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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1942-2024

Form and content of the unique device identifier

医疗器械唯一标识的形式和内容

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Table of Contents

1 Scope

YY/T 1942 fixes what a Chinese unique device identifier is made of. It specifies the form and the content of the UDI: the device identifier that names the model and the production identifiers that carry lot, serial number, expiry and manufacturing date, and the rules governing how they are constructed and expressed. UDI is the backbone of traceability, recall and post-market surveillance, and it only works if every party reads the same string the same way, which is why the syntax is standardised rather than left to issuing agencies. It is the companion to YY/T 1943 on applying the identifier across packaging levels. For a manufacturer building UDI into its labelling and master data for China, this is the document the identifier structure has to conform to.

This Document specifies the form and content of the unique device identifier, data separators and the parsing of unique identifier. This Document is applicable to the implementation and application of unique device identifier by all relevant parties.

2 Normative References

The provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

YY/T 1681 Basic terms of unique device identification system

YY/T 1943 UDI implementation and application in medical device package levels

3 Terms, Definitions and Abbreviations

3.1 Terms and definitions For the purposes of this Document, the terms and definitions

given in YY/T 1681 apply.

3.2 Abbreviations The following abbreviations are applicable to this Document. AIDC: Automatic Identification and Data Capture HRI: Human Readable Information RFID: Radio Frequency Identification UDI: Unique Device Identifier UDID: Unique Device Identification Database

4.2.4 Manufacturers should consider guiding the AIDC carrier containing the UDI in an appropriate manner, such as using the UDI graphic symbol in Clause 5

d) of YY/T 1879-2022.

4.2.5 A comparison of the three common AIDC forms, 1D code, 2D code and RFID, is shown in Appendix A. For the selection of AIDC readers, please refer to the considerations for selecting AIDC readers in the IMDRF UDI application guide, see Appendix B.

4.3 HRI

4.3.1 HRI enables medical staff, patients, regulatory agencies and other users of the UDI system to read UDIs without technical assistance and enter them into data systems (such as medical records or reports submitted to regulatory agencies). It should serve as an additional mechanism for collecting UDIs when the AIDC carrier form cannot be read.

4.3.2 HRI shall contain UDI-DI and UDI-PI parts, as well as corresponding data separators.

4.3.3 HRI can be displayed as single-line or multi-line text. Single data fields (data separators and their defined information fields) shall not wrap and shall be displayed below or near the AIDC.

4.3.4 The form of HRI shall meet the coding rules of the code-issuing agency.

5 Content of UDI

5.1 The content of UDI in this Document refers to the data information contained in UDI and its corresponding HRI and AIDC forms.

5.2 UDI includes UDI-DI and UDI-PI, among which the production batch number, serial number, production date, expiration date, and version number of independent software belong to UDI-PI. If otherwise specified by national laws and regulations and standards, they shall prevail.

5.3 It is not recommended that manufacturers add other content other than UDI information (UDI-DI and UDI-PI), such as quantity, to the UDI data carrier. If it is necessary to add, it shall comply with relevant laws and regulations and the relevant rules and requirements of the code- issuing agency; and its data separator shall be distinguished from the data separators of UDI- DI and UDI-PI.

5.4 The order of data in the data carrier shall follow the rule that UDI-DI is placed before UDI- PI and UDI-PI is placed before other content.

6 Data Separator

6.1 Data separators are characters or character sets that define specific data information and are used to identify specific data information content in the encoded data string. A - product identifier; B - product name; C - specification and model; D - registration certificate No.; E - registered/recorded by; F - production batch number; G - production date; H - expiration date; I - unit; J - quantity; K - syringe; L - GXZZ. NOTE 1: In this method, it needs to manually enter the UDI-PI field and complete UDI information. NOTE 2: Other required content shall be filled in the corresponding link according to the needs. Figure 4 - A diagram of using HRI method to obtain relevant information in UDID by searching and selecting UDI-DI

d) According to the rules and formats of the involved code-issuing agencies, parse the UDI into UDI-DI and the corresponding UDI-PI; and fill in the corresponding fields of the system, respectively. NOTE 3: For other contents in the data carrier (if any), parse and record them according to the definitions provided in

e) Perform necessary information correctness checks according to the rules of the code-issuing agency, and prompt any found errors.

f) Perform UDID association search and data information extraction through UDI-DI online or local storage. If through local storage, consider docking with UDID to obtain version update information.

g) According to YY/T 1943, establish the conversion relationship of UDI-DI identification quantity for different product packaging levels.