MEDICAL DEVICE TESTING

A medical device encompasses any product used in healthcare for diagnosis, investigation, prevention, monitoring, cure and treatment of a disease or condition. It includes any instrument, apparatus, appliance, material or other articles, whether used alone or in combination, including the software necessary for its proper application intended for use in human beings.

Biological evaluation of medical devices must be performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The device material should not, either directly or through the release of their material ingredients produce local or systemic effects; be carcinogenic; or produce reproductive and developmental effects.

Therefore, evaluation of any device intended for human use should provide data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks produced by the device materials. The US Food and Drug Administration (FDA) 1995, in ensuring the safety of medical devices has enacted guidance for biological evaluation of medical devices incorporating the ISO 10993 testing matrix comprising in vitro and in vivo evaluations.