国家药监局UDID数据同步实施指南(NMPA UDID GDSN Implementation Guide)

*For the Implementation Guide in English, please visit here.

一、背景介绍 [Background]

中国国家药品监督管理局分别于2018年12月20日和2019年7月24日发布了“YY/T 1630-2018 《医疗器械唯一标识基本要求》”和“YY/T 1681-2019 《医疗器械唯一标识系统基础术语》”，并将分别于2020年1月1日和2020年8月1日实施。该两项医药行业标准对医疗器械唯一标识的基本原则、产品标识和生产标识做出了一系列要求，**凡在中国境内销售、使用的医疗器械须遵守这些要求**。随后，国家药品监督管理局信息中心组织编制了《医疗器械唯一标识数据库基本数据集》和《医疗器械唯一标识数据库填报指南》两项标准，并于2019年7月发布了征求意见稿。

[China National Medical Products Administration (NMPA) issued "Fundamental Requirements for Unique Device Identifier (YY/T 1630-2018)" on December 20, 2018 and "Basic Terms of Unique Device Identification System (YY/T 1681-2019)" on July 24, 2019, which will be implemented on January 1, 2020 and August 1,2020, respectively. The two pharmaceutical industry standards set out irements for the basic principles of unique identification of medical devices, including product identification and production identification. **All medical devices sold and/or used in China must meet these requirements.** Subsequently, NMPA Information Center organized the drafting of "Basic Data Sets of the Unique Device Identification Database" and "Unique Device Identification Database Guidelines", and their drafts for comments were released in July 2019.]

所属分类

实施指南

> 项目指南

> 中国UDID GDSN项目

2019年8月23日，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》，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》，国家药监局制定并发布了《医疗器械唯一标识系统规则》，自2019年10月1日起施行。随后，国家药品监督管理局根据前述标准和规则，建设了医疗器械唯一标识数据库（NMPA UDID），以供医疗器械企业填报UDI数据。2019年12月10日，该数据库正式上线，进入试点阶段：2019年12月至2020年6月仅对试点企业开放数据申报功能。

[On August 23, 2019, NMPA formulated and issued the "Rules of the Unique Device Identification System", effective as of October 1,2019, according to the "Regulations for the Supervision and Administration of Medical Devices", aimed at implementing the "Notice of the General Office of the State Council on Issuing the Reform Plan for the Control of High-value Medical Consumables", standardizing the construction of the unique device identification system, and strengthening the whole-life-cycle management of medical devices. On December 10, 2019, NMPA launched its UDI Database (NMPA UDID) for selected pilot medical device enterprises to report their UDI data. The pilot is planned to last from December 2019 to June 2020.]

中国物品编码中心（GS1 China）是中国医疗器械唯一标识的主要发码机构，其中国商品信息服务平台是GS1 GDSN认证数据池。为方便系统成员统一填报和管理数据，特提供全球商品数据共享平台（http://b2b.gds.org.cn/），帮助国内外医疗器械行业的GS1系统成员通过GDSN向国家药监局UDID发布和管理UDI数据，以实现以下重要优势：

[GS1 China is a major unique identification and coding institution for medical devices in China, and its China Product Information Service Platform is a GS1 GDSN certified data pool. In order to facilitate GS1 system members to report and manage data in a unified manner, we hereby provide a global product data sharing platform (http://b2b.gds.org.cn/)to release and manage UDI data in NMPA UDID through GDSN data pool(s) at home and abroad, so as to achieve the following important advantages:]

1. 单一数据源：为所有客户提供单一数据源的产品信息。通过使用全球公认的GS1标准和适用于所有供应商的GDSN流程，共享统一的产品主数据属性；

[Single data source: provide all customers with product information from a single data source. A unified set of master data attributes is shared through the adoption of globally recognized GS1 standards and GDSN process that apply to all suppliers;]

2. 促进统一性：通过全球商品数据共享平台与中国商品信息服务平台的互连互通，实现基本数据的统一性；

[Consistency: realize the consistency of basic data through the connection of the global product data sharing platform with China Product Information Service Platform;]

3. 增强合规性：通过从源头直接提供准确及时的产品信息，提高数据可视性，促进符合中国医疗器械可追溯性政策和法规。

[Compliance: improve data visibility by providing accurate product information directly from the data source in a timely manner to promote compliance with China's medical device traceability policies and regulations.]