Provisions on the Administration of Manuals, Labels and Package Marks of Medical Devices（Order No. 10 ）

Order of State Food and Drug Administration

(No. 10)

The Provisions on the Administration of Manuals, Labels and Package Marks of Medical Devices, which were deliberated and adopted at the executive meeting of State Food and Drug Administration on June 18, 2004, are hereby promulgated and shall come into force as of the date of promulgation.

Commissioner: Zheng Xiaoyu

July 8, 2004

Provisions on the Administration of Manuals, Labels and Package Marks of Medical Device

Article 1 These Provisions are enacted according to the Regulation on the Supervision and Administration of Medical Devices for the purpose of regulating the manuals, labels and package marks of medical devices, and ensuring the safety in the use of medical devices.

Article 2 Medical devices sold or used within the territory of the People's Republic of China shall be accompanied by manuals, labels and package marks according to these Provisions. For the easy-to-use products, one or two items of manuals, labels and package marks may not be furnished if State Food and Drug Administration (hereinafter referred to as SFDA) has so provided.

Article 3 The users of medical devices shall operate the devices in accordance with their manuals for use.

Article 4 The manuals for use of medical devices means technical documentation prepared by the manufacturer and provided to the users together with products, covering safe and effective basic information of the current product, and used to

instruct installation, commissioning, operation, use, and maintenance.

The labels of medical devices mean description, graphics, and symbols used to identify product characteristics and attached on the medical devices or on the package.

The package mark of medical devices means description, graphics, and symbols reflecting main technical characteristics of the devices and indicated on the package.

Article 5 The manuals, labels and package marks shall be authentic, complete, accurate and scientific and shall be consistent with the product characteristics.

The contents of the labels and package marks for the medical devices shall be in line with those in the manuals for use, as relevant.

Article 6 The description of manuals, labels and package marks must be in Chinese and the other languages may be inserted, as appropriate. The Chinese description shall be in accordance with national general rules of language and characters.

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