The 11th Joint Conference of Taiwan and Japan on Medical Products Regulation

UDI Regulations in Taiwan

Division of Medical and Cosmetics, TFDA

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Mr. Hsiu-Te Lin
Section Chief

衛生福利部
食品藥物管理署
Taiwan Food and Drug Administration

Progress in UDI Advancement

2013

1. Maintain a firm grasp of international regulations and trends of UDI.
2. Seek to understand the general situation and needs for introducing UDI domestically.

2015

1. Announce domestic UDI practice.
2. Establish a domestic UDI Database (TUDID) information management platform.

2018

1. Assist domestic manufacturers and importers in introducing UDI.
2. Encourage license holders of high-risk medical devices to upload device identifier information to the TUDID platform.
3. Hold related seminars, meetings, and training courses to collect relevant comments from the industry and medical institutions.

2021

Announce the provisions for requiring medical device label to indicate the Unique Device Identifier.

2023

Update the provisions for "requiring medical device label to indicate the Unique Device Identifier".

Strategy according to IMDRF Guideline

Recommendation from IMDRF (UDI WG/N48 FINAL:2019):

1. Develop a standardized system of identifiers
2. Placement of UDIs in two formats on labels
3. Build UDI data elements to a UDI database
4. **Set appropriate** transitional and implementation arrangements

Corresponding Solution:

1. Define the standardized format in the UDI practice
2. Need to amend regulations for mandatory implementation
3. Need to establish a database for information uploading
4. Need to pay attention to international trends and provide adequate assistance to the industry

Official Implementation of Medical Devices Act

Realization of UDI by Medical Devices Act

- **Mandatory labeling**

Article 33 (Subparagraph 10 of Paragraph 1)

Medical device firms shall indicate the following particulars on the labels, instructions, or packaging of medical devices, as approved, registered and approved, or listed in accordance with Paragraph 2 of Article 13 and Paragraph 1 of Article 25. **…**

10. Other particulars that shall be indicated as announced by the central competent authority.

According to Medical Devices Act, UDI has been one of the announced mandatory items to be placed on the label.

Taiwan UDI Regulation (1/3)

Harmonized with IMDRF UDI Guidance

- IMDRF/UDI WG/N7FINAL:2013
- IMDRF/UDI WG/N48FINAL:2019

✓ Labeling Requirements for Unique Device Identification, April 6, 2021.

1. Development of a standardized system of Unique Device Identifiers (UDIs)
2. Placement of UDIs in human readable and AIDC formats/forms on package labels and in some cases, on the device itself
3. Submission of core UDI data elements to a UDID
4. Setting of appropriate transitional and implementation arrangements to ensure a smooth UDI system implementation

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Taiwan UDI Regulation (2/3)

UDI Labeling Transition Period

- Effective date of the Taiwan UDI labeling requirements:

1. Class III implantable devices: June 1, 2021
2. Class III devices: June 1, 2022
3. Class II devices: June 1, 2023

UDI Labeling Principles

Responsibilities (MD/IVD license holder):

1. UDI Coding Standard: GS1, HIBCC, ICCBBA
2. UDI labeling: An UDI labeling on the device or the label of the device immediate container
3. UDI database: Taiwan UDID (TUDID)

Taiwan UDI Regulation (3/3)

Updated "Labeling Requirements for Unique Device Identification", **February 13, 2023**

- ✓ **The following Class II medical devices are not required to be labeled with production identifier (PI):**

Blood pressure cuff	Medical Impedance plethysmograph	Ear, nose, and throat drug administration device	Alcohol pad	Providone-Iodine pad	Nonresorbable gauze/sponge for external use	Medical apparel
Saline solution for wound irrigation	Clinical electronic thermometer	Medical adhesive tape and adhesive bandage	Medical support stocking	Condom	Menstrual cup	menstrual tampon
Soft (hydrophilic) contact lens	Rigid gas permeable contact lens	contact lens care products	Motorized vehicle for medical purpose	Powered wheelchair		

Taiwan UDI Database (TUDID)

http://udid.fda.gov.tw

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Required TUDID Data Elements

24 required TUDID data elements:

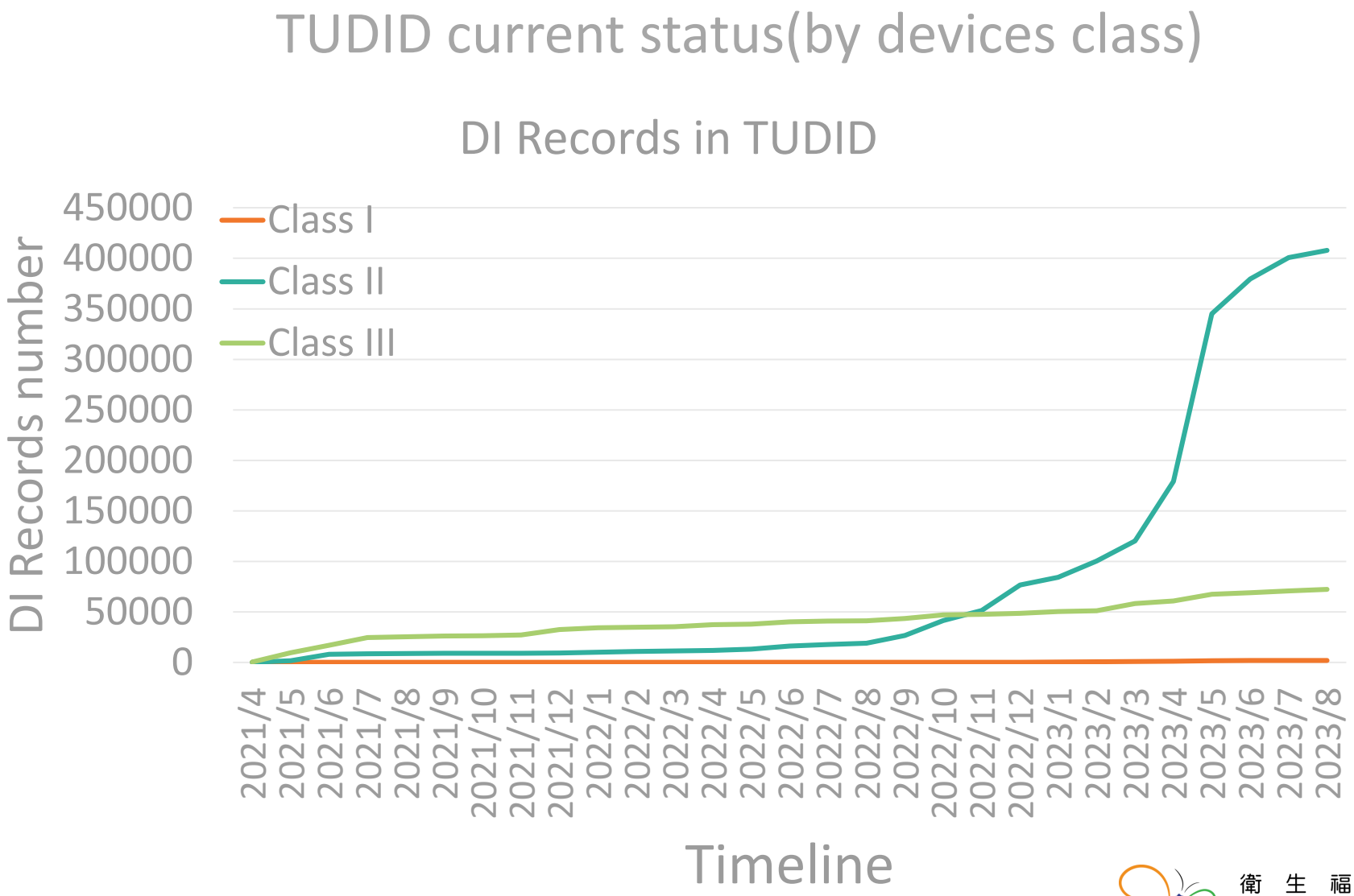
License Number	License Number (Type)	UDI Issuing Agency	Primary DI Number	Catalog Number	Device description
Manufacturer Contact Number	Manufacturer Email	For Single-Use (T/F)	For Multiple-Use (T/F)	Device label containing Lot or Batch Number (T/F)	Device label containing Manufacturing Date (T/F)
Device label containing Serial Number (T/F)	Device label containing Expiration Date (T/F)	Device required to be labeled as containing natural rubber latex or dry natural rubber (T/F)	Device required to be labeled as containing DEHP (T/F)	Size Type	Size Value
Unit of Measure (Size)	Other Size Type	Storage and Handling, Type	Storage and Handling, Low (min) value	Storage and Handling, High (Max) value	Storage and Handling, Unit of Measure

TUDID Current Status (1/2)

TUDID records as of August 3, 2023

Records	• 465,492 UDI records
MD Licenses	• Domestic MD licenses: 2,280 • Import MD licenses: 12,549
Holders of the medical device license	• Domestic licenses holders: 498 • Import licenses holders: 504

TUDID Current Status (2/2)



UDI Online Help Desk

- Web-based query system for comments and feedback available at http://shorturl.at/tvwS7

UDI Seminars and Ongoing TUDID Training Workshops

- UDI Seminar in Taipei

- UDI Training Workshop

- UDI Seminar in Taichung

- UDI Expert Consensus Meeting

Thank you for your attention!

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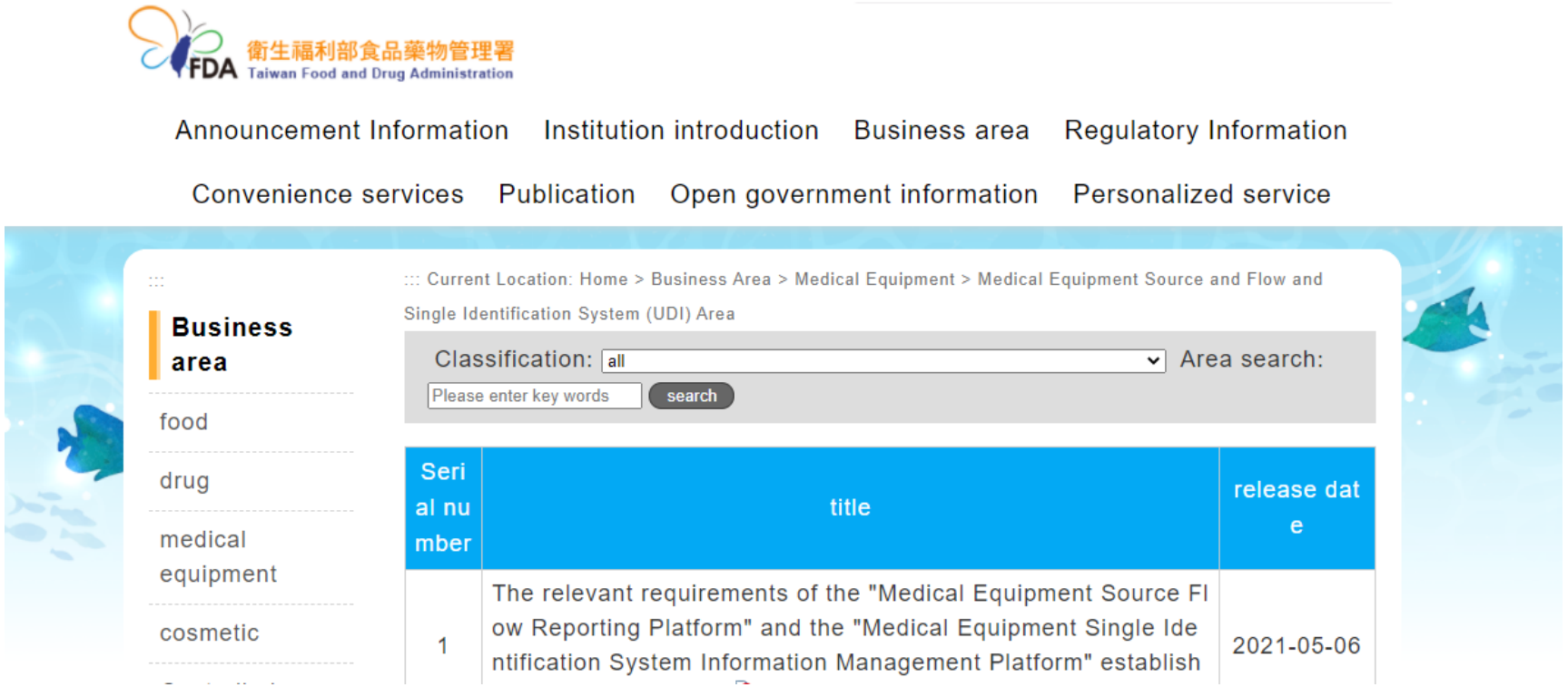
http://www.fda.gov.tw/

TFDA UDI Resources



- https://www.fda.gov.tw/TC/siteList.aspx?sid=10090

Taiwan UDI Regulation (2/3)

The list of Class II medical device's UDI without production identifier

Item	Medical Device	Item	Medical Device
1	Blood pressure cuff	12	Condom
2	Medical Impedance plethysmograph	13	Condom with spermicidal lubricant
3	Ear, nose, and throat drug administration device	14	Menstrual cup
4	Alcohol pad	15	Scented or scented deodorized menstrual tampon
5	Providone-Iodine pad	16	Unscented menstrual tampon
6	Nonresorbable gauze/sponge for external use	17	Soft (hydrophilic) contact lens
7	Medical apparel	18	Rigid gas permeable contact lens
8	Saline solution for wound irrigation	19	Rigid gas permeable contact lens care products
9	Clinical electronic thermometer	20	Soft (hydrophilic) contact lens care products
10	Medical adhesive tape and adhesive bandage	21	Motorized vehicle for medical purpose
11	Medical support stocking	22	Powered wheelchair

Taiwan UDI Regulation (3/3)

Updated "Labeling Requirements for Unique Device Identification", **February 13, 2023**

- ✓ Some Class II medical devices (including 22 items) could not required labeled with production identifier (PI)

Alcohol pad

Medical apparel

Motorized vehicle for medical purpose

Soft (hydrophilic) contact lens

Blood pressure cuff