

Regulations Governing Management of Medical Devices

Article 1. This set of Regulations is formulated in accordance with regulations of Paragraph 2, Article 13 of the Pharmaceutical Affairs Act.

Article 2. Medical devices are, by degree of risks, classified as follows:

Degree 1: low risk

Degree 2: moderate risk

Degree 3: high risk

Article 3. Medical devices are, by their functions, use and operational principles, classified as follows:

- (1) Clinical Chemistry and Clinical Toxicology
- (2) Hematology and Pathology
- (3) Immunology and Microbiology
- (4) Anesthesiology
- (5) Cardiovascular Medical Science
- (6) Dentistry
- (7) Ear Nose and Throat
- (8) Gastroenterology and Urology
- (9) General and Plastic Surgery
- (10) General Purpose Apparatus for Hospital and Individual Use
- (11) Neuroscience
- (12) Obstetrics and Gynecology
- (13) Ophthalmology
- (14) Orthopedics

(15) Physical Therapy

(16) Radiology

(17) Others as determined by the central competent health authority.

The detailed classification of medical devices mentioned in the preceding Paragraph is specified in Appendix 1.

Article 4. The manufacturing of medical devices shall comply with specifications of the Standards for the Establishment of Pharmaceutical Manufacturing Factories, Volume 4: Medical Device GMP Standards. However, items listed in Appendix 2 are not included.

Article 5. Medical devices required of domestic clinical trials are listed in Appendix 3.

Article 6. Pharmaceutical dealers and individuals may pay a fee and enclose the following documents to the central competent health authority for inquiries regarding medical devices categorization and management specifications:

- (1) Device specifications manual (or the catalogue) issued by the original factory, and its detailed Chinese translation (including, method of administration, functions and operational principles);
- (2) Information on categorization of the said product prepared by the United States or the European Union;
- (3) Any other information designated by the central competent health authority.

Article 7. Medical devices that have been managed in accordance with other regulations prior to the implementation of this set of Regulations shall complete application for correction in accordance with this set of

Regulations before June 20, 2005.

Article 8. This set of Regulations shall be implemented on the day of announcement.