Latest Status of the Medical Devices Act

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食品藥物管理署
Taiwan Food and Drug Administration

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Outline

- Medical Devices Act implementation
- Regulation overview
- Premarket registration
- Postmarket management

Medical Devices Act Implementation

The Medical Devices Act (MDA) takes effect from May 1st, 2021
(authorizes the announcement of 22 regulations and 16 legal orders).

Speed up the procedures for new medical devices to be made commercially available to meet urgent medical demands in Taiwan

Encourage R&D to develop medical devices brands from Taiwan

Simplify clinical trials of medical devices and speed up R&D of domestically manufactured medical devices

Implement risk management and simplify the procedures for low-risk medical devices

Control the management of new sales types for business development

Improve management of medical device dealers and enhance consumer protection

Establish good distribution practice to ensure product quality

Establish medical device flow management to track product and flow

Strengthen autonomous management of medical device dealers and post-market surveillance

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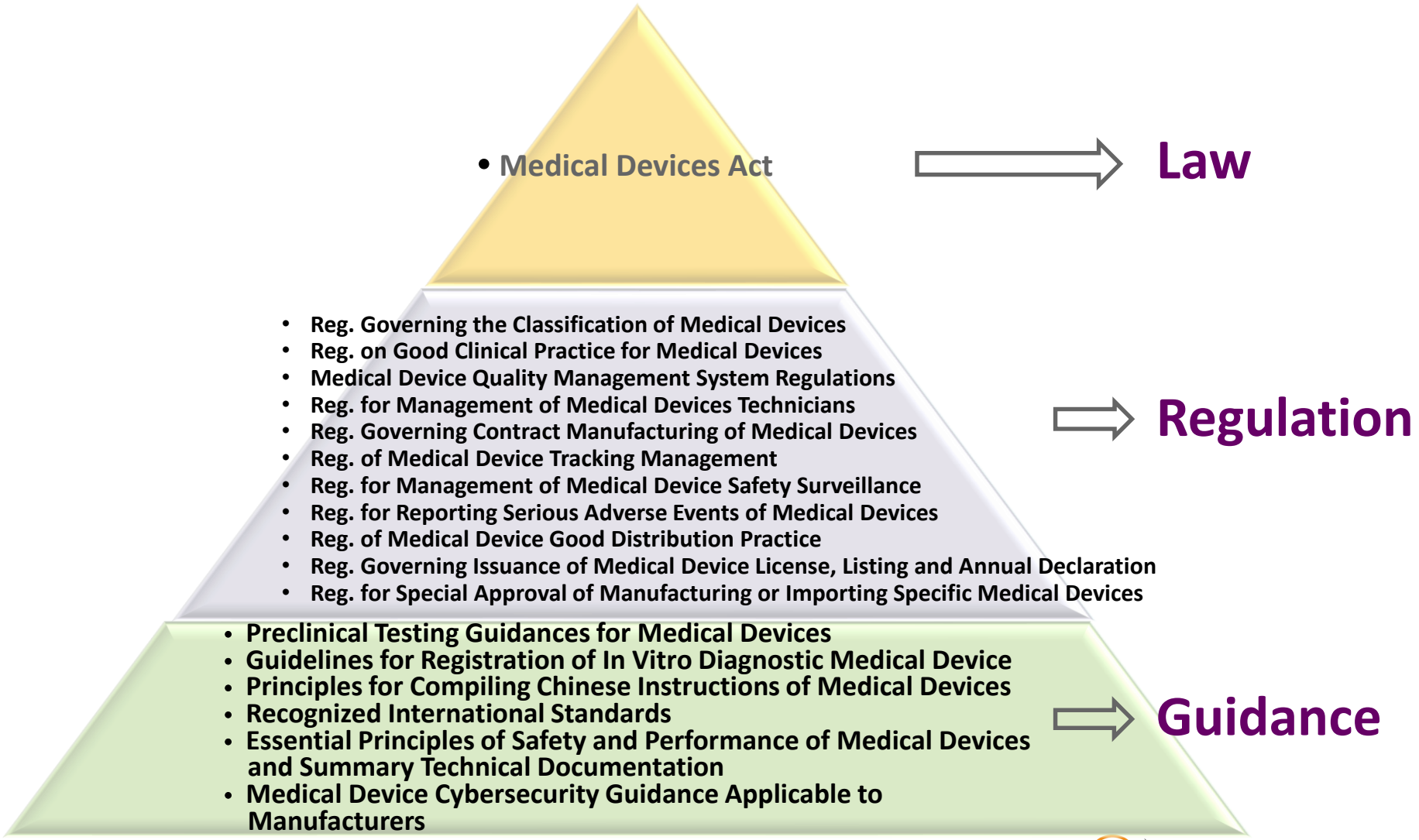
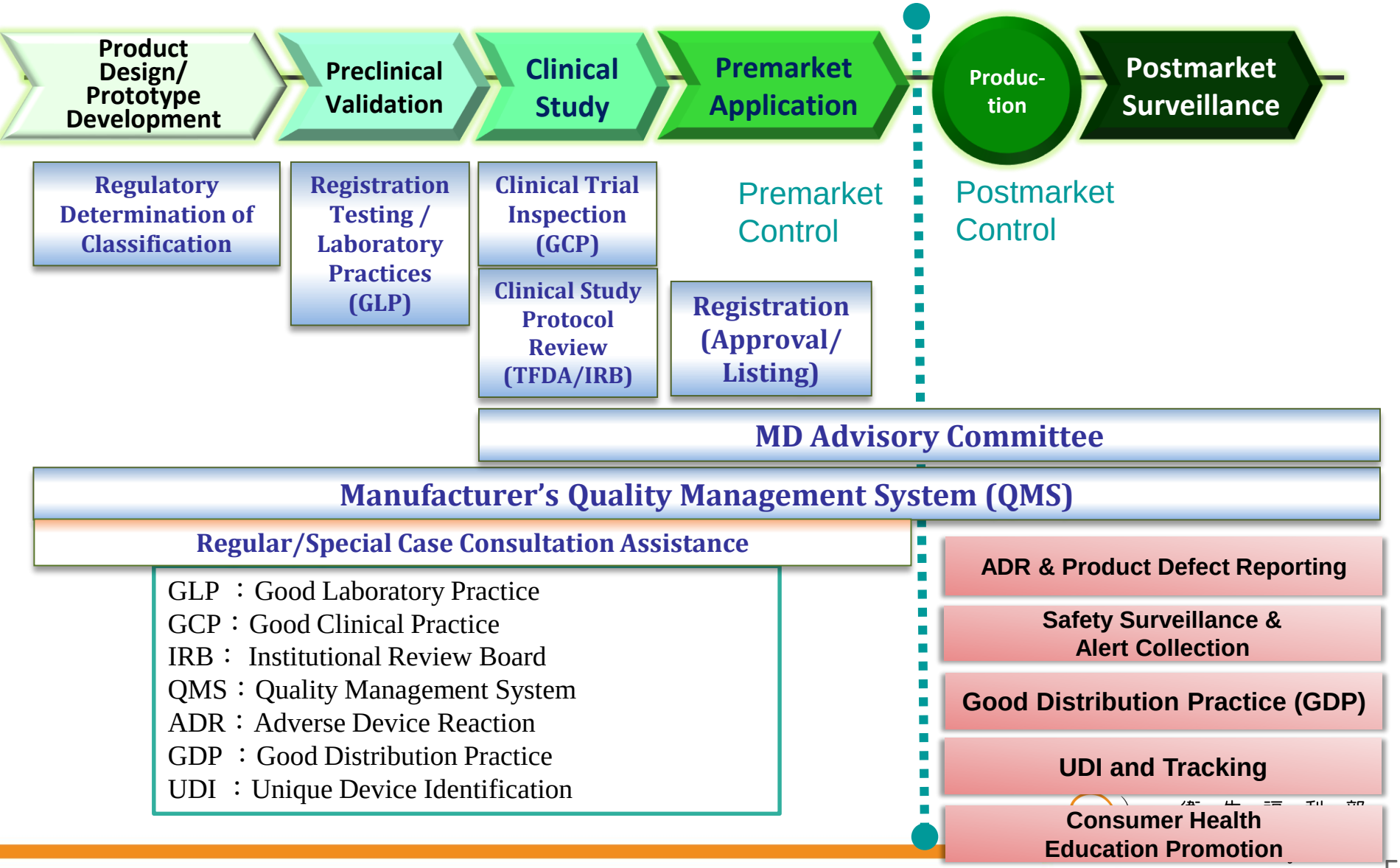
Basis of Medical Device Regulation



Medical Device Life Cycle Management



Medical Device Categories

A. Clinical Chemistry and Clinical Toxicology Devices
B. Hematology, Pathology, and Genetics Devices
C. Immunology and Microbiology Devices
D. Anesthesiology Devices
E. Cardiovascular Devices
F. Dental Devices
G. Ear, Nose, and Throat Devices
H. Gastroenterology and Urology Devices
I. General, Plastic Surgery, and Dermatology Devices
J. General Hospital and Personal Use Devices
K. Neurological Devices
L. Obstetrical and Gynecological Devices
M. Ophthalmic Devices
N. Orthopedic Devices
O. Physical Medicine Devices
P. Radiology Devices

IVD

16 Categories

non-IVD

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Risk Based Classification

QMS/QSD*	QMS/QSD*	QMS/QSD*
Class 1	Class 2	Class 3

3 Classes

➢ **Paper Submission**

- Admin doc
- Basic product info (if necessary)
- Technical doc (for some devices)

- Admin doc
- Basic product info
- Technical doc**
- Clinical evidence info**

- Admin doc
- Basic product info
- Technical doc
- Clinical evidence info**

➢ **Online Listing**
(for certain devices)

*QSD: Quality System Documentation

**Exemption or replacement may apply for devices with predicates

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Diverse Review Mechanisms for Accelerating Time to Market

- According to Article 13 of the Medical Devices Act, any business with the intent to become a medical device firm shall file an application with the municipal or county/city competent authority for approval and registration, and shall start the operation only after having obtained the **business permit**.

Class 1 (Registration/Listing)

- Online Listing & Annual Declaration
- Paper Submission
- Online Submission

Class 2 & 3 (Registration)

- Standard Review
- Simplified Review*
- Flexible Validity Period Review**
- Priority Review

*An affidavit or a product comparison and conformity statement may replace technical information.

**License validity period may be shorter than 5 years.

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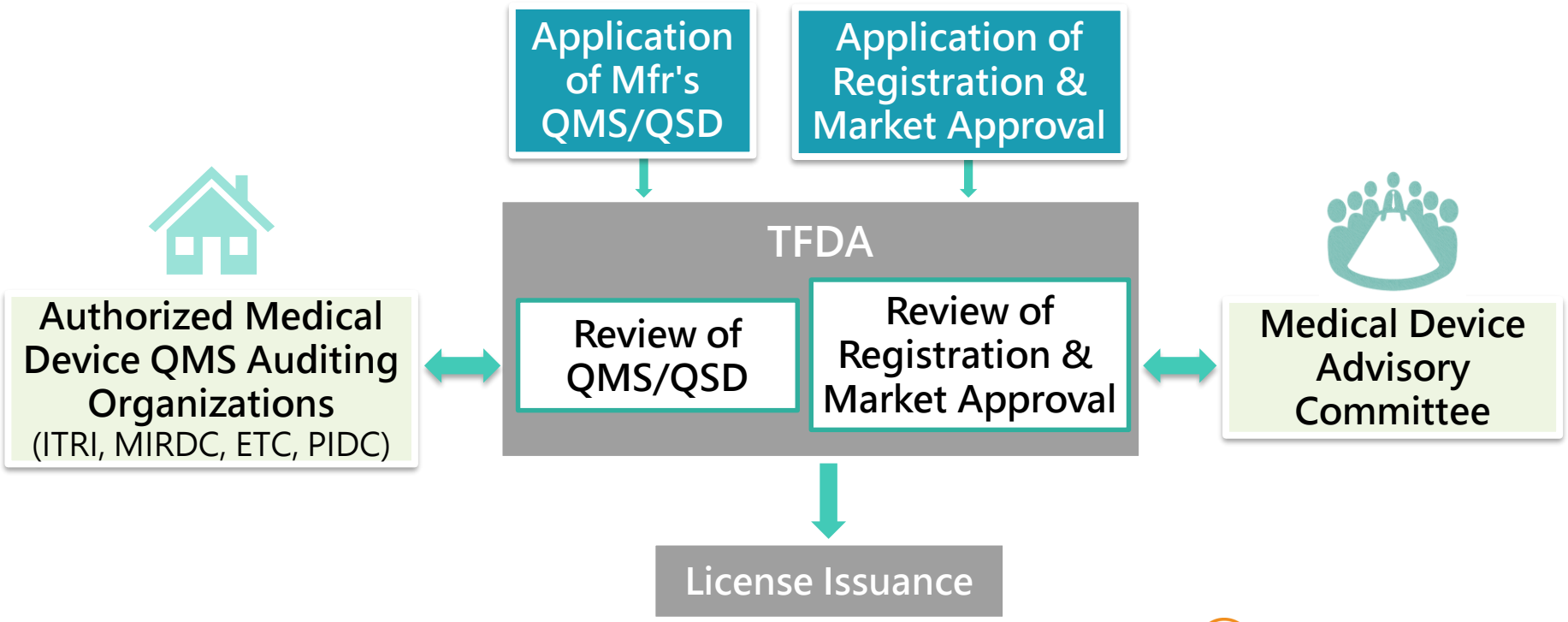
Medical Device Registration and Market Approval

- According to Article 25 of the Medical Devices Act, for the manufacture and import of medical devices, an application shall be filed with the central competent authority for **registration and market approval**. No manufacture or import shall be allowed until such approval is granted and a medical **device license** is issued.



Class 2 & 3 Medical Device Priority Review

Applicable Scope
(if any of the following circumstances applies)

- For use in the prevention, diagnosis, or treatment of **life-threatening diseases or diseases causing severe disability**, with no appropriate medication, medical device, or suitable alternative treatment available yet domestically.
- For use in the prevention, diagnosis, or treatment of **rare diseases** as specified in Paragraph 1 of Article 3 of the Rare Disease and Orphan Drug Act.
- Having **received priority assistance** in accordance with government policies, been **subsidized for research and development** from the central competent authority or other authority, and conducting or will be conducting clinical trial domestically to verify product safety and efficacy, or **meeting the domestic public health or urgent medical needs**.

- It is recommended to send an inquiry letter to TFDA and ask about the applicability. If an approval letter is received, please submit it with the application of registration and market approval to expedite review process.

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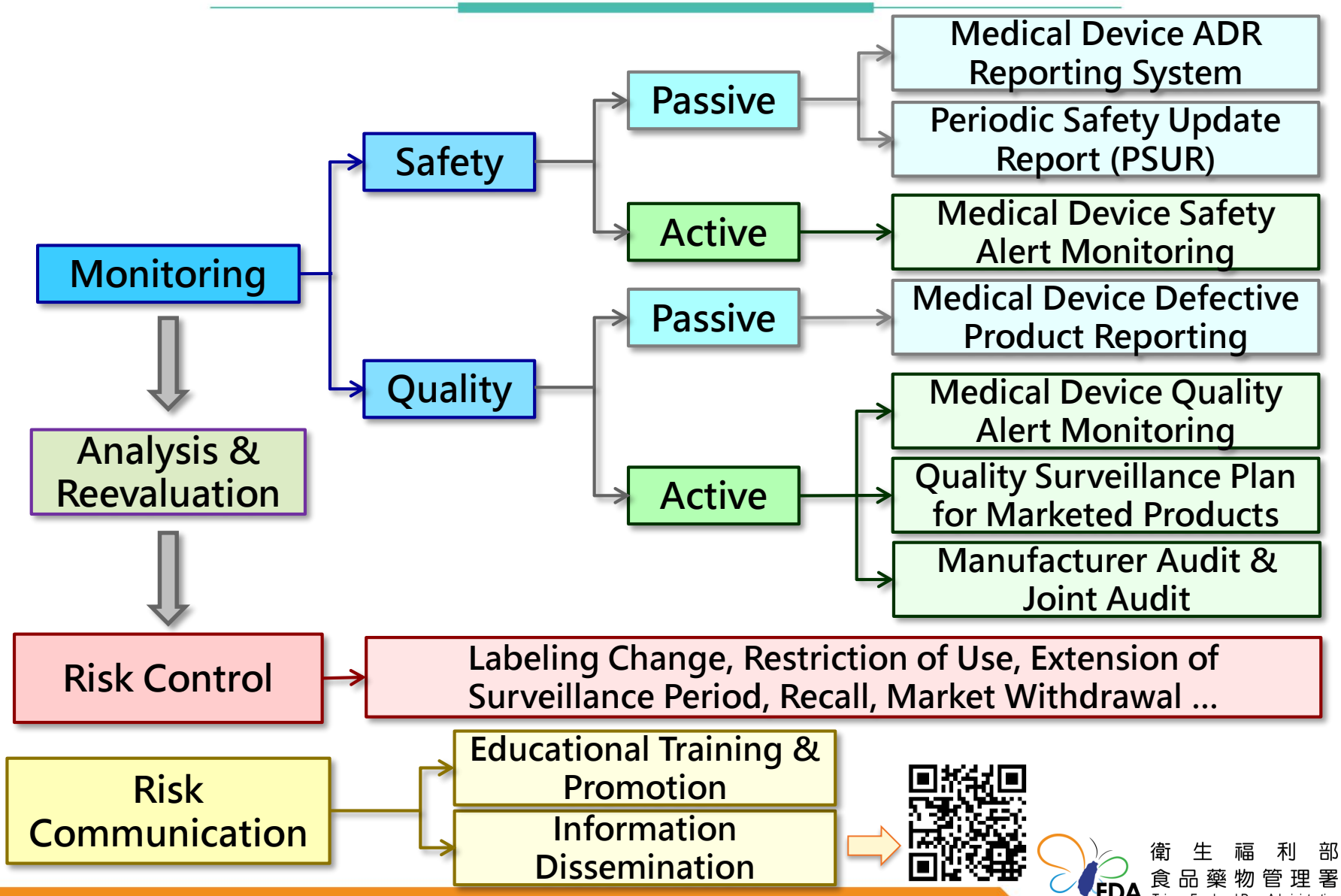
Medical Device Post-Market Risk Management



Taiwan UDI Regulation

Requirements harmonized with IMDRF UDI guidances:
IMDRF/UDI WG/N7FINAL:2013 and IMDRF/UDI WG/N48FINAL:2019

Mandatory Labeling

According to Subparagraph 10 of Paragraph 1, Article 33 of Medical Devices Act, UDI has been one of the announced mandatory items to be placed on the label.

UDI Labeling Transition Period

Effective dates 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 issuing agency: GS1, HIBCC, ICCBBA
2. UDI labeling: A UDI labeling on the device or the label of the device immediate container
3. UDI database: Taiwan UDID (TUDID)

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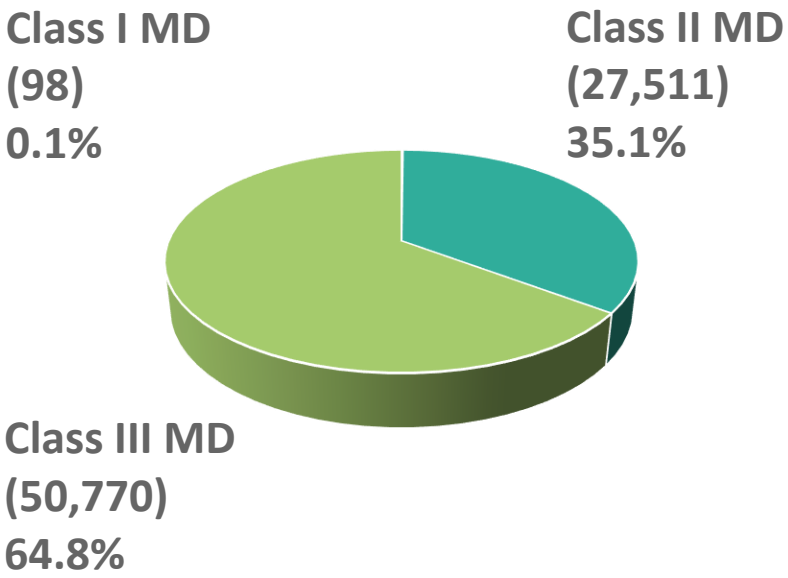
Taiwan UDI Database (TUDID)

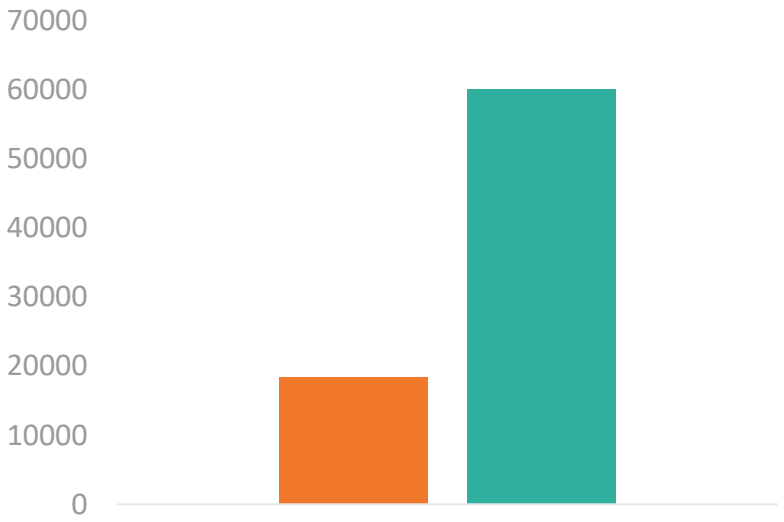
- Published DI records (as of Sept. 30, 2022):

- By device class



Total records: 78,379

- By license



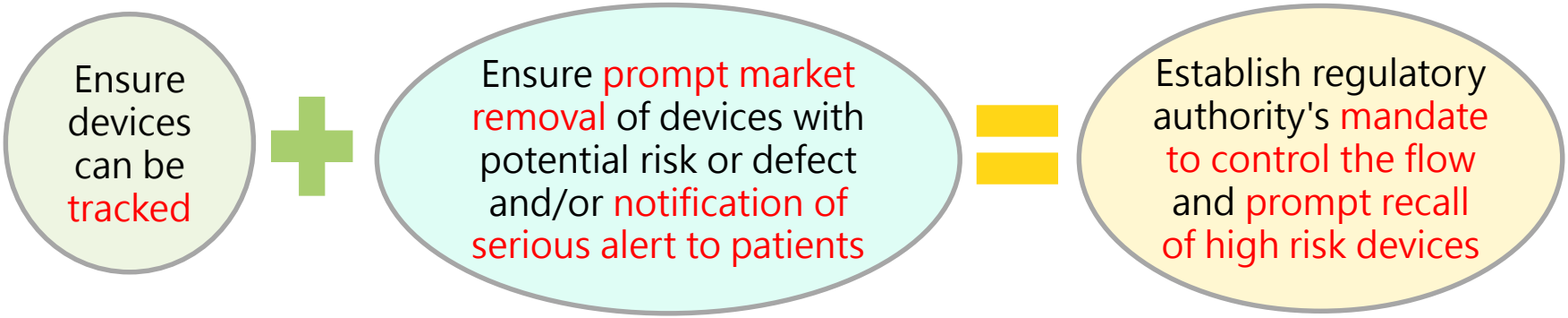
Domestic licenses: 18,338
Import licenses: 60,041

- http://udid.fda.gov.tw

Tracking Management System

In accordance with Article 19 of the Medical Devices Act, starting from May 1, 2021, for devices with certain risk class as announced by TFDA:

- **Data on direct supply sources and flow of products** shall be established and maintained by medical device firms and medical institutions:
  - ✓ 202 Class II and III implantable devices have been announced
  - ✓ Data shall be kept on file for inspection
- If their devices are the following, data shall be reported electronically to TFDA's system once every quarter:
  - ✓ Implantable pacemaker pulse generator
  - ✓ Silicone gel-filled breast prosthesis
  - ✓ Surgical mesh for transvaginal pelvic organ prolapse repair



Key Points of Future Policy Administration and Regulatory Perspectives

Thank you

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