https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20190827092601750.html

Announcement of National Medical Products Administration (NMPA) on Issuing the Medical Device Unique Device Identification System Rules (No.66, 2019)

In order to implement the "Notice of the General Office of the State Council on Printing and Distributing the Reform Plan for Governing High-value Medical Consumables" (No.37, [2019] of the General Office of the State Council), standardize the construction of Unique Device Identification System, and strengthen the management of the full life cycle of medical devices; in accordance with the "Regulations for the Supervision and Administration of Medical Devices"; the NMPA has formulated the "Medical Device Unique Device Identification System Rules". It is hereby issued and shall come into force on October 1, 2019.

It is hereby announced.

National Medical Products Administration

August 23, 2019

Attachment: Medical Device Unique Device Identification System Rules

Attachment

Medical Device Unique Device Identification System Rules

Article 1 In order to standardize the construction of Unique Device Identification System, strengthen the management of the full life cycle of medical devices, in accordance with the "Regulations for the Supervision and Administration of Medical Devices", this Rules is developed.

Article 2 The unique identification system of medical devices sold and used within the territory of the People's Republic of China shall comply with this Rules.

Article 3 The Unique Device Identification System referred to in this Rules consists of the unique device identification, unique identification data carrier, and unique identification database.

The unique device identification refers to a code composed of numbers, letters or symbols attached to the product or packaging of a medical device. It is used to uniquely identify the medical device.

The data carrier for the unique device identification refers to a data medium which stores or transmits the unique identification of a medical device.

The database for the unique device identification refers to the database which stores the product identification and related information of the unique device identification.

Article 4 The construction of Unique Device Identification System shall actively learn from international standards and follow the principles of government guidance, enterprise implementation, overall planning, and step-by-step implementation.

Article 5 The NMPA is responsible for establishing the policy for Unique Device Identification System; formulating a plan for the construction of Unique Device Identification System; encouraging all parties to actively apply the unique device identification; promoting the management of the full life cycle of medical devices.

The drug regulatory authorities of provinces, autonomous regions, and municipalities directly under the Central Government are responsible for guiding and supervising the registrants/filers in their respective administrative regions to carry out work related to the construction of Unique Device Identification System.

Article 6 The registrant/filer is responsible for creating and maintaining the unique device identification in accordance with this Rules; assigning data carriers for the unique device identification on the product or packaging; uploading relevant data; using the unique device identification to strengthen the management of the entire product process.

Encourage medical device production and operation enterprises and using organizations to actively apply the unique device identification for related management.

Article 7 The unique device identification includes product identification and production identification. The product identification is a unique code for identifying the registrant/filer, the model specification and packaging of the medical device. The production identification is composed of the codes of the

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