Rules for the Classification of Medical Devices[1]

Authority: **China FDA (dissolved)**

Document order: Order No. 15 of the China Food and Drug Administration

Promulgation Date: July 14, 2015

Effective Date: January 1, 2016

Article 1

These Rules are formulated in accordance with the *Regulations on the Supervision and Administration of Medical Devices* for the purpose of regulating the classification of medical devices.

Article 2

These Rules are intended to guide the development of the medical device classification catalogue and the determination of management categories for new medical devices.

Article 3

For the purposes of these Rules, the following terms are defined as follows:

1-Intended Purpose: Refers to the function a medical device is expected to achieve as specified in its instructions for use, labeling, or promotional materials.

2-Passive Medical Device: A medical device that does not rely on electrical energy or any other form of energy for operation but performs its function using energy generated by the human body or gravity.

3-Active Medical Device: Any medical device that operates by relying on electrical energy or any other form of energy, excluding energy generated directly by the human body or gravity.

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

4-Invasive Device: A device that, in whole or in part, enters the human body through the surface of the body by surgical means and comes into contact with internal tissues, the circulatory system, or the central nervous system. This includes instruments used in interventional procedures, sterile single-use surgical instruments, and devices temporarily or short-term implanted in the body. This definition does not include reusable surgical instruments.

5-Reusable Surgical Instrument: A passive medical device used during surgery for cutting, dissecting, drilling, sawing, grasping, scraping, clamping, suctioning, or similar procedures, which is not connected to any active device and can be reused after proper reprocessing.

6-Implantable Device: A device that is wholly or partially introduced into the human body or a body orifice by surgical means, or that replaces the epithelial surface or surface of the eye, and is intended to remain in the body for 30 days or more, or to be absorbed by the human body.

7-Body-Contacting Device: Any medical device that directly or indirectly contacts a patient or is capable of being introduced into the human body.

8-Duration of Use:

(1) Continuous Use: uninterrupted use of a medical device for its intended purpose.

(2) Transient Use: continuous use for less than 24 hours.

(3) Short-Term Use: continuous use for 24 hours or more but less than 30 days.

(4) Long-Term Use: continuous use for 30 days or more.

9-Skin: Refers to intact, unbroken human skin.

10-Body Orifice (Cavity): Includes natural openings such as the oral cavity, nasal cavity, esophagus, external auditory canal, rectum, vagina, urethra, and permanent artificial openings.

11-Wound: Damage to the structural integrity or function of human tissue caused by various injury mechanisms.

12-Tissue: Human tissues, including bone, dental pulp, or dentin, excluding the circulatory system and central nervous system.

13-Circulatory System: The heart and blood vessels, excluding capillaries.

14-Central Nervous System: The brain and spinal cord.

15-Standalone Software: Software with one or more medical purposes, capable of achieving its intended use independently of any medical device hardware, and operating on a general-purpose computing platform.

16-Medical Device with Measuring Function: A device used to quantitatively measure physiological, pathological, or anatomical parameters, or to measure quantities of energy or substances entering or exiting the body. The accuracy of such measurements may significantly impact patient health and safety.

17-Chronic Wound: A wound that fails to heal over a long period due to various causes, including venous ulcers, arterial ulcers, diabetic ulcers, traumatic ulcers, and pressure ulcers.

Article 4

Medical devices shall be classified into Class I, Class II, and Class III in ascending order of risk.The risk level of a medical device shall be comprehensively determined based on its intended purpose, structural characteristics, mode of use, usage conditions, and whether it contacts the human body, among other factors.

Article 5

According to the factors that affect the risk levels of medical devices, medical devices may be classified into:

1-Passive medical devices and active medical devices, based on the structural features of medical devices.

2-Contacting devices and non-contacting devices, based on whether they are in contact with the human body.

3-Based on their different structural features and whether they are in contact with the human body, medical devices in terms of their form of use include:

(1) Passive contacting devices: devices intended for channeling liquids, devices intended for modifying the blood or other body liquids, medical dressings, invasive devices, reusable surgical instruments, implantable devices, devices used for contraception and birth control, as well as other passive contacting devices.

(2) Passive non-contacting devices: patient care equipment, devices used for cleaning, rinsing or disinfecting medical devices, as well as other passive non-contacting devices. Active contacting devices: energy treatment devices, devices for diagnosis and monitoring, devices intended for channeling liquids, devices for ionized radiation, implantable devices, as well as other active contacting devices.Active non-contacting devices: clinical testing equipment, stand-alone software, devices used for disinfecting or sterilizing medical devices, as well as other active non-contacting devices.

4-According to their different structural features, whether they are in contact with the human body and their form of use, medical devices in terms of their status of use or possible impacts include the following circumstances:

(1) Passive contacting devices: according to duration, they are classified into those intended for transient use, those intended for short-term use, and those intended for long-term use; according to the parts that these devices are in contact with the human body, they are classified into those used for skin or body orifice (opening), those used for wounds or tissues, or those used for the circulatory system or the central nervous system.

(2) Passive non-contacting devices: basically no impact, indirect impact, and substantial impact, according to the impact that these devices have on treatment.

(3) Active contacting devices: the degree of injuries caused by malfunction of these devices ranges from minor injuries, injuries, and serious injuries.

(4) Active non-contacting devices: the impact that these devices have on treatment ranges from basically no impact, indirect impact, substantial impact.

Article 6

The classification of medical devices shall be determined according to the *Table for Determination of Medical Device Classification*. Under the following circumstances, the classification shall follow these principles:

(1) If a medical device falls under multiple classifications, the classification with the highest risk shall apply. For kits composed of multiple devices, the classification shall be that of the highest-risk component.

(2) For accessories, classification shall consider their impact on the safety and effectiveness of the main device. If the accessory has a significant impact, its classification shall not be lower than that of the main device.

(3) Devices designed to monitor or affect key functions of another device shall be classified the same as the device being monitored or affected.

(4) Drug-device combination products with the medical device function as the primary mode of action shall be managed as Class III.

(5) Devices absorbable by the human body shall be managed as Class III.

(6) Active body-contacting devices that significantly affect treatment shall be managed as Class III.

(7) Medical dressings shall be classified as Class III if they:

-Are intended to prevent tissue or organ adhesion,

-Serve as artificial skin,

-Contact wounds involving deep dermis or subcutaneous tissue damage,

-Are used for chronic wounds,

-Are wholly or partially absorbable by the body.

(8) Sterile devices shall be classified as Class II or above.

(9) Orthopedic devices that apply continuous active force to the body through traction, expansion, torsion, compression, bending, or similar means and allow dynamic limb positioning (excluding devices merely used for fixation, surgical assistance, or post-surgical support) shall be classified as Class II or above.

(10) Devices with measuring functions shall be classified as Class II or above.

(11) Devices clearly intended for treatment of specific diseases shall be classified as Class II or above.

(11) Passive reusable surgical instruments used under endoscopy for tissue clamping, cutting, stone removal, or similar procedures shall be managed as Class II.

Article 7

In vitro diagnostic reagents shall be classified in accordance with applicable regulations.

Article 8

The CFDA shall analyze and evaluate changes in medical device risks based on their production, distribution, and use, and shall revise the medical device classification catalogue in a timely manner.

Article 9

The CFDA may organize an expert committee on medical device classification to formulate and revise the classification catalogue.

Article 10

These Rules shall come into effect on January 1, 2016. The *Rules for the Classification of Medical Devices* issued on April 5, 2000 (Order No. 15 of the former State Drug Administration) shall be repealed simultaneously.