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**QUALITY MANAGEMENT, GENERAL SAFETY, AND DESIGN**

**BIOLOGICAL EVALUATION OF MEDICAL DEVICES**

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Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity, 2ed
Part 4: Selection of tests for interactions with blood, 2ed and 2006 Amendment
Part 5: Tests for in vitro cytotoxicity, 3ed
Part 6: Tests for local effects after implantation, 2ed
Part 7: Ethylene oxide sterilization residuals, 3ed
Part 9: Framework for identification and quantification of potential degradation products, 3ed
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Part 11: Tests for systemic toxicity, 2ed
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Part 12: Sample preparation and materials requirements, 4ed
Part 13: Identification and quantification of degradation products from polymeric medical devices, 2ed
Part 14: Identification and quantification of degradation products from ceramics, 4ed
Part 15: Identification and quantification of degradation products from metals and alloys, 1ed
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Part 16: Toxicokinetic study design for degradation products and leachables, 2ed
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Biological evaluation of medical devices - Part 19: Physio-chemical, morphological and topographical characterization of materials, 1ed
Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices, 1ed

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Biomedical Equipment

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| ANSI/AAMI ST40:2004(R)2010 | Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities, 2ed |
| ANSI/AAMI ST41:2008(R)2012 | Ethylene oxide sterilization in health care facilities: Safety and effectiveness, 4ed |
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