ISO/TR 37137:2014-05 (E)

Cardiovascular biological evaluation of medical devices - Guidance for absorbable implants

Contents

Page

Foreword iv

1 Scope 1

2 Termsanddefinitions 1

3 General considerations 1

4 Sterilization considerations 2

5 Drug-device combination product considerations 3

6 Part listing and description of absorbable related issues in addition to the relevant parts of ISO 10993 series "Biological evaluation of medical devices" 4
6.1 ISO 10993-1:2009, Evaluation and testing within a risk management process 4
6.2 ISO 10993-2:2006, Animal welfare requirements 4
6.3 ISO 10993-3:2003, Tests for genotoxicity, carcinogenicity and reproductive toxicity 4
6.4 ISO 10993-4:2002, Selection of tests for interactions with blood 4
6.5 ISO 10993-5:2009, Tests for in vitro cytotoxicity 5
6.6 ISO 10993-6:2007, Tests for local effects after implantation 6
6.7 ISO 10993-7:2008, Ethylene oxide sterilization residuals 8
6.8 ISO 10993-9:2009, Framework for identification and quantification of potential degradation products 8
6.9 ISO 10993-10:2010, Tests for irritation and delayed-type hypersensitivity 8
6.10 ISO 10993-11:2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity 9
6.11 ISO 10993-12:2012, Sample preparation and reference materials 9
6.12 ISO 10993-13:2010, Identification and quantification of degradation products from polymeric medical devices 13
6.13 ISO 10993-14:2001, Identification and quantification of degradation products from ceramics 13
6.14 ISO 10993-15:2000, Identification and quantification of degradation products from metals and alloys 13
6.15 ISO 10993-16:2010, Toxicokinetic study design for degradation products and leachables 13
6.16 ISO 10993-17:2002, Establishment of allowable limits for leachable substances 13
6.17 ISO 10993-18:2005, Chemical characterization of materials 13
6.18 ISO/TS 10993-19:2006, Physico-chemical, morphological and topographical characterization of materials 14
6.19 ISO/TS 10993-20:2006, Principles and methods for immunotoxicology testing of medical devices 14

Annex A (informative) Nomenclature of absorb, degrade and related terms 15

Bibliography 16