EVALUATION OF MEDICAL DEVICES

Pace Analytical Life Sciences (PLS) offers analytical chemistry and physical testing services for the qualitative and quantitative assessment of medical devices. We understand that bringing innovative medical device technology to the global marketplace is a major financial investment and high-risk venture. Pace provides our clients with comprehensive testing capabilities and reliable test data in a timely manner. PLS offers testing services to evaluate the safety, purity, performance and characterization of medical devices.

Medical Device Tests

- Material Characterization (ISO 10993-18)
- Extractables / Leachables Testing
- Drug Release / Elution Profiles
- Impurity Profiles
- Physical / Functional Testing
- Ethylene Oxide Sterilization Residuals (ISO 10993-7)
- Degradation products from polymeric medical devices (ISO 10993-13)
- Degradation products from metals and alloys (ISO 10993-15)
- Surface Cleanliness
  - Total Particulates
  - Bacterial Endotoxins
  - Bioburden

Our labs are cGMP-compliant, FDA registered, DEA registered and ISO/IEC 17025:2005 accredited.