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**DDL Tested and Proven**

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**DDL Quizzler Uncovers Packaging Professionals Extreme Knowledge in the Importance of Extended Shelf Life Validation**

*Validating Medical Device Packaging for Extended Shelf Ensures Sterility*

MINNEAPOLIS –September X, 2008 -- <http://www.testedandproven.com/> -- DDL, leader in medical device package and product testing announced that, via findings from their September *Validation for Extended Shelf Life* Quizzler, nearly 100 percent of the [medical device packaging](http://www.testedandproven.com/medical_device_testing.html) engineers who responded understand the importance of  medical device package validation testing for extended shelf life.

“We are pleased to have learned that the packaging engineers who participated in our September Quizzler are aware of the requirements for validating the extended shelf life of medical device packaging,” Patrick Nolan, COO of DDL, stated.

The government requires that all sterile medical device products claiming a shelf life or expiration date must have data to support the claim and their packaging must also withstand the same shelf life capability.

“Without proper evidence to support a claimed shelf life capability the product could be recalled by a regulatory body which could significantly delay product introduction to the market,” Nolan said.

Before validating a medical device for extended shelf life, several questions must be answered;

1. What types of packages are we validating?
2. What type of expiration date do we want?
3. Which strength and integrity methods do we use?
4. What are the glass-transition, melt, and heat-distortion temperatures of the package and device?

“All sterile medical device products and their packaging must have data to validate their shelf life,” Nolan said. “The expiration date can range anywhere from 1-5 years with 3 years being the most common.”

Testing for package integrity and sterility is vital to ensuring that there was no loss in package integrity due to the aging study. Generally speaking, ASTM standard F88 is used for strength testing and F1929 is used for integrity testing. Dye leak testing is commonly done on thermoform trays and bubble leak testing is performed on pouches.

To gain more insight into the importance of extended shelf life validation for medical device packaging, please visit <http://www.testedandproven.com/shelf_life.html>.

**About The DDL Packaging Quizzler**DDL’s Packaging Quizzler is a semi-monthly online challenge which poses real world packaging questions Medical Device Packaging Professionals encounter on a daily basis.

One randomly-selected winner who correctly answers The Packaging Quizzler will be awarded a prize, such as an iPod.

To participate in the next Quizzler, please visit “The Packaging Quizzler” at <http://www.testedandproven.com/lp/quizzler4/>.

**About DDL**   
DDL offers expert package, product and material testing services, including shock testing, vibration testing, tensile testing, leak testing and validation services. DDL also recently implemented a package design, development and prototyping department. DDL maintains full service testing labs in Minnesota, Southern California and New Jersey. ([www.testedandproven.com](http://www.testedandproven.com))

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