YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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UDI implementation and application in medical device package levels

医疗器械唯一标识的包装实施和应用

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1 Scope

YY/T 1943 covers how the unique device identifier is applied across the levels of a medical device's packaging. Chinese UDI regulation requires that a device be identifiable from its immediate packaging up through cartons and shipping units, and the practical difficulty is not the code itself but the relationships between levels: which identifier goes on which package, how the hierarchy is expressed, and how a scan at any level resolves to the right product record. This document is the implementation companion to YY/T 1942, which fixes the form and content of the identifier itself. For a manufacturer preparing for Chinese UDI compliance, or adapting a labelling system already built for the US or European requirements, this is the standard the packaging and labelling design is measured against.

This document specifies the implementation of unique identification of packaging at each product packaging level for medical devices and its analysis in the supply chain. This document applies to the implementation and application of unique device identifiers of multi-level packaging medical device products.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this text. Among them, for referenced documents with dates, only the versions corresponding to the dates are applicable to this document; for referenced documents without dates, the latest versions (including all amendments) are applicable to this document.

YY/T 1681 Basic terms of unique device identification system

YY/T 1752 Basic data set of unique device identification database

YY/T 1753 Reporting guide of unique device identification database

YY/T 1942 Form and content of the unique device identifier

3 Terms, definitions and abbreviations

3.1 Terms and definitions The terms and definitions defined in YY/T 1681 apply to this document.

3.2 Abbreviations The following abbreviations apply to this document. AIDC. automatic identification and data capture HRI. human readable information UDI. unique device identifier UDID. unique device identification database UDI-DI. device identifier UDI-PI. production identifier UoU UDI-DI. unit of use device identifier

4 General rules

4.1 The packaging in this document refers to the product packaging level where the products contained therein have the same minimum sales unit UDI-DI and production batch number. NOTE. A product packaging level contains a fixed number of medical devices.

4.2 Product packaging levels do not include shipping containers. Examples of product packaging levels and shipping containers are shown in Appendix A. NOTE. From a traceability perspective, the shipping container itself is traceable in the logistics system without the need for UDI.

4.3 The composition of UDI-PI for different packaging levels of medical devices of the same specification and model should be consistent.

4.4 New packaging configurations shall be assigned a new UDI-DI.

4.5 When a product has multiple product packaging levels, a packaging identifier (if applicable) should be used to distinguish different levels of packaging. The compilation of the packaging identifier shall comply with the rules of the coding agency.

5 Implementation of UDI packaging

5.1 The minimum sales unit contains 1 unit of use When the minimum sales unit of a medical device contains 1 unit of use and the higher- level packaging has only a unique packaging quantity form, the minimum sales unit of the medical device and the higher-level packaging should be assigned UDI-DI and given a unique identifier data carrier. In UDID, the information corresponding to the minimum sales unit shall be uploaded to UDID and linked to the highest level of packaging layer by layer in accordance with the requirements of YY/T 1752 and YY/T 1753.The different product packaging levels with a single packaging quantity and their association in the UDID are shown in Table 1. the minimum sales unit in accordance with the relevant requirements of YY/T 1942;

d) The UDI information recorded in the information systems of all parties in the supply chain shall be consistent with the product UDI;

e) Since UDIs of different product packaging levels may be scanned during warehousing

and consumption, the warehousing, consumption, and inventory quantities shall be balanced after conversion;

f) Establish records containing UDI information in accordance with laws, regulations and related document requirements to ensure traceability. Examples of conversion and analysis of packaging in this case are given in Appendix B.

6.2 The minimum sales unit contains multiple units of use When management at the unit-of-use level is required, the analysis of each level of UDI packaging is based on 6.1, and usually the following shall also be considered.

a) Establish the quantity conversion relationship between the unit-of-use of a medical device and the minimum sales unit in the information systems of all parties in the supply chain;

b) After the minimum sales unit of a medical device is opened and becomes the unit-of-use of a medical device, the quantity of the unit-of-use is obtained according to the conversion relationship, and the unit conversion is performed, see Appendix C;

c) When the unit-of-use of a medical device is consumed, the UDI-PI of its corresponding minimum sales unit shall be recorded;