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Biological Evaluation Plan

The Biological Evaluation Plan details the strategy used to address biological risk, or biocompatibility, for medical devices. A Biological Evaluation Plan is a requirement that will examine available information concerning the medical device's configuration, material composition, manufacturing, intended use, any extant testing information and clinical history. The Biological Evaluation Plan will then identify any biocompatibility gaps that exist for the medical device and provide expert recommendations for how to best fill these gaps based on ISO 10993-1 and product or country specific documentation.

The development of a Biological Evaluation Plan is consistent with current regulatory expectations. Furthermore ISO 10993-1 states "The biological evaluation shall be planned, carried out, and documented by knowledgeable and experienced professionals," underscoring the need to involve those with the appropriate expertise.

The Eurofins Medical Device Testing network of laboratories provides the necessary expertise to not only create your medical device's Biological Evaluation Plan but also conduct required testing. Ideally the Biological Evaluation Plan is completed prior to the conduct of extensive biocompatibility testing, but Eurofins Medical Device Testing can help create a plan at whatever stage a medical device is at and incorporate all pertinent testing information. Eurofins Medical Device Testing will also help to provide the rationale for the testing strategy consistent with recommendations in the ISO 10993 series of standards.

Choose Eurofins Medical Device Testing to help you:

- Build your Biological Evaluation Plan and create a strategy to meet current ISO 10993-1 expectations.
- Avoid wasted time in the development process by understanding where your biocompatibility gaps are so that you can address them in a timely manner.
- Demonstrate to regulatory agencies that the biological evaluation plan was assembled by those with appropriate expertise.