

American National Standard

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Biological evaluation of
medical devices—Part 16:
Toxicokinetic study design
for degradation products
and leachables

Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables

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Abstract: This document provides principles on designing and performing toxicokinetic studies relevant to medical devices. Annex A describes the considerations for inclusion of toxicokinetic studies in the biological evaluation of medical devices.

Keywords: toxicokinetic studies, medical device

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Committee representation

Association for the Advancement of Medical Instrumentation

BE/WG13, Toxicokinetics

The adoption of ISO 10993-16 as an American National Standard was initiated by the AAMI/BE/WG13, Toxicokinetics working group. AAMI/BE/WG16 provides input to the AAMI Biological Evaluation committee (AAMI/BE), which is the responsible group for providing the U.S. input to the relevant group in ISO/TC 194. U.S. representatives from AAMI/BE/WG13 and the TAG played an active part in developing the ISO document.

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