAL DEVICE PRODUCT TESTING

Medical device manufacturers use DDL one-stop package, product and materials testing services to certify medical devices such as catheters, syringes, needles, cannulae and other intravascular applications. We perform test methods, such as strength testing, luer gauging, flow rate testing and stress testing, on intravascular medical devices to ensure that they conform to ISO standards.

DDL is dedicated to using the most effective and sustainable testing techniques in an effort to ensure the accuracy and reliability of your tests. Our professional engineers and technicians provide reliable, quality-assured testing services and documentation throughout every step of the critically important testing and validation process.

ASSURING PRODUCT INTEGRITY AND STRENGTH

Testing the Life of a Package
Medical, pharmaceutical, food & beverage, heavy chemical, appliance, electronics, and even military organizations, all manufacture and distribute products that are eventually transported within a package.

In order to deliver a product that remains sterile, and has not been damaged during shipment or aging, it is extremely important for a manufacturer to seek out and engage a package testing professional with ASTM testing expertise:

Package Integrity Testing
✓ Bubble Leak F2096
✓ Vacuum D3078
✓ Dye Leak F1929

Package Strength Testing
✓ Pull Strength F88/F1140
✓ Peal Strength F88
✓ Burst Testing F1140

PACKAGE INTEGRITY

Identifying Shelf Life
The best way for manufacturers to confidently affix valid expiration dates to their products is to first submit their package to accelerated aging testing is delivered. These are often indicators of future project performance, willingness to consult and even a clear understanding of your testing needs. Another way to determine validation expertise is by posing detailed questions regarding how a vendor would develop a statistically relevant sample.
Medical Device Testing

DETERMINE PACKAGE DETERIORATION RATES

Tested and Proven Package Testing

This testing standard calls for determination of the rate of the chemical reactions which cause package deterioration. Once this is identified by DDL package testing engineers, package shelf can be clearly identified.

PHARMACEUTICAL PACKAGE TESTING
As regulators increasingly look for proof of pharmaceutical product stability throughout the supply chain, it is critical for manufacturers to ensure stable temperatures and endure handling from warehouse - to transit - to shelf.

DDL performs thermal performance testing, accelerated aging stability testing and transportation simulation testing validation on packaging containing pharmaceutical products.

PACKAGE TESTING TIPS
When identifying package expiration dates, DDL accelerates exposure to:
✓ Climate: High and low temperature and humidity
✓ Shipping and handling: Vibration, manual handling and stacking

DDL HELPS MEDICAL MANUFACTURERS
Accelerated Aging Testing, from DDL, INC., has helped thousands of Medical Manufacturers to clearly identify package expiration dates.

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a TCP Reliable Company
DDL can assist you in testing product performance, including the dynamic and environmental hazards inherent in the environments in which they're operated and used. We can test products for their shock, fragility and durability, as well as how they withstand vibration of various intensities.

DDL offers industry standard methods for evaluating product performance, including IEC, military, governmental, ISO Standards and ASTM Standards.

DDL employs product testing professionals that not only test your products but also act as consulting engineers, helping you solve any problems identified by your test results.

**PRODUCT TESTING SERVICES**

DDL is proud to offer expertise in the following tests:

- Compression Testing
- Accelerated Aging Testing
- Distribution Simulation
- Fatigue Testing
- Flexural Testing
- Strength Testing
- Transportation Simulation Testing
- Tensile Testing
- Thermal Shock Testing
- Thermal Performance Testing
- Shock Testing
- Vibration Testing

**PRODUCT & MATERIAL TESTING INDUSTRY STANDARDS**

DDL is experienced in performing tests that comply with the following product testing industry standards:

- AAMI - Association for the Advancement of Medical Instrumentation
- ANSI - Association National Standards Institute
- ASTM - American Society for Testing & Materials
- CENELEC - European Committee for Electrotechnical Standardization
- EIA - Electronic Industries Alliance
- ETS - European Telecommunications Standard
- IEC - International Electrotechnical Commission
- ISO - International Organization for Standardization
- JIS - Japanese Industry Standards
- MIL - Military Specifications
- SAE - Society of Automotive Engineers
- JEDEC - Joint Electronic Device Engineering Council
DDL Inc. is proud to offer a wide range of material testing services that draw upon industry standards. **DDL** uses the most effective and sustainable testing techniques in an effort to ensure the accuracy and reliability of your tests. Our material testing engineers possess an extensive equipment background which enables them to:

**DDL** material testing capabilities include:

- Strength Testing
- Fatigue Testing

The information that **DDL**, Inc engineers compile from these tests help you to select the optimal material for your specific application.
DDL is your single source for package design, development, prototyping, low volume manufacturing, consulting and testing qualification services.

DDL provides a broad range of package engineering expertise to client companies with unbiased design and materials input. We put our combined one hundred plus years of packaging engineering experience to work for you.

DDL’s package design center’s unique business model is a complete packaging solution with capabilities for regulatory compliance for the specified industry. Materials are specified and designs are challenged and qualified for the client. The client hires a packaging engineer for their team on a contract basis. Our principals are seasoned, package engineering experts in the medical device and temperature controlled packaging industries. We offer package design and engineering consulting to a broad range of industries including;

- Package project management
- Package prototyping
- Low volume packaging manufacturing, including sustainable package design and compliance – EU standards
- Regulatory and compliance consulting for health care clients
- Package testing per industry standards and client custom protocols
  - Design verification and feasibility testing
  - Complete package design validation, including packaging equipment specification, installation, and operational qualification.

**CURRENT DESIGN AND PROTOTYPING CAPABILITIES**

- Thermoformed parts
- Structural packaging designs (Kongsberg design table with Artios CAD design software)
  - Shippers
  - Folding carton
  - Inserts
  - Clamshell
  - Blister Card
  - Display
  - Point of Purchase Component
  - Miscellaneous
- Cushioning materials and designs
- Pouches and bags of all material compositions
- Shipping systems
- Label
- Pouch and tray inserts
- Temperature controlled packaging
- Film and blister heat sealing

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