

ISO 10993-6 2016: Implantation study design recommendations

Optimise Your Implantation Studies with Eurofins

The assessment of local tissue effects after implantation is essential for evaluating the interactions of medical devices having direct contact with human tissues during clinical use.

Regulatory

ISO 10993-6:2016 provides general requirements for evaluating the local tissue effects after implantation of biomaterials intended for use in medical devices in subcutaneous tissue, muscle, bone or brain tissue.

This guideline describes biological evaluation in general terms and requires testing strategies that mirror the medical device's intended clinical use without giving detailed test procedures.

To comply with Standard requirements, study designs must be well thought-out and carefully justified.

Choose Eurofins Medical Device Testing to help you:

- Define implantation study design recommendations along with justifications according to ISO 10993-6 requirements for your specific medical device (customised test design recommendations)
- Assess the relevance and feasibility of conducting a combined implantation/long-term systemic toxicity study in accordance with applicable standards (ISO 10993-6 and ISO 10993-11)
- Determine the most cost-effective, but scientifically relevant and regulatory compliant study
- Communicate with testing laboratories in charge of the *in-vivo* testing
- Facilitate exchanges with notified bodies upstream of *in-vivo* studies

In-vivo testing could be performed by our partner labs

Testing Services

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