別紙

○ 引用規格および参考資料（年号未記入の規格は最新版を意味する）

（日本）

1. 平成 17 年 2 月 16 日付け薬食機発第 0216003 号厚生労働省医薬食品局審査管理課医療機器審査管理室長通知「医療機器の製造販売承認申請書添付資料概要作成の手引きについて」
2. 平成 16 年 11 月 15 日付け医療機器審査 No. 19 厚生労働省医薬食品局審査管理課医療機器審査管理室事務連絡「医療用具の有効性、安全性評価手法に関する国際ハーモナイゼーション研究『医療用具の製造（輸入）承認申請書における原材料記載について』の報告書の送付について」
3. 平成 15 年 2 月 13 日付け医薬審発第 0213001 号厚生労働省医薬局審査管理課長通知「医療用具の製造（輸入）申請に必要な生物学的安全性試験の基本的考え方について」
4. 平成 15 年 3 月 19 日付け医療機器審査 No. 36 厚生労働省医薬局審査管理課事務連絡「生物学的安全性試験の基本的考え方に関する参考資料について」
5. 「生物由来原料基準を定める件」（平成 15 年厚生労働省告示第 210 号）
6. JIS T 0993-1:2004　医療機器の生物学的評価　―　第 1 部：評価及び試験方法
7. 「医療機器の安全性に関する非臨床試験の実施の基準に関する省令」（平成 17 年厚生労働省令第 37 号）
8. 「医療機器の臨床試験の実施の基準に関する省令」（平成 17 年厚生労働省令第 36 号）
9. 「医薬品、医薬部外品、化粧品及び医療機器の製造販売後安全管理の基準に関する省令」（平成 16 年厚生労働省令第 135 号）
10. 「医薬品、医薬部外品、化粧品及び医療機器の品質管理の基準に関する省令」（平成 16 年厚生労働省令第 136 号）
11. 「医療機器及び体外診断用医薬品の製造管理及び品質管理の基準に関する省令」（平成 16 年厚生労働省令第 169 号）
12. 「医療機器の製造販売後の調査及び試験の実施の基準に関する省令」（平成 17 年厚生労働省令第 38 号）

（ISO）

1. ISO 9000: 2000, Quality management systems - Fundamentals and vocabulary.
2. ISO 9001: 2000, Quality management systems - Requirements.
3. ISO 9004: 2000, Quality management systems - Guidelines for performance

improvements.

4. ISO 10993 - 1: 2003 Biological evaluation of medical devices - Part 1: Evaluation and testing
5. ISO 10993 - 2: 1998, Biological evaluation of medical devices - Part 2:Animal welfare requirements
6. ISO 10993 - 3: 2003, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
7. ISO 10993 - 4: 2002, Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood
8. ISO 10993 - 5: 1999, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
9. ISO 10993 - 6: 1994, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
10. ISO 10993 - 7: 1996, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
11. ISO 10993 - 9: 1999, Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
12. ISO 10993 - 10: 2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed - type hypersensitivity
13. ISO 10993: 11: 1996, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
14. ISO 10993 - 12: 1996, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
15. ISO 10993: - 13: 1998, Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric materials
16. ISO 10993 - 14: 2004, Biological evaluation of medical devices - Part 14: Identification and quantification of degradation from products from ceramics.
17. ISO 10993 - 15: 2000, Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
18. ISO 10993 - 16: 1997, Biological evaluation of medical devices - Part 16, Toxicokinetic study design for degradation products and leachables.
19. ISO 10993 - 17: 2003, Biological evaluation of medical devices - Part 17,

Methods for the establishment of allowable limits for leachable substances.
20. ISO 10993 - 18: 2004, Biological evaluation of medical devices - Part 18: Chemical characterization of materials.
21. ISO 10993 - 19 : 2005, Physico-chemical, morphological and topographical characterization of materials.
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23. ISO 14415-1, Clinical investigation of medical devices for human subjects - Part 1: General requirements
24. ISO 14415-2. Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plants
25. ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes.
26. ISO 13448:1996, Quality systems - Medical devices - Particular requirements for the application of ISO 9002.
27. ISO 14971: 2000, Medical Devices - Application of risk management to medical devices.
28. ISO/DIS 22442-1 Application of risk management, Medical devices utilizing animal tissues and their derivatives
29. ISO/DIS 22442-2 Control on sourcing, collection and handling, Medical devices utilizing animal tissues and their derivatives
30. ISO/DIS22442-3 Validation of the elimination and / or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents, Medical devices utilizing animal tissues and their derivatives
31. ISO 11134 Sterilization of health care products-Requirements for validation and routine control - industrial moist heat sterilization
32. ISO 11135:1994 Medical devices; validation and routine control of ethylene oxide sterilization
33. ISO 11137; 1995, Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization
34. ISO 11737-1; 1995, Sterilization of medical devices- Microbiological methods - Part 1; Estimation of population of *microorganisms* on products
35. ISO 13408 series, Aseptic proceeding of health care products
36. ISO 13638; 1997, Sterilization of health care products - Requirements for Validation and routine control of moist heat sterilization in health care facilities

37. ISO 14160; 1998, Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid sterilants
38. ISO 14937, Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
39. ISO 17664, Sterilization of medical devices - Information to be provided by manufacture for the processing of resterilizable medical devices
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42. ISO-14708-5: 2005, Implants for surgery - Active implantable medical devices - Part 5: Particular requirements for circulatory support devices (2005)
43. ISO 5198, Centrifugal, mixed flow axial flow pumps - Code for hydraulic performance tests - Precision grade
44. ISO 4409, Hydraulic fluid power - Positive displacement pumps, motos and integral transmissions - Determination of steady-state performance
45. ISO 5840, Cardiovascular implants - Cardiac valve prostheses
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1. IEC 60300-3-2, Dependability management - Part 3 - 2: Application guide - Collection of essential performance
2. IEC 60601-1, Medical electrical equipment - Part 1: General requirement for safety and essential performance
3. IEC 60601-1-2, Medical electrical equipment - Part 1: General requirement for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
4. IEC 60601-1-6, Medical electrical equipment - Part 1; General requirement for safety - Collateral standard: Usability
5. IEC 60601-1-8, Medical electrical equipment - Part 1 - 8: General requirement for safety - Collateral Standard: Alarms
6. IEC - CISPR-11, Industrial scientific and medical (ISM) radio-frequency

equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement
7. IEC/TR 60878, Graphical symbols for electrical equipment in medical practice
8. IEC 62304, Medical device software - Software life - cycle processes

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7. ASTM F1841-97, Standard practice for Assessment of hemolysis in continuous flow blood pumps