INTRODUCTION TO GHWP UDI PROGRESS

&

IMPLEMENTATION RECOMMENDATIONS

GHWP WG9

Victoria QU (Industry Co-Chair)

March 23, 2023

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BACKGROUND

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PART 01

GHWP UDI Development & Background

GHWP WG 9 Historical Development

Global Harmonization Working Party
Towards Medical Device Harmonization

- Start pushing forward the UDI and nomenclature regional harmonization work since China's 1st Chairmanship back in 2009
- Approved by AHWP Chair and upgraded from STG to WG9 in 2017
- Will continuously working on UDI and Medical Device Nomenclature global harmonization and share experiences among members.

List of Document Already Implemented (WG9)

GHWP

Global Harmonization Working Party

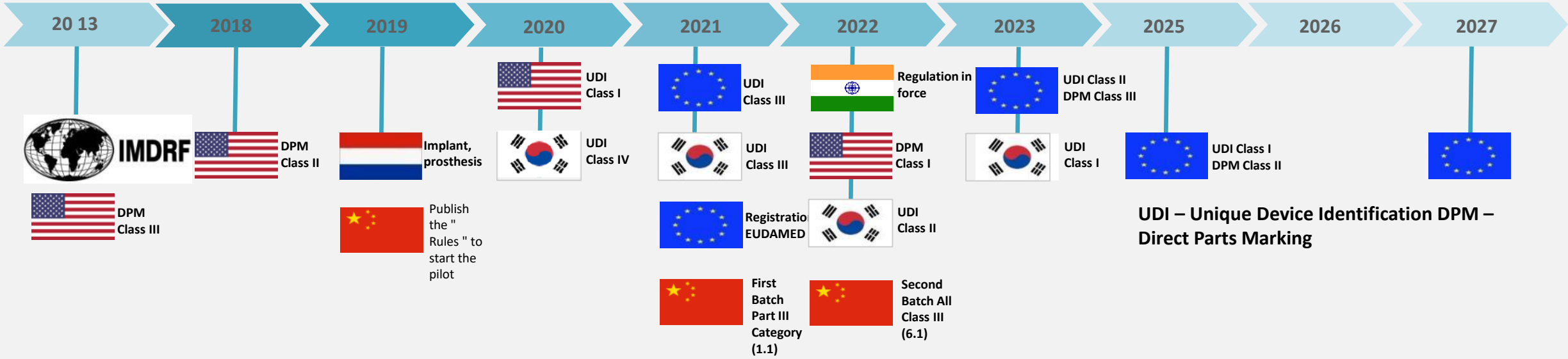
Towards Medical Device Harmonization

9. 第九工作组：医疗器械唯一标识和命名工作组

WG9: UDI and Nomenclature WG

文件编号 Document No.	文件描述 Description	发布日期 Date	文件链接 Document
AHWP/WG9/F001:2019	实施全球协调的UDI系统的挑战和建议 Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system	2019年12月2日 2 Dec 2019	下载文件：实施全球协调的UDI系统的挑战和建议.pdf Download file: Challenges and Recommendations for the Implementation of a Globally Coordinated UDI system.pdf
AHWP/STG/F001:2015	医疗器械命名原则 Guidance for Medical Device Naming Rule	2015年11月6日 6 Nov 2015	下载文件：医疗器械命名原则.pdf Download file:AHWP-STG_Guidance for Medical Device Naming Rule_FINAL.pdf

KEEP MONITORING - GLOBAL UDI IS IN PROGRESS …



- IMDRF - IMDRF UDI Guidance
- United States - "Final Rule - Unique Device Identification System 2013”
- European Union
  - Medical Device Regulation (MDR)
  - In Vitro Diagnostics Regulation (IVDR)
- India – Drugs and Cosmetics Act (2019)
- China – State Council Order 739 (2021)
- South Korea – Integrated MD Information System (IMDIS)

ALSO ACTIVELY UPGRATE LOCAL REGULATIONS…

AUSTRALIA, SAUDI ARABIA, JAPAN, SINGAPORE, COLUMBIA_, BRAZIL, RUSSIA, NEW ZEALAND, TURKEY, CANADA, …

DELIVER TRAINING AT AHWP/GHWP PLATEFORM

2018 in-person training at AHWP Annual Meeting

1. IMDRF UDI Guidance
2. Country experience sharing

- Advanced
- In-progress
- To be started

IMDRF

US FDA

EU

KOREA

Saudi Arabia

China

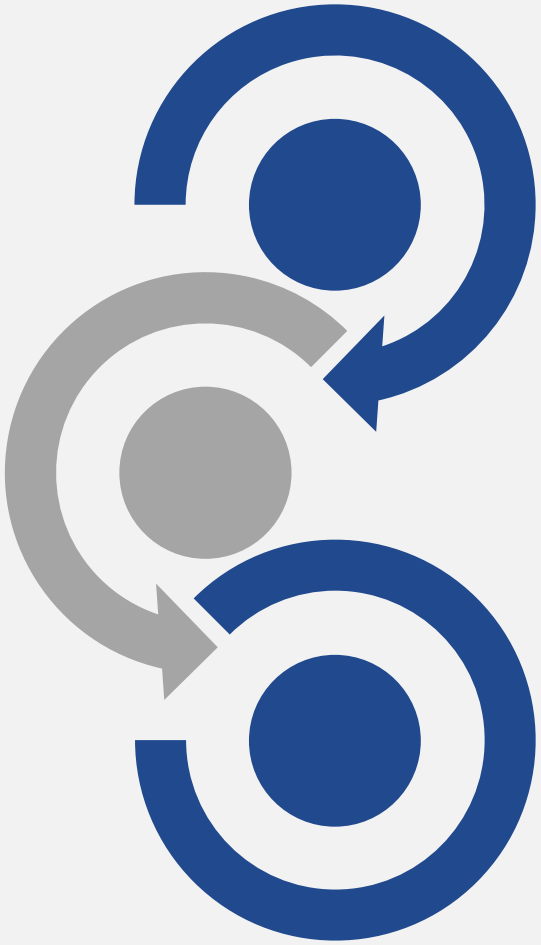
Subsequential Trainings:

- 2019 During Annual Meeting
- 2021 Virtual Meeting

PART 02

GUIDANCE, POLICIES & REGULATIONS

KEY CONTENT OF UNIQUE IDENTIFICATION SYSTEM FOR MEDICAL DEVICES



Unique Device Identification (UDI)

Create a medical device unique identifier with sufficient uniqueness

Medical device unique identification data carrier

Assign the unique identification data carrier of the medical device to the device label or body

Medical device unique identification database

Create and maintain a medical device unique identification database

UDI System Rules – General Considerations

Requirements	Purpose
In order to strengthen the life cycle management of medical devices and standardize the construction of UDI system	Basis and Purpose of the Rules
UDI system = UDI + UDI data carrier + UDI database, and the definition of each component	UDI system
Actively learn from the international community, follow government guidance, ensure implementation with regards to overall planning, and implementation througout manufacture and distribution chain	UDI system construction
Responsibilities of production enterprises, operating enterprises and users	Responsibilities of related parties

UDI System Rules - UDI

Requirements	Purpose
UDI=DI+PI , and the requirements of DI and PI ; When a product changes that may affect device identification, traceability or regulatory requirements, a new DI should be created ; Requirements for	Composition of UDI
The unique identification of medical devices should comply with the principles of uniqueness, stability and scalability.	Basic requirements of UDI
The registrant / filer shall create and maintain UDI in accordance with the UDI compilation standards .	UDI Creation Requirements
The code-issuing agency should have a sound system and meet data security requirements; Code-issuing organizations should provide implementation standards and guidance Code-issuing institutions to adopt relevant international standards to establish a unique identification operation system.	Requirements of code-issuing agencies

UDI System Rules - UDI Data Carriers

Requirements	Purpose
AIDC+HRI Encourage the adoption of advanced AIDC technology Can be connected in series or in parallel, RFID needs to have a barcode at the same time	UDI data carrier requirements
Select the appropriate data carrier Minimum sales unit and higher-level packaging or product body coding legibility of the carrier	Data carrier assignment requirements

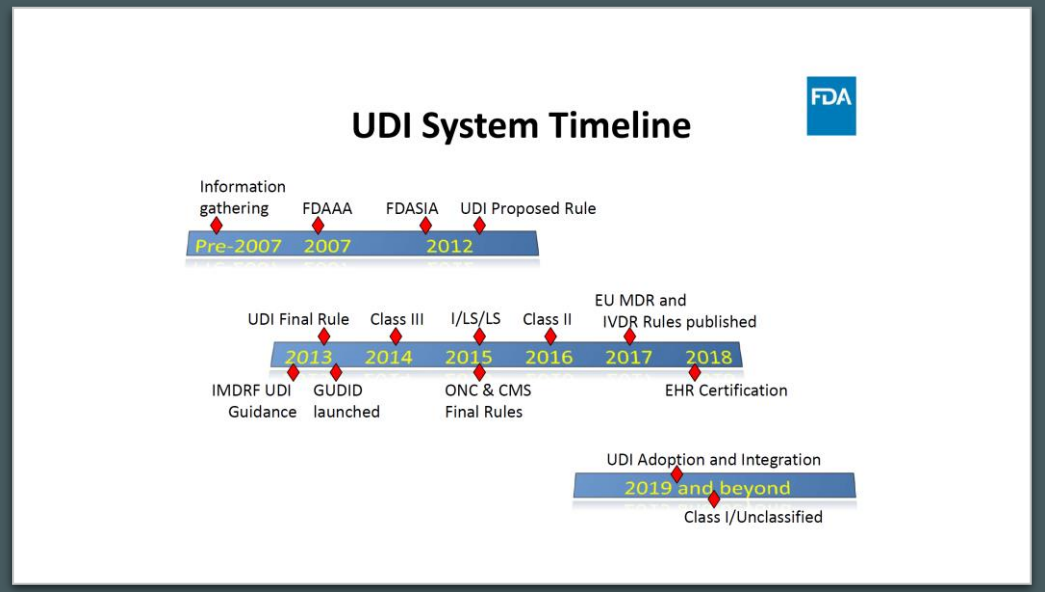
UDI System Rules - UDI Database

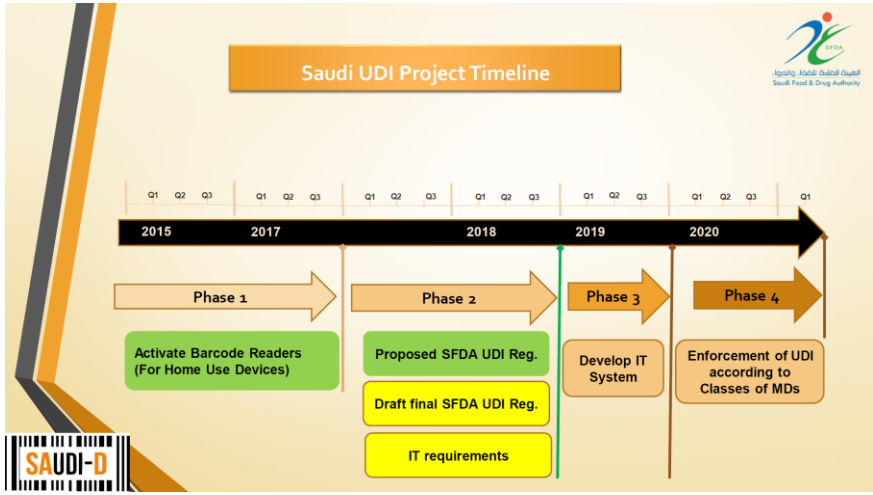
Requirements	Purpose
The database contains product identification and related data for medical devices. Local Regulatory Authority formulates standards and specifications related to the unique identification data of medical devices, and organizes the establishment of a unique identification database for medical devices for public inquiries.	Contents of database construction
Medical device registrant / filer uploads, maintains and updates relevant data in accordance with relevant standards or specifications, and is responsible for the authenticity, accuracy and completeness of the data	Responsible body for data upload
If applicable, local authrity could request registration applicant to submit the product identification in the registration / filing system, and upload the product identification and related data to the database before the product launch on the market.	Data Submission Requirements

UDI System Implementation Best Practice – a Phased-in Approach

国家药品监督管理局
National Medical Products Administration

UDI Rule released	1st batch, part of Class III, high risk	2nd Batch, Class III medical devices (including Class III IVDs)	3rd Batch, Call for comments, part of Class II to bear with UDI starting June 1, 2024.
26 Aug. 2019	1 Jan. 2021	1 June 2022	End 2022





PART 03

STANDARDS & APPLICATIONS

Relevant Standards For Unique Identification System For Medical Devices

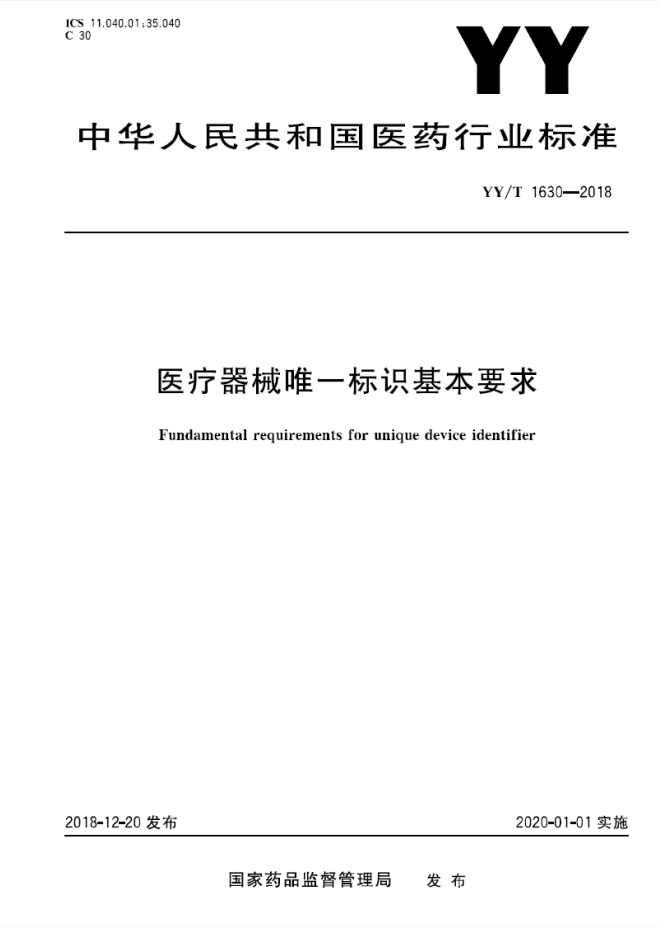
BASIC COMMON CRITERIA
(STANDARD MANAGEMENT CENTER)

- YY/T 1681-2019 " Basic Terminology of Unique Identification System for Medical Devices "
- YY/T 1630-2018 " Basic Requirements for Unique Identification of Medical Devices "
- YY/T 1879-2022 " Creation and Assignment of Unique Identification for Medical Devices "

INFORMATION STANDARD
(INFORMATION CENTER)

- YY/T 1752-2020 " Basic Data Set of Medical Device Unique Identification Database "
- YY/T 1753-2020 " Guidelines for Filling in the Unique Identification Database for Medical Devices "

YY/T 1630-2018 Basic Requirements for Unique Identification of Medical Devices



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中华人民共和国医药行业标准

YY/T 1630—2018

医疗器械唯一标识基本要求

Fundamental requirements for unique device identifier

2018-12-20 发布　　2020-01-01 实施

国家药品监督管理局　发布

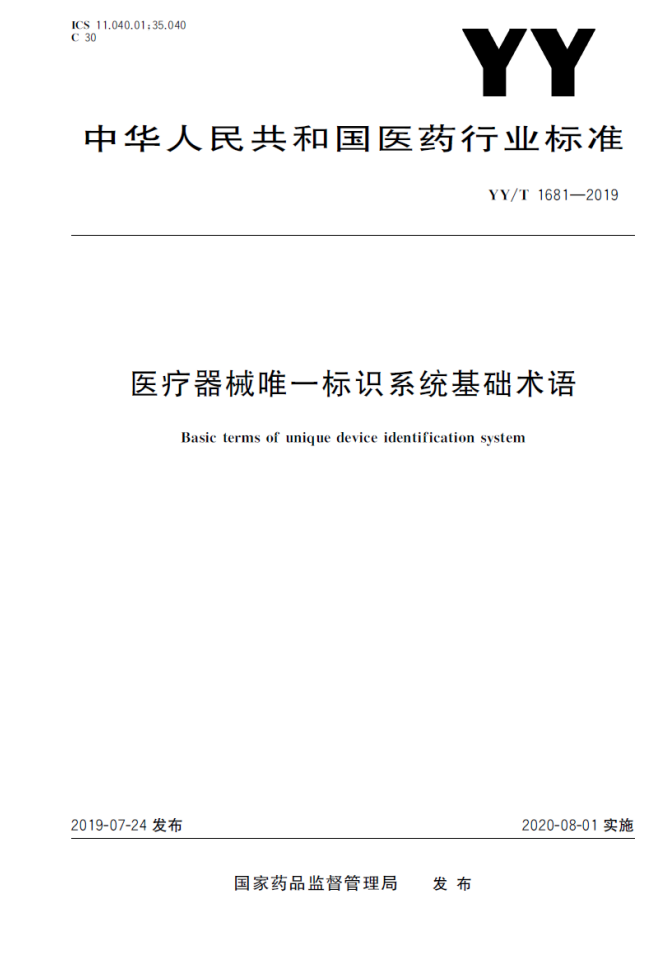
Scope Of Application:

- This standard specifies the relevant terms and definitions, basic principles, requirements for product identification and production identification for medical device unique identification.
- This standard applies to the management of the unique identification of medical devices

Main Content:

- Terms and Definitions
- Basic principles of unique identification of medical devices
- Product Identification Requirements
- production labeling requirements

YY/T 1681-2019 Basic Terminology of Unique Identification System for Medical Devices



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中华人民共和国医药行业标准

YY/T 1681—2019

医疗器械唯一标识系统基础术语

Basic terms of unique device identification system

2019-07-24 发布　　2020-08-01 实施

国家药品监督管理局　发布

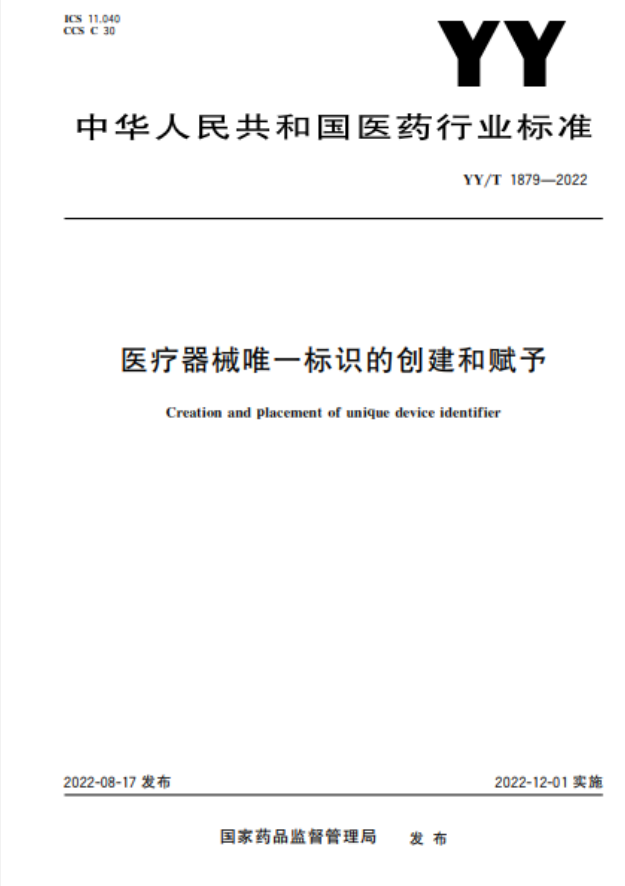
Scope Of Application:

This standard specifies the basic terms and definitions of the unique identification system for medical devices.

Main Content:

- General term
- Unique identification of medical devices
- Medical device unique identification data carrier
- Medical device unique identification database

YY/T 1879-2022 Creation and Granting of Unique Identification for Medical Devices



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中华人民共和国医药行业标准

YY/T 1879—2022

医疗器械唯一标识的创建和赋予

Creation and placement of unique device identifier

2022-08-17 发布　　2022-12-01 实施

国家药品监督管理局　发布

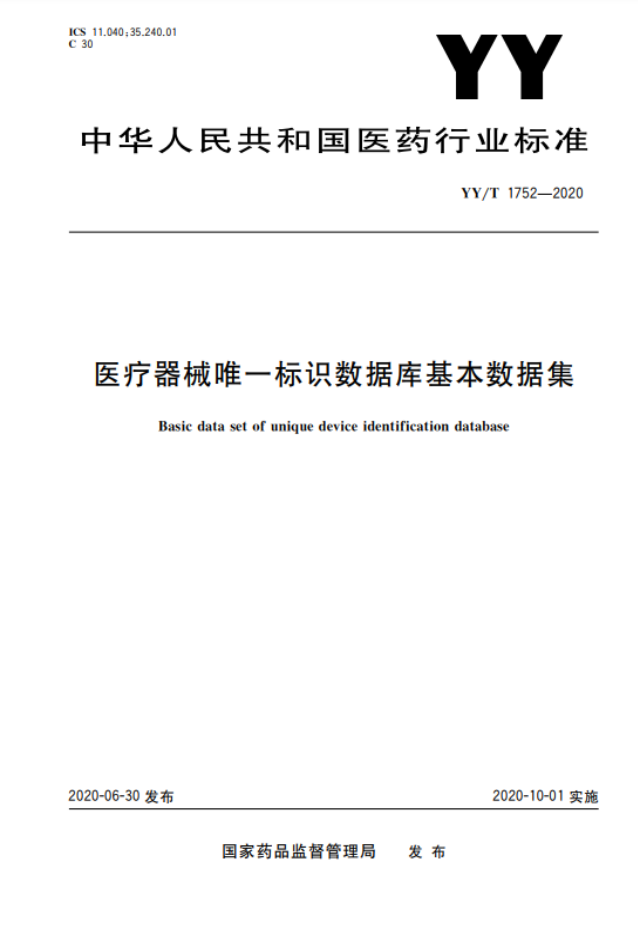
Scope:

- This standard specifies the requirements for the creation and assignment of unique identifications for medical devices.
- This standard is applicable to the implementation and application of the unique identification of medical devices by all relevant parties

Main Content:

- UDI Creation
- UDI -endowed links
- Requirements for the creation and assignment of
  - Medical Kit
  - Independent Software
  - Implanted Device

UDI Informatization Standard - Database Construction and Filling



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中华人民共和国医药行业标准

YY/T 1752—2020

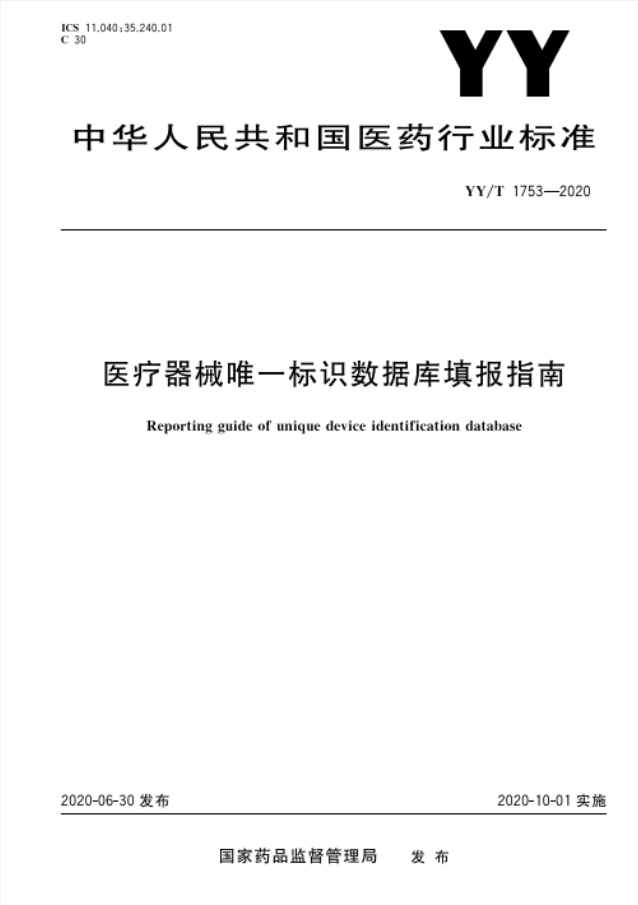
医疗器械唯一标识数据库基本数据集

Basic data set of unique device identification database

2020-06-30 发布　　2020-10-01 实施

国家药品监督管理局　发布

UDI Database Construction



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中华人民共和国医药行业标准

YY/T 1753—2020

医疗器械唯一标识数据库填报指南

Reporting guide of unique device identification database

2020-06-30 发布　　2020-10-01 实施

国家药品监督管理局　发布

UDI Database Filling

2023 ONWARD - MEDICAL DEVICE INDUSTRY STANDARD TO BE DEVELOPED

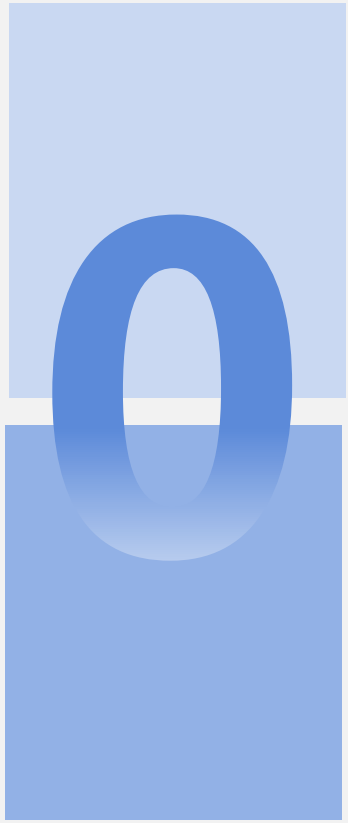
1. Packaging implementation and application of the unique identification of medical devices

2. The form and content of the unique identification of medical devices

3. ….*more to come*

PART 04

NEXT STEPS & SUGGESTIONS



KEY TAKE-AWAYS

Linkages between levels of packaging

- UDI shall be assigned to the smallest sales unit of a medical device , and higher-level packaging (excluding transport packaging) shall have its own UDI ;
- Different UDI-DIs shall be assigned to each product packaging level of the medical device , see Table B.1 of YY/T 1630-2018 , and the association relationship shall be maintained in the UDID ;

UDI-PI constituent elements

- UDI-PI should be consistent with the content of the label. For example, when the medical device label contains one or more of the production batch number, serial number, production date and expiration date of the medical device product, it is recommended to be used as the UDI-PI .
- The component part, its content should be consistent with the corresponding information on the label; if the expression format of the date is involved, it should meet the coding rules of the selected code issuing agency;

Necessity of develop more detailed regulatory requirements and standard/guidelines for code segment settings, barcode quality, and coding levels

- UDI should be created according to the coding rules of the selected code-issuing institution , and if it is otherwise stipulated in national regulations and standards, the regulations shall be complied with;
- UDI shall be granted in accordance with the standards or specifications of the code-issuing institution, and the code-issuing institution shall provide the data carrier rules adopted by its standard, including but not limited to the requirements for carrier type, size, placement and carrier quality, as well as the corresponding HRI representation form suggestion;

RECOMMENDATIONS FOR NEXT STEPS

- Leverage experiences among GHWP member, provide guidance and experiences within GHWP members community to carry out UDI work (progress varies among members)
- Improve the standardization of implementation
- Starting to carry out the transformation of the registration management system
- Actively promote UDI application in post-market supervision and other applicable areas

THANK YOU !