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China UDI Regulation

TRANSLATION OF CHINESE UDI REGULATION

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Section 1 – Translation with original Chinese script

国家药监局关于发布医疗器械唯一标识系统规则的公告

（2019 年 第 66 号）

Announcement of the National Medical Products Administration (NMPA) on Issuing the Unique Device Identification (UDI) System Rules for Medical Devices

为贯彻落实《国务院办公厅关于印发治理高值医用耗材改革方案的通知》（国办发〔2019〕37 号），规范医疗器械唯一标识系统建设，加强医疗器械全生命周期管理，依据《医疗器械监督管理条例》，国家药监局制定了《医疗器械唯一标识系统规则》，现予发布，自 2019 年 10 月 1 日起施行。

特此公告。

In order to thoroughly implement the *Notice of the General Office of the State Council on Releasing the Reform Plan for Regulating High-value Medical Consumables (GBF [2019] No. 37*), standardize the construction of UDI system, and strengthen the life cycle management of medical devices, the NMPA formulates *UDI System Rules for Medical Devices* in accordance with the Regulations for the Supervision and Administration of Medical Devices. It is hereby promulgated and shall go into effect as of October 1, 2019.

附件：医疗器械唯一标识系统规则

Annex: UDI System Rules for Medical Devices

国家药监局

2019 年 8 月 23 日

NMPA

August 23, 2019

附件：医疗器械唯一标识系统规则

Annex: Unique Device Identification (UDI) system rules for medical devices

第一条　为规范医疗器械唯一标识系统建设，加强医疗器械全生命周期管理，根据《医疗器械监督管理条例》，制定本规则。

Article 1 In order to standardize the construction of the unique identification system for medical devices and strengthen the life cycle management of medical devices, these rules are formulated in accordance with the Regulations for the Supervision and Administration of Medical Devices.

第二条　在中华人民共和国境内销售、使用的医疗器械，其唯一标识系统应当符合本规则。

Article 2 The UDI system for the medical devices sold and used within the territory of the People's Republic of China shall comply with these Rules.

第三条　本规则所称医疗器械唯一标识系统，由医疗器械唯一标识、唯一标识数据载体和唯一标识数据库组成。

医疗器械唯一标识，是指在医疗器械产品或者包装上附载的，由数字、字母或者符号组成的代码，用于对医疗器械进行唯一性识别。

医疗器械唯一标识数据载体，是指存储或者传输医疗器械唯一标识的数据媒介。

医疗器械唯一标识数据库，是指储存医疗器械唯一标识的产品标识与

关联信息的数据库。

Article 3 The UDI system referred to in these Rules consists of a UDI, a UDI data carrier and a UDI database.

UDI refers to a code consisting of numbers, letters or symbols attached to a medical device product or package. It is used to identify the uniqueness of the medial devices.

UDI data carrier refers to the data medium that stores or transmits UDI.

UDI database refers to a database that stores product identification and related information uniquely identified by the medical device.

第四条 医疗器械唯一标识系统建设应当积极借鉴国际标准，遵循政府引导、企业落实、统筹推进、分步实施的原则。

Article 4 The construction of UDI system for medical devices shall actively draw on international standards and follow the principles of government guidance, enterprise implementation, overall planning, and step-by-step implementation.

第五条 国家药品监督管理局负责建立医疗器械唯一标识系统制度，制定医疗器械唯一标识系统建设规划，推动各方积极应用医疗器械唯一标识，促进医疗器械全生命周期管理。

省、自治区、直辖市药品监督管理部门负责指导并监督本行政区域内注册人/备案人开展医疗器械唯一标识系统建设相关工作。

Article 5 The National Medical Products Administration (NMPA) shall be responsible for the establishment of UDI system for medical devices, formulating a plan for the construction of UDI system for medical devices, promoting the active application of UDI for medical devices by all parties

and promoting the life cycle management of medical devices.

The Medical Products Administration of the province, autonomous region or municipality directly under the Central Government shall be responsible for guiding and supervising the Registration/Filing Applicant in the administrative area to carry out related work for the construction of the UDI system for medical devices.

第六条　注册人/备案人负责按照本规则创建和维护医疗器械唯一标识，在产品或者包装上赋予医疗器械唯一标识数据载体，上传相关数据，利用医疗器械唯一标识加强产品全过程管理。

鼓励医疗器械生产经营企业和使用单位积极应用医疗器械唯一标识进行相关管理。

Article 6　The Registration/Filing Applicant is responsible for creating and maintaining the UDI for medical devices in accordance with these rules, providing an UDI data carrier on the product or packaging, uploading relevant data, and using UDI to strengthen the whole process management of the product.

Companies in the medical device manufacturing and related industries are encouraged to actively apply the UDI for related management.

第七条　医疗器械唯一标识包括产品标识和生产标识。产品标识为识别注册人/备案人、医疗器械型号规格和包装的唯一代码；生产标识由医疗器械生产过程相关信息的代码组成，根据监管和实际应用需求，可包含医疗器械序列号、生产批号、生产日期、失效日期等。

产品发生可能影响医疗器械识别、追溯的变更或者监管要求变化时，应当创建新的产品标识。

医疗器械停止销售、使用的，其产品标识不得用于其他医疗器械；重

新销售、使用时，可使用原产品标识。

Article 7 UDI includes product [device] identification and production identification. The product [device] identification is a unique code identifying the Registration/Filing Applicant, medical device model specifications and packaging; the production identification consists of the code of the medical device production process information, which, depending on regulatory and practical application requirements, may include the medical device serial number, production batch number, production date, expiration date, etc.

A new product identification should be created when there are changes on products that
may affect medical device identification, retrospective changes, or changes on regulatory requirements.

If the medical device is no longer for sale or usage, its product [device] identification shall not be used for other medical devices; when the medical device is for sale or usage again, it can use the original product identification.

第八条 医疗器械唯一标识应当符合唯一性、稳定性和可扩展性的要求。

唯一性，是指医疗器械唯一标识应当与医疗器械识别要求相一致。

稳定性，是指医疗器械唯一标识应当与产品基本特征相关，产品的基本特征未变化的，产品标识应当保持不变。

可扩展性，是指医疗器械唯一标识应当与监管要求和实际应用不断发展相适应。

Article 8 UDI for medical device shall meet the requirements of uniqueness, stability and scalability.

Uniqueness means that UDI should be consistent with the medical device identification requirements.

Stability means that UDI should be related to the basic characteristics of

the product. If the basic characteristics of the product have not changed, the product [device] identification should remain unchanged.

Scalability means that UDI shall be compatible with the regulatory requirements and the continuous development of practical applications.

第九条　注册人/备案人应当按照医疗器械唯一标识的编制标准创建、维护医疗器械唯一标识。

医疗器械唯一标识编制标准应当符合国家药品监督管理局以及符合本规则要求的发码机构制定的相关标准。

Article 9　The Registration/Filing Applicant shall create and maintain UDI for medical devices in accordance with the standards for UDI for medical devices.

The standards for UDI for medical devices shall comply with the relevant standards established by NMPA and the code-issuing agencies that meet the requirements of these Rules.

第十条　发码机构应当为中国境内的法人机构，具备完善的管理制度和运行体系，确保按照其标准创建的医疗器械唯一标识的唯一性，并符合国家数据安全有关要求。

发码机构应当向注册人/备案人提供执行其标准的流程并指导实施，应当将其编码标准上传至医疗器械唯一标识数据库并动态维护，每年 1 月 31 日前向国家药品监督管理局提交按照其标准创建的唯一标识上一年度的报告。

国家鼓励发码机构采用相关国际标准建立唯一标识运行体系。

Article 10　The code-issuing agency shall be a legal entity within China, and shall have a sound management system and operation system to

ensure the uniqueness of created UDI for medical devices in accordance with its standards and meeting the requirements of national data security.

The code-issuing agency shall provide the Registration/Filing Applicant with the process of implementing its standards and guide the implementation. The code-issuing agency shall upload the coding standards to the UDI database and dynamically maintain it. The code-issuing agency shall submit the report to NMPA about the UDIs created by its standards for the previous year before January 31 of each year.

The nation encourages code-issuing agencies to establish the UDI operation system using relevant international standards.

第十一条 医疗器械唯一标识数据载体应当满足自动识别和数据采集技术以及人工识读的要求。如空间有限或者使用受限，应当优先采用符合自动识别和数据采集技术的载体形式。

自动识别和数据采集技术包括一维码、二维码或者射频标签等形式，鼓励采用先进的自动识别和数据采集技术。

采用一维码时，可将产品标识和生产标识串联，也可多行并联；采用射频标签时，应当同时具备一维码或者二维码。

Article 11 The UDI data carrier shall meet the requirements of automatic identification and data acquisition technology as well as manual reading. If space is limited or usage is limited, the form of carrier that conforms to automatic identification and data acquisition techniques should be preferred.

Automatic identification and data acquisition technologies include one-dimensional barcode, two-dimensional barcode or RFID tags. It is encouraged to use advanced automatic identification and data acquisition technologies.

When a one-dimensional barcode is used, the product [device] identification and the production identification may be connected in series or in parallel with multiple lines; when RFID tags are used, the

one-dimensional barcode or the two-dimensional barcode should be provided at the same time.

第十二条 注册人/备案人应当选择与其创建的医疗器械唯一标识相适应的数据载体标准，对以其名义上市的医疗器械最小销售单元和更高级别的包装或者医疗器械产品上赋予唯一标识数据载体，并确保在医疗器械经营使用期间唯一标识数据载体牢固、清晰、可读。

Article 12 The Registration/Filing Applicant shall select the data carrier standards that are compatible with the UDI it creates. It shall assign UDI data carriers to the minimum sales unit of the medical device and the highest level of packaging for medical device products. It shall ensure that the data carriers are secure, clear and readable during the operation of the medical device.

第十三条 国家药品监督管理局制定医疗器械唯一标识数据相关标准及规范，组织建立医疗器械唯一标识数据库，供公众查询。

Article 13 NMPA formulates relevant standards and specifications for UDI data. It organizes and establishes UDI database for public inquiry.

第十四条 注册人/备案人应当按照相关标准或者规范要求上传、维护和更新唯一标识数据库中的相关数据，并对数据的真实性、准确性、完整性负责。

Article 14 The Registration/Filing Applicant shall upload, maintain and update the relevant data in UDI database in accordance with relevant standards or specifications, and shall be responsible for the authenticity, accuracy and completeness of the data.

第十五条 第十五条 注册人/备案人应当在申请医疗器械注册、注册变更或者办理备案时，在注册/备案管理系统中提交其产品标识。

注册人/备案人应当在产品上市销售前，将产品标识和相关数据上传至

医疗器械唯一标识数据库。

Article 15 The Registration/Filing Applicant shall submit the product [device] identification data in the registration/filing management system when it applies for medical device registration, registration change or filing.

The Registration/Filing Applicant shall upload the product [device] identification and relevant data to UDI database before the product launch.

第十六条 药品监督管理部门可根据监管需求调用和管理相关数据。

鼓励各相关方采用先进信息化手段、应用医疗器械唯一标识，对医疗器械在生产、经营、使用等环节进行管理。

Article 16 The Medical Products Administration may use and/or manage relevant data according to regulatory requirements.

All relevant parties are encouraged to adopt advanced information technology and apply UDI systems to manage the production, operation and utilization of medical devices.

第十七条 本规则下列用语的含义：

自动识别和数据采集，是指不通过键盘直接将数据输入计算机系统或者其他微处理器控制的设备的技术。

人工识读，是指与机器识读媒介相对应的，可由人眼直接识别的编码信息。

Article 17 The meanings of the following terms in these rules:

Automatic identification and data acquisition refer to the technology that directly input data into a computer system or other microprocessor-controlled device without using a keyboard.

Manual reading refers to the encoded information that can be directly recognized by the human eye, as opposed to the machine reading

medium.

第十八条　本规则自 2019 年 10 月 1 日起施行。分类实施的具体步骤另行制定并公布。

Article 18　These Rules shall come into force on October 01, 2019. The specific steps for the implementation of the classification will be separately formulated and published.

Section 2 - Consolidated English-only Translation

Announcement of the National Medical Products Administration (NMPA) on Issuing the Unique Device Identification (UDI) System Rules for Medical Devices

In order to thoroughly implement the *Notice of the General Office of the State Council on Releasing the Reform Plan for Regulating High-value Medical Consumables (GBF [2019] No. 37*), standardize the construction of UDI system, and strengthen the life cycle management of medical devices, the NMPA formulates *UDI System Rules for Medical Devices* in accordance with the Regulations for the Supervision and Administration of Medical Devices. It is hereby promulgated and shall go into effect as of October 1, 2019.

Annex: UDI System Rules for Medical Devices

NMPA
August 23, 2019

ANNEX: Unique Device Identification (UDI) system rules for medical devices

Article 1
In order to standardize the construction of the unique identification system for medical devices and strengthen the life cycle management of medical devices, these rules are formulated in accordance with the Regulations for the Supervision and Administration of Medical Devices.

Article 2
The UDI system for the medical devices sold and used within the territory of the People's Republic of China shall comply with these Rules.

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The UDI system referred to in these Rules consists of a UDI, a UDI data carrier and a UDI database.

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The Medical Products Administration of the province, autonomous region or municipality directly under the Central Government shall be responsible for guiding and supervising the Registration/Filing Applicant in the administrative area to carry out related work for the construction of the UDI system for medical devices.

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The Registration/Filing Applicant shall create and maintain UDI for medical devices in accordance with the standards for UDI for medical devices.

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Article 12

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