The Ultimate Guide to

The China NMPA UDI System and Database

Rimsys®

Contents

Overview

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The current Chinese medical device regulatory regime kicked-off in 2014 with the Regulation on Supervision and Administration of Medical Devices. This core set of registration requirements, modeled after the United States and European Union systems, established a set of device classifications (class I, II, and III) based on risk and procedures for obtaining market clearance for each type of device.

Medical devices in China are regulated by the National Medical Products Administration (NMPA). Class I devices, such as clinical laboratory equipment or non-invasive skin dressings, require only notification to the NMPA for marketing authorization, and that authorization does not expire. Class II and III devices such as implantable devices or devices with a measuring function require full registration and a formal review before market clearance can be obtained.

These initial regulations have been expanded since their introduction, adding accelerated pathways to market for certain products in certain regions, easing acceptance of clinical data from overseas, and more specific roles and responsibilities for local agents of international manufacturers. In addition, in 2019, the regulations added a provision that medical devices carry a unique device identification (UDI). China's UDI requirements are similar to those in the US and European Union. They establish specific device ID and labeling requirements, as well as a central, state-administered database of devices.

This eBook walks through the basics of medical device UDIs, the specifics of China's implementation, and how MedTech companies who market their devices in China can prepare for the full rollout of these regulations in the coming years.

Chapter 1

UDI Basics & Benefits

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UDI Basics & Benefits

A UDI is a unique alphanumeric code that is designed to identify medical devices sold in a particular country/region from manufacturing, through distribution, to use by a patient. Like other aspects of the medical device regulatory regime, the UDI system in China follows the approach taken by the United States FDA and European Commission, and is based on the guidance from the International Medical Device Regulators Forum (IMDRF). Generally, UDI systems are designed to improve patient safety and optimize care by:

- Increasing the traceability of medical devices, including field safety corrective actions
- Providing an unambiguous identification method for medical devices throughout distribution and use
- Making adverse event reports more accessible
- Reducing medical errors by providing detailed information related to the device
- Simplifying medical device documentation and making it more consistent

There are three components to the UDI system in China:

- **UDI code:** The actual UDI code can be assigned by one of three (3) issuing agencies and contains information about the product, it's expiration date, and the manufacturing batch/lot it's associated with.
- **UDI labeling:** Put simply, medical devices must carry the UDI code on them. The regulations stipulate how devices and their packaging must be labeled for compliance.
- **UDI database:** In addition to labeling, all device UDIs must be submitted to a central database that is administered by the NMPA.

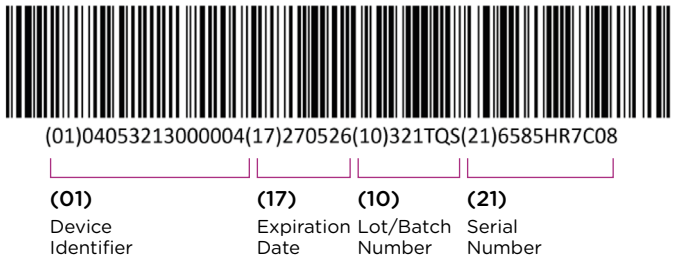
The following sections explore each of these components in more detail.

The UDI Code

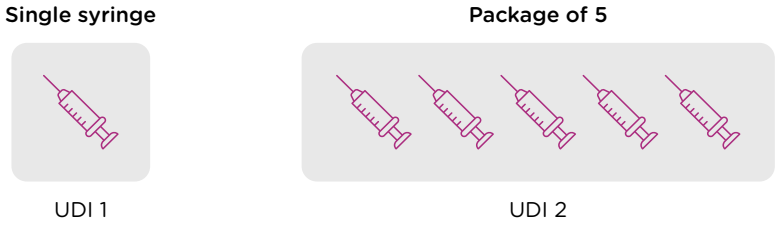
The first element of the UDI system is the code itself. The UDI code is the alphanumeric identifier that is associated with a specific medical device. UDI codes have two (2) elements to them, the UDI device identifier (UDI-DI) or static portion, and the UDI production identifier (UDI-PI) or dynamic portion. You can see the two components in the UDI diagram below:

The UDI-DI contains information about the issuing entity—the organization that is authorized to assign UDI codes. In China, this can be one of three entities: GS1, an international barcode and electronic data interchange standards organization, and two domestic organizations: the Zhongguancun Industry & Information Research Institute (ZIIOT), and AliHealth. Additional details about the issuing agencies are covered in Chapter 2. In addition, the UDI-DI contains information about the manufacturer and the specific model or version of the device.

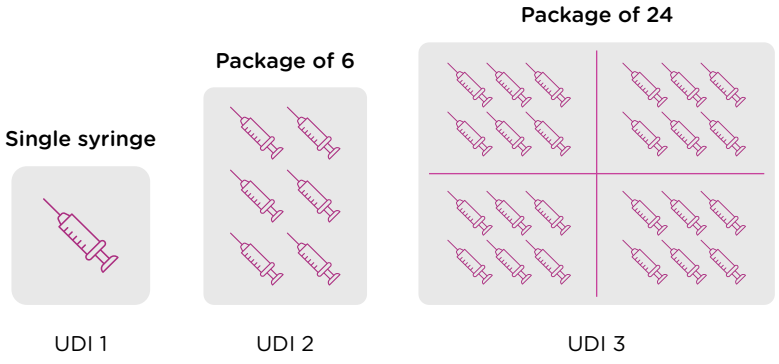
The UDI-PI contains information about the manufacturing and production of the device. This typically includes information about the lot or batch number in which the device was manufactured, the manufacturing date and expiration date for the device (if applicable), and the specific serial number for the device. Here you can see all of the components marked up using the same UDI example:



Note that each packaging permutation and level for a given device will need to be assigned its own UDI. So for example, let's say that a company manufactures 5ml enteral (oral) syringes in two packaging options: 1 - packaged individually and 2 - packaged in a box of 5. Each packaging option would need its own UDI, despite the fact that the underlying product is the same.



Now looking at packaging levels, let's assume that the manufacturer packages the single syringe offering into boxes of 6, and again into larger containers of 24. Each of those packaging options needs its own UDI as well.



Labeling

In addition to obtaining UDI code for each device as outlined in the previous section, medical device manufacturers are required to ensure that devices are appropriately labeled with the assigned UDI. This label is called the UDI Carrier. The UDI is represented in two forms on the UDI Carrier: a machine-readable form and a human-readable form.

The machine-readable form or automatic identification data capture (AIDC) is a barcode or some other technology that can be used to automatically capture UDI information. The NMPA regulations support 3 types of machine-readable formats: 1-dimensional barcode, 2-dimensional barcode, and radio-frequency identification (RFID).

1D Barcode | 2D Barcode | RFID

The regulations note that "use of advanced automatic identification and data collection technologies is encouraged"—prompting manufacturers to use more modern 2D and RFID machine-readable carriers where possible. Note, however, that if a device uses RFID, the UDI Carrier must also include the UDI in barcode format.

The human-readable form or human-readable interpretation (HRI) is the numeric or alphanumeric code for the UDI that can be read and manually entered into systems.

The UDI Carrier should be included on the device and on all levels of packaging. The UDI Carrier must be clear and readable during the operation and use of devices. If there isn't room on the device for both the human and machine-readable forms of the UDI, then manufacturers should prioritize the machine-readable form.

UDI Database

The third component of the NMPA UDI system is the UDI database. This is a centralized database of UDI and product information, administered by the NMPA. Manufacturers are required to submit UDI information into the database within 60 days after a product is approved (for sale in China) and before it is commercialized. The database contains a more detailed product record than what is included in the UDI itself, and it is the responsibility of the manufacturer (and/or their in-country representative) to submit the information correctly, and ensure that it's kept up to date.

Chapter 3 of this eBook goes into detail about the specific fields and data requirements for UDI database submissions.

Chapter 2

UDI Format & Issuing Entities

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As part of the new UDI regulations the NMPA has identified 3 issuing agencies which will be able to provide UDI codes for the Chinese market. The regulations also stipulate that the issuing agency must be a legal entity within China. These issuing organizations are tasked with developing the standard rules and conditions for a UDI assignment, and establishing processes that ensure the uniqueness of each issued UDI. Every UDI contains a company identifier as a prefix to the UDI-DI to identify the issuing entity. The three approved issuing entities for China are:

Issuing Entity	System Name	Identifier
GS1	Global Trade Item Number (GTIN)	(01)
ZIIOT	IDcode	MA
AliHealth 阿里健康	TBD*	TBD*

*At this time it's unclear exactly which form UDI codes issued by AilHealth will take, but their medical device services will likely align with their current pharmaceutical traceability programs.

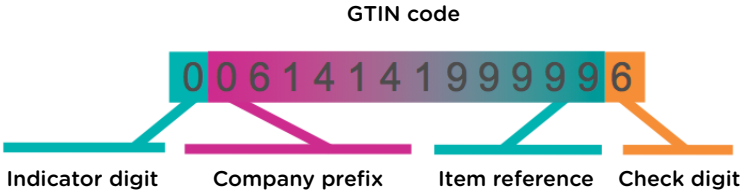
GS1 and GTIN

GS1 is the most commonly used issuing entity for UDI around the world. (The UDI examples used in the previous chapter are in the GS1 format). GS1 is a global non-profit organization focused on developing standards-based solutions for data exchange.

The GS1 UDI system incorporates GS1's global trade item number (GTIN) as the device identifier (UDI-DI). The GTIN standard is a numeric and machine readable code that is widely used for product identification and supply chain management across a number of different industries.

The GTIN code contains four elements:

1. **Indicator digit:** This is a numeric value from 1 to 9 that identifies the packaging level. This is always 0 for the individual/consumable device, and is higher for higher levels of packaging
2. **Company prefix:** This a globally unique number assigned by GS1 to a company or organization.
3. **Item reference:** A number assigned by the manufacturer to identify the model or version of the device.
4. **Check digit:** A single-digit number at the end of the GTIN that is calculated from the other digits to ensure data integrity and prevent keying errors.



UDI codes in the GS1 system use numeric prefixes as delimiters between specific types of information within the UDI. The prefixes are in parentheses, and the UDI components are listed below:

UDI Segment with Corresponding GS1 Standard	
UDI Component	**Application Identifiers (AI)**
Issuing Body (GS1) Identifier	(01)
Production/Manufacturing Date	(11)
Expiration Date	(17)
Batch/Lot Number	(10)
Serial Number	(21)

ZIIOT and IDcode

The Zhongguancun Industry and Information Research Institute of Two-Dimensional Code Technology is a Chinese research organization focused on 2D code technology research and standards. Their IDcode technology, also referred to as a "MA code", is a broadly used 2D encoding method that has become part of the international ISO/IEC 15459 standard. Here you can see an example of a UDI using the IDcode format:

MA.156.M9.1001.N30-45085.S1909000953.P190523.L2119.E240522.C5

The IDcode UDI format is similar to that of GS1 - with the first portion, the UDI-DI, conveying manufacturer and product information, and the second half conveying information related to the manufacturing of the specific device. The manufacturer code has three components: A country classification (3 digits), an industry classification (2 digits), and a unique manufacturer ID assigned by ZIIOT.

The IDcode format uses specific letters to delimit fields within the code rather than numeric prefixes. The UDI components with their letter delimiters are listed below:

UDI Segment with Corresponding ZIIOT Standard	
UDI Component	**Letter Delimiter**
Issuing Body (ZIIOT) Identifier	MA.
Production/Manufacturing Date	.M
Expiration Date	.E
Valid Period	.V
Batch/Lot Number	.L
Serial Number	.S
Sterilization Lot Number	.D

These elements can be expanded to include traceability and medical insurance codes, a product URL, and other additional information fields that the manufacturer would like to include in the UDI.

AliHealth

AliHealth is a subsidiary of China's Alibaba Group that is focused on the healthcare industry. Their stated focus is to use technology to bring affordable and accessible medical and healthcare services to Chinese consumers. They operate a pharmaceutical eCommerce and supply chain platform, and a drug traceability system called Ma Shang Fang Xin.

The Ma Shang Fang Xin system uses a 20-digit numeric 1-dimensional barcode system to code pharmaceutical products. The code has three (3) parts: a product identifier which includes manufacturer code, product code, and dosage information, a single item serial number, and a set of check digits. This number is encoded using Code 128C specification.

At this time it's not clear how AliHealth will implement UDI codes or the format they'll be using. While they have been named as an issuing entity, it is uncertain if they will be creating their own UDI standard based on their approach to pharmaceutical traceability, or building on the ZIIOT approach.

Chapter 3

The UDI Database & Submission Requirements

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The NMPA UDI system includes a central database of all medical devices. Under the new regulations, manufacturers will be required to submit specific information before placing a device on the market. The core data elements provided through the UDI database will be publicly accessible. This section details the specific fields and data requirements for UDI database submissions.

Part 1 – Device Identifier (DI) Information	
Coding system	Which issuing entity (GS1, ZIIOT, AliHealth) issued the UDI code
Minimum sales unit UDI-DI	The product identification of the smallest sales unit (or level of packaging) for the device
Minimum sales unit quantity	The number of units included in the smallest sales unit (or level of packaging) for the device
Unit of use UDI-DI	If the number of units in the minimum sales unit is greater than 1, the manufacturer must supply a UDI-DI for the unit of use.
Release Date	The date that UDI information should become publicly available. Typically this coincides with when a manufacturer gains market approval or plans to begin marketing their product in China.
UDI Carrier type	Indicate whether the machine-readable portion of the UDI carrier will be a 1D barcode, 2D barcode, or RFID.
Submission UDI/product Identification	If a UDI or product identification that is different from the minimum sales unit UDI was used for the market approval submission, the submission ID must be provided.
Device body UDI/product Identification	This is applicable if the device itself has a UDI carrier (on the device itself) that is different from the UDI associated with the smallest sales unit. If so manufacturers must submit the UDI that is on the device.

Part 2 – Product Information	
Product name	Public/common name of the device
Set/kit	Whether the product is a bag set or kit (such as a first aid or surgical kit)
Model/version	Information about the product specs and/or model. This should correspond with what was supplied in the market clearance application. For software, this should be the version number.
Product description	Product description from the product registration certificate. If the product is a set/kit the names and quantities of all components should be included in this field.
Product category	Indicate whether the product is a medical device or in-vitro diagnostic reagent.
Classification code	The product classification category, based on the NMPA Medical Device Classification Catalogue.
Registrant name	Name of the company/organization that is completing the submission. Note that Chinese names should be used for international/overseas companies.
Registration certificate number	Filing/certificate number for the device (from the market clearance application).
Device category	Indicate whether the product (assuming it's a device) is considered a consumable device or medical equipment.
Single use	Indicate whether the device is marked for single-use or not.
Aseptic packaging	Indicate whether the device has been sterilized as part of the production and/or packaging process.
Sterilization required	Does the product need to be sterilized prior to use (yes/no)?
Sterilization method	Guidelines for sterilization if it's required prior to use.

Part 3 – Production Identifier (PI) Information	
Production batch	Does the UDI-PI include the production batch number (yes/no)?
Serial number	Does the UDI-PI include a product serial number (yes/no)?
Production date	Does the UDI-PI include the production date (yes/no)?
Expiration date	Does the UDI-PI include the expiration date (yes/no)?

In addition to the mandatory fields detailed in the preceding section, manufacturers have the option to add information about the product packaging (including the UDI-DI for the packaging level if the submission is for a packaging level higher than the minimum sales unit). Manufacturers can also submit information about storage and handling instructions for the device as well as specifics about the size/measurements of the device.

Chapter 4

Implementation of UDI & the UDI database in China

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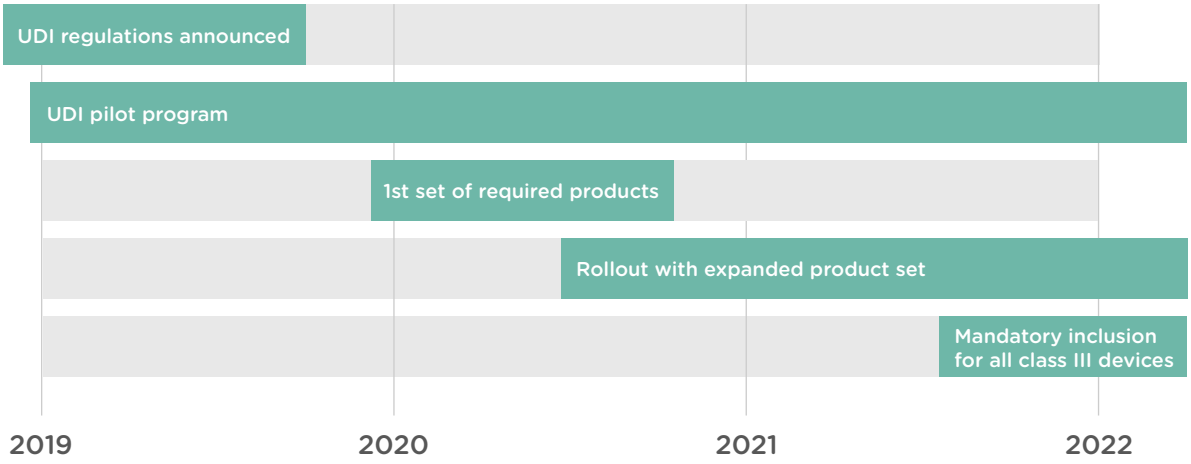
The full timeline for UDI rollout in China has so far been a moving target. The regulation announcement in 2019 was accompanied by a pilot program that is currently running. The initial planned implementation for a select set of device types was planned for October 2020, and subsequently moved to January 2021. It is expected that the regulations will expand to cover all class III devices starting in 2022. Manufacturers are encouraged to participate in the program even if it is not currently mandatory for their devices.



The first set of mandatory products was announced in October 2019 with an expected implementation date of October 2020. The list of products comprised 64 categories of high-risk, implantable class III devices including:

- Cryoablation needles and catheter
- Absorbable sutures
- Cardiovascular Interventional Instruments - balloons and catheters
- Capsule endoscope systems
- Hemodialysis equipment
- Implantable pacemakers, defibrillators and cardiac monitoring equipment
- Implantable neurostimulators
- Implantable hearing devices
- Implantable drug infusion equipment
- Osseointegration, spine, and joint replacement implants
- Cardiovascular stents and patches
- Artificial heart valves and blood vessels

In September 2020, a subsequent announcement postponed the initial rollout (due primarily to the COVID pandemic) to January 2021 and added 5 additional categories of devices that would be included in the initial implementation including in-ear prostheses and spinal interbody fixation/ replacement systems.

After this initial rollout, the UDI program will be expanded to all class III devices. This next phase is expected to start in January 2022, pending final regulation updates from the NMPA.

Glossary

Glossary

AIDC – Automatic Identification and Data Capture is a technology used to automatically capture data. AIDC technology can include bar codes, smart cards, biometrics, and RFID

AliHealth – AliHealth is a subsidiary of China's Alibaba group focused on healthcare technology. They provide pharmaceutical eCommerce services, supply chain management services, and a traceability system. They are one of the issuing entities for UDI codes in China.

Carrier – see UDI Carrier

Company Identifier – A prefix included before the UDI-DI on the UDI Carrier to identify the Issuing Entity for the UDI.

Device Identifier (DI) – A mandatory, fixed portion of the UDI that identifies the manufacturer and specific, detailed information about the model of device. (see also UDI-DI)

GS1 – An Issuing Entity for UDI. (see also GTIN)

Global Trade Identification Number (GTIN) – A system created and operated by GS1 that is used internationally for product identification and supply-chain management across a variety of industries. The GTIN format is used for the UDI-DI.

HRI – Human Readable Interpretation is a legible view of the data characters on a UDI label (or encoded directly on a device) and is required in case there is no automatic system to read the code.

IDCode – A two-dimensional barcode system developed by the Zhongguancun Industry and Information Research Institute of Two-Dimensional Code Technology (ZIIOT) used for product identification and supply chain management. The IDCode system is used by UDI codes issued by ZIIOT.

Issuing Entities – Entities approved by the NMPA to develop a system of standard terms and conditions for UDI assignment in China. All UDI codes must conform to the requirements of the issuing entity.

NMPA – The National Medical Products Association is the regulatory body that governs pharmaceutical, medical device, and cosmetic products in China.

Production Identifier (PI) – A conditional, variable portion of the UDI that contains information about the manufacturing and production of that device. (See also UDI-PI)

UDI – The Unique Device Identifier (UDI) is a specific code assigned to all devices and higher levels of packaging to provide identification of the device throughout its distribution and use history.

UDI Carrier – The portion of the device or packaging label that contains the UDI. The UDI Carrier contains a machine-readable component and a human-readable component.

UDI-DI – The unique Device Identifier is a mandatory, fixed portion of a UDI label that identifies the device manufacturer and the specific version, make, or model of a device. It's the static part of the UDI number.

UDI-PI – The unique Production Identifier, a mandatory, fixed portion of a UDI label that identifies the device's serial number, lot number, expiration date, and manufacturing date. It's the dynamic part of the UDI.

Unit of Use DI – Used to associate a device in which a UDI is not directly labeled on an individual device at the level of its intended use. Its purpose is to associate the use of a device being delivered to/or used on a patient when one base package contains more than one device. (i.e. packing several devices of the same product together in a box for a single shipment.)

ZIIOT – The Zhongguancun Industry and Information Research Institute of Two-Dimensional Code Technology is a Chinese research and standards organization that is one of the selected issuing entities for UDI codes in China. UDIs issued by ZIIOT use their IDCode standard.

About Rimsys

Rimsys is the leading provider of Regulatory Information Management (RIM) software for medical technology companies. Built by and for regulatory affairs professionals, Rimsys digitizes, automates, and creates regulatory order to ensure products adhere to changing global regulations. It is the only holistic RIM software for medical devices, in-vitro diagnostics, and medical device software that makes it easy to manage global UDI requirements and navigate the pillars of regulatory affairs, including product registration, standards management, essential principles/ GSPR, and regulatory intelligence.

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