

# **Medical Device Testing**







## **Syringe Testing**

Syringe Testing is a critical step in developing and commercializing needle-based injection systems for medical use. By testing mechanical properties, such as break-loose and glide force, as well as biocompatibility, extractables and leachables, sterility, packaging and transit properties, we can determine if the device is within standard specifications, reducing the likelihood of improper function.

Eurofins Medical Device Testing has experience performing an array of standard and non-standard testing on syringes to verify their safety.

#### **Choose Eurofins Medical Device Testing to help you:**

- Determine the necessary testing requirements for your device
- Write GMP-compliant and ISO standard driven protocols and methods
- Perform the required tests to demonstrate that the expected performance criteria are satisfied
- Complete batch release activities and/or gain regulatory approval

### **Testing Available**

Eurofins Medical Device Testing offers global capabilities on a diverse range of needle-based injection systems. We are able to perform the tests outlined in the applicable ANSI, AAMI, ASTM and ISO standards for the following areas:

- Mechanical Testing for syringes, described in ISO 11608, including Break-Loose, Glide Force, Luer Fitting, Syringe to Hub Retention and Syringe Accuracy (TOGC)
- · Biocompatibility Testing
- Transit Testing
- · Package and Sterile Seal Integrity Testing
- · Sterilization Testing
- Residual EtO
- EP/USP Testing
- · Siliconization Testing



· Extractables & Leachables Testing

We work closely with our clients to understand the unique characteristics of the delivery device to provide accurate and meaningful data.

#### Instrumentation

- A range of Instron® and Zwick testing systems with validated software to perform mechanical tests
- More than 500 state-of-the-art chromatographic and mass spectrometric analyzers for chemical characterization
- More than 5,300 m³ (187,000 ft³) of environmental chamber space for shelf life testing
- Over 6,300 m² (68,000 ft²) of lab space for microbiological testing