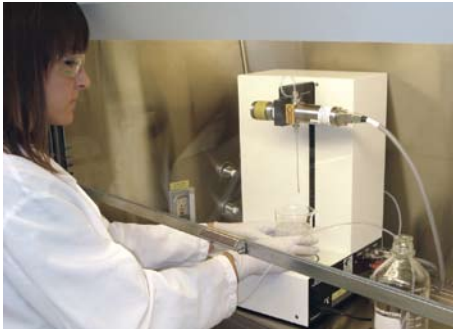


## BIOLOGICAL EVALUATION OF MEDICAL DEVICES



Biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. When selecting the appropriate tests for biological evaluation of a medical device, one must consider the chemical characteristics of device materials and the nature, degree, frequency and duration of its exposure to the body. Pace Analytical Life Sciences performs a series of ISO 10993 standards for evaluating the biocompatibility of a medical device prior to a clinical study. These standards are part of the safe use evaluation of medical devices.

### The services that we offer for the biological evaluation of medical devices include:

- Genotoxicity – ISO 10993-3
- Cytotoxicity – ISO 10993-5
- Ethylene Oxide Sterilization Residuals – ISO 10993-7
- Identification and quantification of degradation products from polymeric medical devices – ISO 10993-13
- Identification and quantification of degradation products from ceramics – ISO 10993-14
- Identification and quantification of degradation products from metals and alloys – ISO 10993-15
- Material characterization – ISO 10993-18
- Surface Cleanliness
  - Particle Testing – Laser Diffusion Method
  - Endotoxin
  - Bioburden

**For more information on our medical device testing capabilities or any of our pharmaceutical capabilities, please contact our Business Development group: (651)-738-2728.**



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