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PHARMACEUTICAL INDUSTRY STANDARD
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Basic Data Set of Unique Device Identification Database

医疗器械唯一标识数据库基本数据集

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Basic Data Set of Unique Device Identification Database

1 Scope

This Standard specifies the categories and data subsets and the like contents of the basic data sets of unique device identification database.

This Standard is applicable to the construction of a unique device identification database.

2 Normative References

The following documents are essential to the application of 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.

GB/T 2260 Codes for the Administrative Divisions of the Peoples Republic of China

GB/T 7408 Data Elements and Interchange Formats - Information Interchange - Representation of Dates and Times

YY/T 1681 Basic Terms of Unique Device Identification System

3 Terms and Definitions

For the purposes of this document, the following terms and definitions given in YY/T 1681 apply.

3.1 Direct marking UDI-DI

The medical device body is directly attached with the product identification in the unique device identification.

4 Abbreviations

The following abbreviations are applicable to this document.

them:

- 1) Those with fewer optional values (3 or less) are listed directly in the "allowable values" attribute.
 - 2) Those with more optional values (more than 3), write the name of the range code table in the "allowed value" attribute; and the range code table is listed in the normative appendix. If the code table belongs to the referenced standard, the standard number shall be indicated.
- b) Non-enumerable range: The range that is specified by the description; and the allowable value of the range shall be accurately described in the "allowable value" attribute.

6.6 Constraints

Descriptor indicates whether a data item is selected. The descriptors are as follows:

- a) Required: It indicates that the data item must be selected;
- b) Optional: It indicates that the data item can or can't be selected according to the actual application;
- c) Conditional required: It indicates that the data item shall be selected when the conditions defined in the constraint conditions are met; and the constraint conditions are explained in the remarks.

7 Relevant Data Subset of the Basic Information of the Unique Device Identification Database

7.1 Data subset of the basic information of the unique device identification database

The data subset of the basic information of the unique device identification database mainly includes: basic information of product identification, basic information of product, packaging product identification and its packaging level association information, basic information of clinical use, etc., see Table 4 for details, of which:

- a) Data items 1~5 are the basic information of product identification;
- b) Data items 6~14 are the basic information of product;
- c) Data items 15~17 are the basic information of the direct marking UDI-DI;
- d) Data items 18~21 are the corresponding packaging product identification and

Appendix B

(Normative)

Instructions of Location Values

B.1 Address-Province (municipalities/autonomous regions)

The digital codes from the code list of provinces, municipalities, autonomous regions, and special administrative regions in GB/T 2260 shall be used.

B.2 Address-City (district/autonomous prefecture/union)

For the digital codes in Tables 2~35 of GB/T 2260, if the relevant city (district/autonomous prefecture/union) fails to be found in GB/T 2260, then it belongs to newly-established city (district/autonomous prefecture/union), and its value shall be compiled according to the following rules:

- a) Find the 6-digit code of the province where the city (district/autonomous state/union) is located as per GB/T 2260.
- b) Code the city (district/autonomous prefecture/union): Change the 4th digit of 0 into A (then B~ Z so on) in the 6-digit code of the province where the city (district/autonomous prefecture/union) is located as per GB/T 2260.

B.3 Address-County (autonomous county/county-level city)

For the county-level digital codes in Tables 2~ 35 of GB/T 2260, if the relevant county (autonomous county/county-level city) fails to be found in GB/T 2260, it belongs to the newly-established county (autonomous county/county-level city), and its value shall be compiled according to the following rules:

- a) Find the 6-digit code of the province where the county (autonomous county/county-level city) is located as per GB/T 2260.
- b) Code the county (autonomous county/county-level city): Change the 6th digit 0 into A (and so on, for B~Z) in the 6-digit code of the province where the county (autonomous county/county-level city) is located as per GB/T 2260.

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