



Global Harmonization Working Party

Towards Medical Device Harmonization

Final Document

Title: UDI Data Elements

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Table of Content

1.0	Introduction	3
2.0	Scope	3
3.0	Common UDI Data Elements across different Databases	3
4.0	UDI Data Elements across different Databases	4

1.0 Introduction

This document provides an overview of the data elements submitted to the current UDI databases. In the meanwhile, this document identified the common UDID data elements with their data element description to help reader to understand the requirements across jurisdictions.

2.0 Scope

This information document is intended to provide a UDI data elements dictionary containing common data elements, full data elements of the database of China, Chinese Taipei, Saudi Arabia, Korea, and European Union.

3.0 Common UDI Data Elements across different Databases

Note: The UDI data elements may vary depending on each regulatory authority. The following items listed are the common UDI data elements collected from existing database across jurisdictions and for reference only.

Minimum Sales Unit UDI-DI

- UDI-DI on the minimum sales unit of medical device of a certain specification and model

Catalog Number

- Code of medical device catalog or number of enterprise product catalogue

package UDI-DI

- UDI-DI on the package of medical device product at current level

Quantities per package

- The package at this level includes the quantity of packages with the same UDI-DI at the next lower level package

Is Lot Or Batch Number in UDI-PI

- Whether UDI-PI barcode of medical device includes lot or batch number

Is Serial Number in UDI-PI

- Whether UDI-PI barcode of medical device includes serial number

Is Manufacturing Date in UDI-PI

- Whether UDI-PI barcode of medical device includes manufacturing date

Is Expiration Date in UDI-PI

- Whether UDI-PI barcode of medical device includes expiration date

Sterilization Method

- Sterilization method for medical device

Certificate Number

- Certificate number specified on medical device registration certificate or filing certificate number specified on filing certificate

4.0 UDI Data Elements across different Databases

This document contains one Annex in an Excel form.

This annex includes information from the jurisdictions that have defined the data fields in their respective UDID systems.

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