Article Content

Title：	Regulations for Governing the Management of Medical Device CH
Amended Date：	2019-07-29
Category：	Ministry of Health and Welfare（衛生福利部）
Attachment：	Annex I.pdf Annex II.pdf Annex Ⅲ.pdf

Article 1 The present regulations are in accordance to the Article 13, Paragraph 2 of the Pharmaceutical Affairs Act.

Article 2 Medical device are classified into the following classes according to their level of risks:
Class I : Low risk
Class II : Medium risk
Class III : High risk

Article 3 In accordance to the function, intended use, instruction for use and working principle, medical devices are classified into the following categories:
1. Clinical Chemistry and Clinical Toxicology Devices
2. Hematology and Pathology Devices
3. Immunology and Microbiology Device
4. Anesthesiology Devices
5. Cardiovascular Devices
6. Dental Devices
7. Ear, Nose, and Throat Devices
8. Gastroenterology and Urology Devices
9. General and Plastic Surgery Devices
10. General Hospital and Personal Use Devices
11. Neurological Devices
12. Obstetrical and Gynecological Devices
13. Ophthalmic Devices
14. Orthopedic Devices
15. Physical Medicine Devices
16. Radiology Devices
17. Other Categories Specified by the National Health Competent Authority
The classification of medical devices into the above categories is as Annex I.
Annex I.pdf

Article 4 The manufacturing of medical devices shall comply with Part 3 Good Manufacturing Practice (GMP) for Medical Device of

Pharmaceutical Good Manufacturing Practice Regulations.
The manufacturing of medical devices listed in the Annex II of this regulation shall comply with Part 3 Chapter 3 Essential Mode of the GMP regulation, except the manufacturing of sterilized devices shall comply with Part 3 Chapter 2 Standard Mode of the GMP regulation.
Annex II.pdf

Article 5 Medical devices that require clinical trial to be performed domestically are stated in Annex III.
Annex Ⅲ.pdf

Article 6 Pharmaceutical entity or the general public may approach the National Health Competent Authority, through a payment service, for inquiry of the classification of a medical device and its regulatory control with the provision of the following:
i. Instruction for use (or catalogue) and its Chinese translation in details (including the instruction for use, function and working principle).
ii. Reference to classification of the product by the European Union or United State of America
iii. Any other information as defined by the National Health Competent Authority.

Article 7 (deleted)

Article 8 The regulations shall be implemented on the date of announcement, except the manufacturing of Optical Impression Systems for CAD/CAM (Classification Number: F.3661) under the amendment of Article 3 Item 2 Annex 1 on January 7th, 2014, shall comply with this regulation from July 1st, 2014.
The manufacturing of Quality Control Material (assayed and unassayed) (Classification Number: A.1660), Ear, Nose, and Throat Drug Administration Device (Classification Number: G.5220), and Corrective Spectacle Lens (Classification Number: M.5844) under the amendment of Article 3 Item 2 Annex 1 on June 3rd, 2015, shall comply with this regulation from September 1st, 2016.
The manufacturing of Influenza virus antigen detection test system (Classification Number: C.3328), Surgical Gloves (Classification Number: I.4460), Patient Examination Gloves (Classification Number: J. 6250)" and Mechanical Wheelchair (Classification Number: O. 3850) under the amendment of Article 3 Item 2 Annex 1 on July 29th, 2019, shall comply with this regulation from July 29th, 2020.