

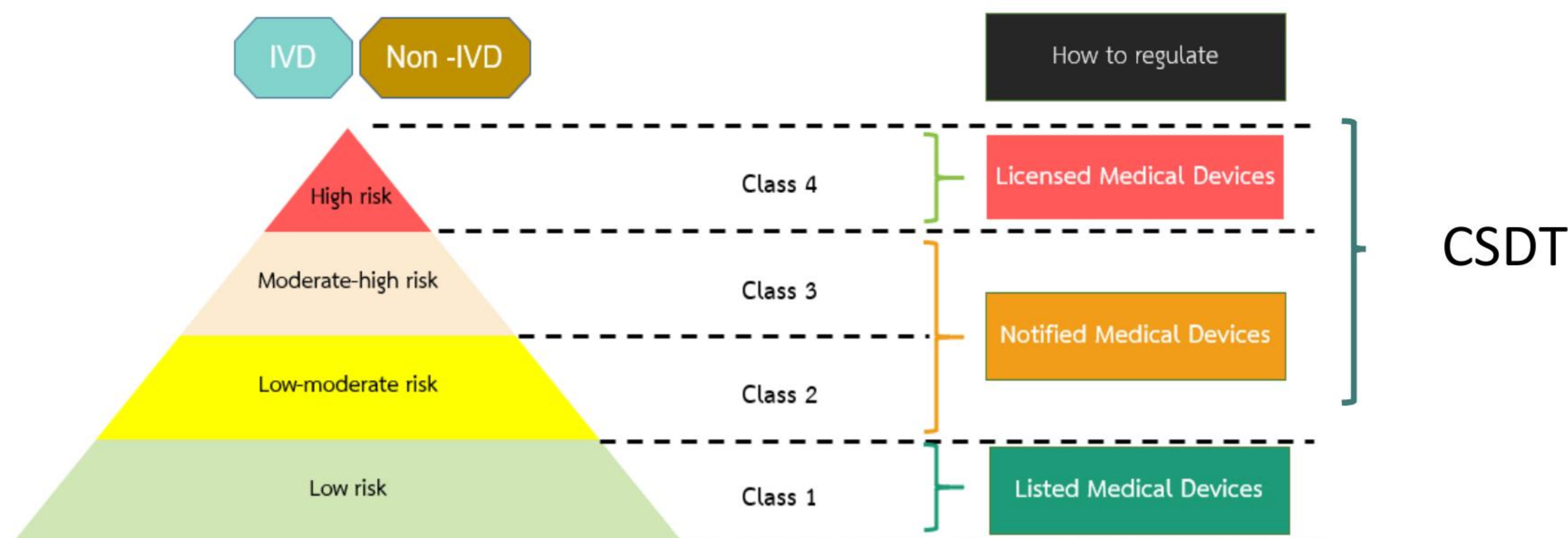
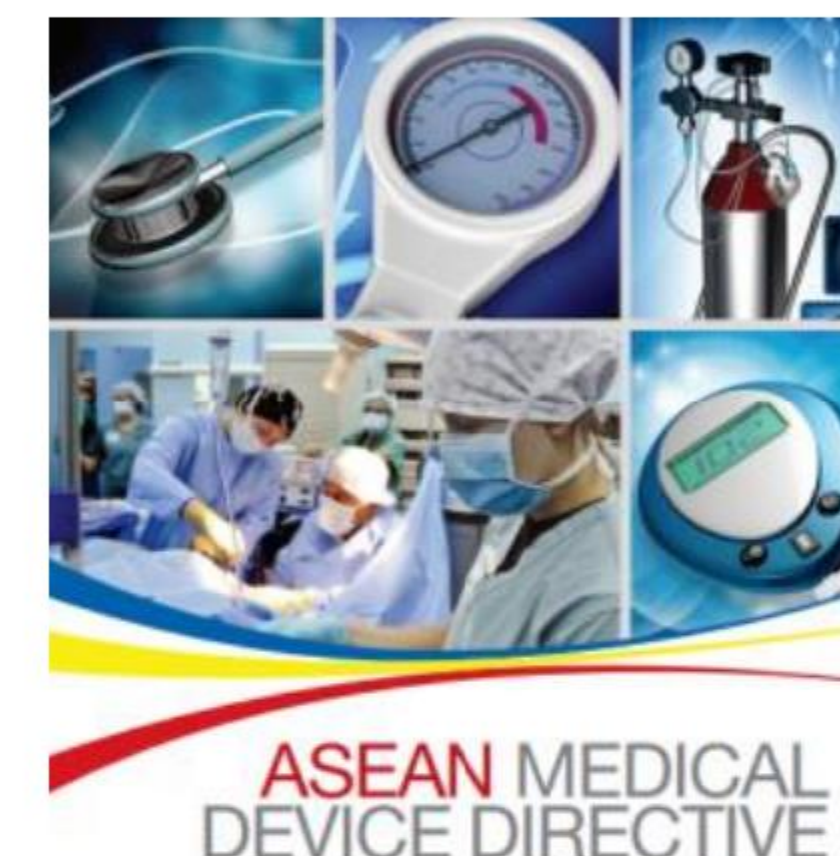
Country Update : THAILAND

29th GHWP Annual Meeting
4th Dec 2025

Overview of THAILAND regulatory framework

Thailand's medical device regulations are aligned with the ASEAN Medical Device Directive (AMDD).

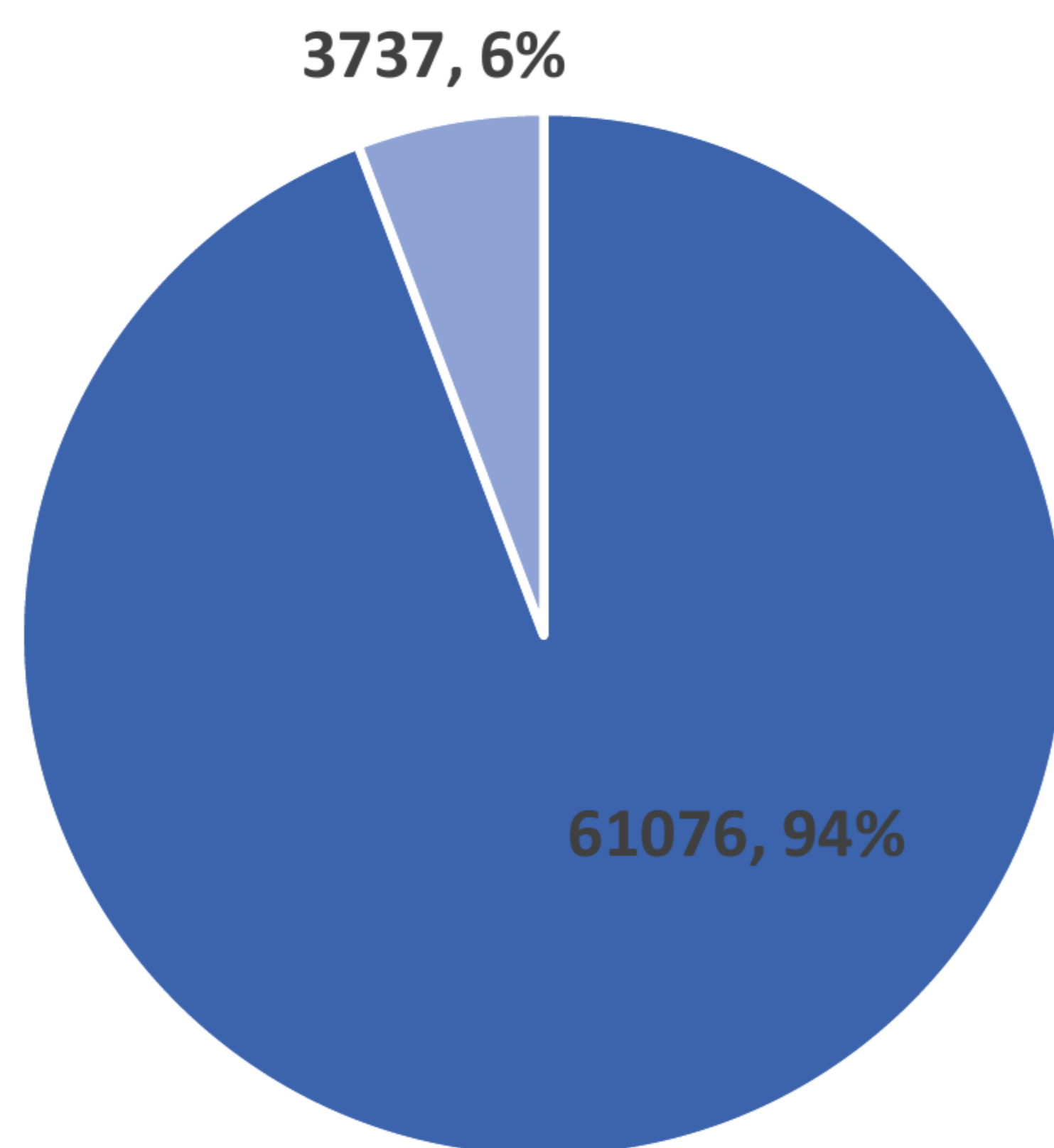
- Risk Classification : Class 1-4 in Thailand = Class A-D in AMDD
- Animal medical devices including IVDs : ☐ AMDD ☒ Thailand



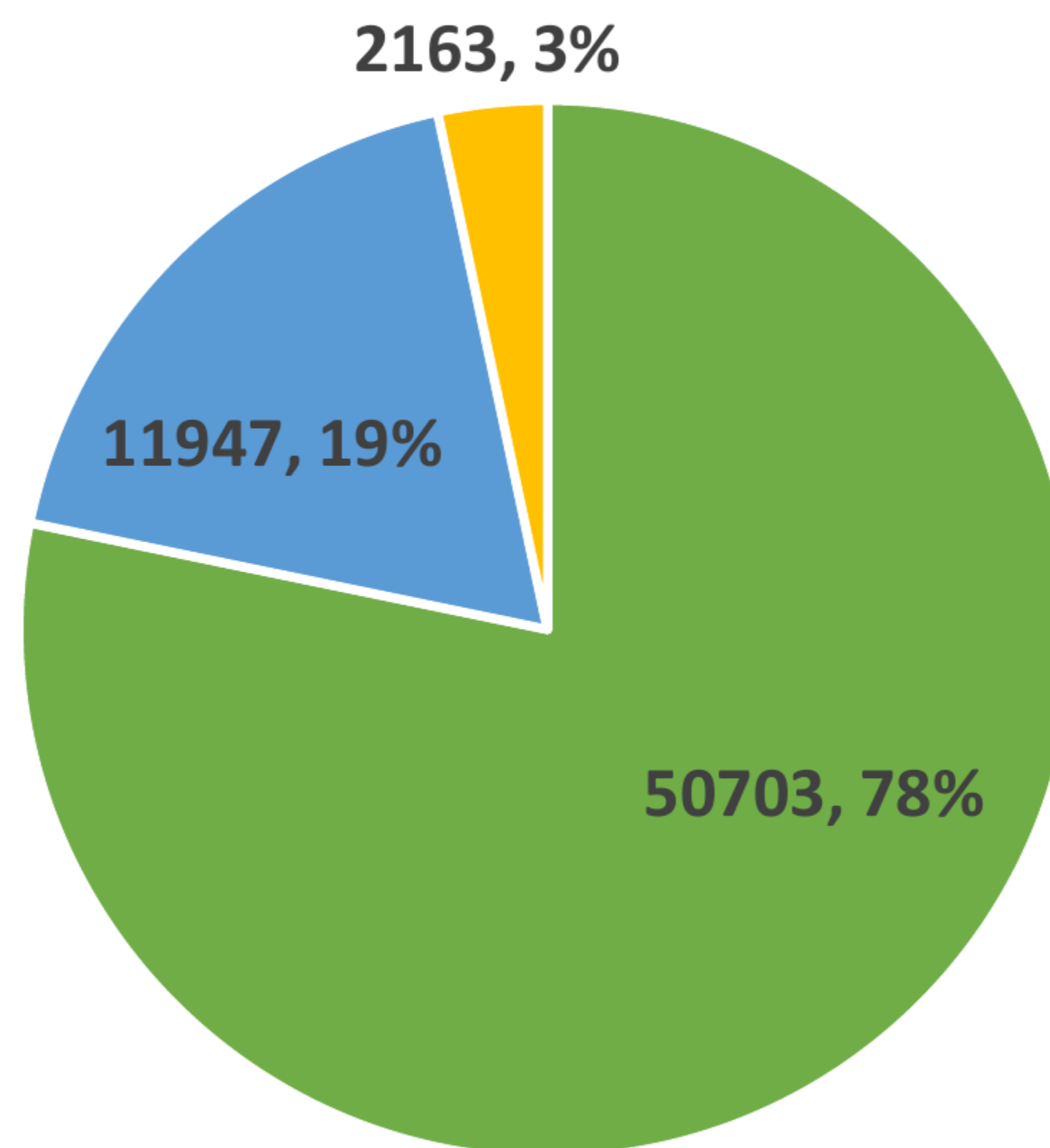
ASEAN Medical Device Directive

The ASEAN Secretariat
Jakarta

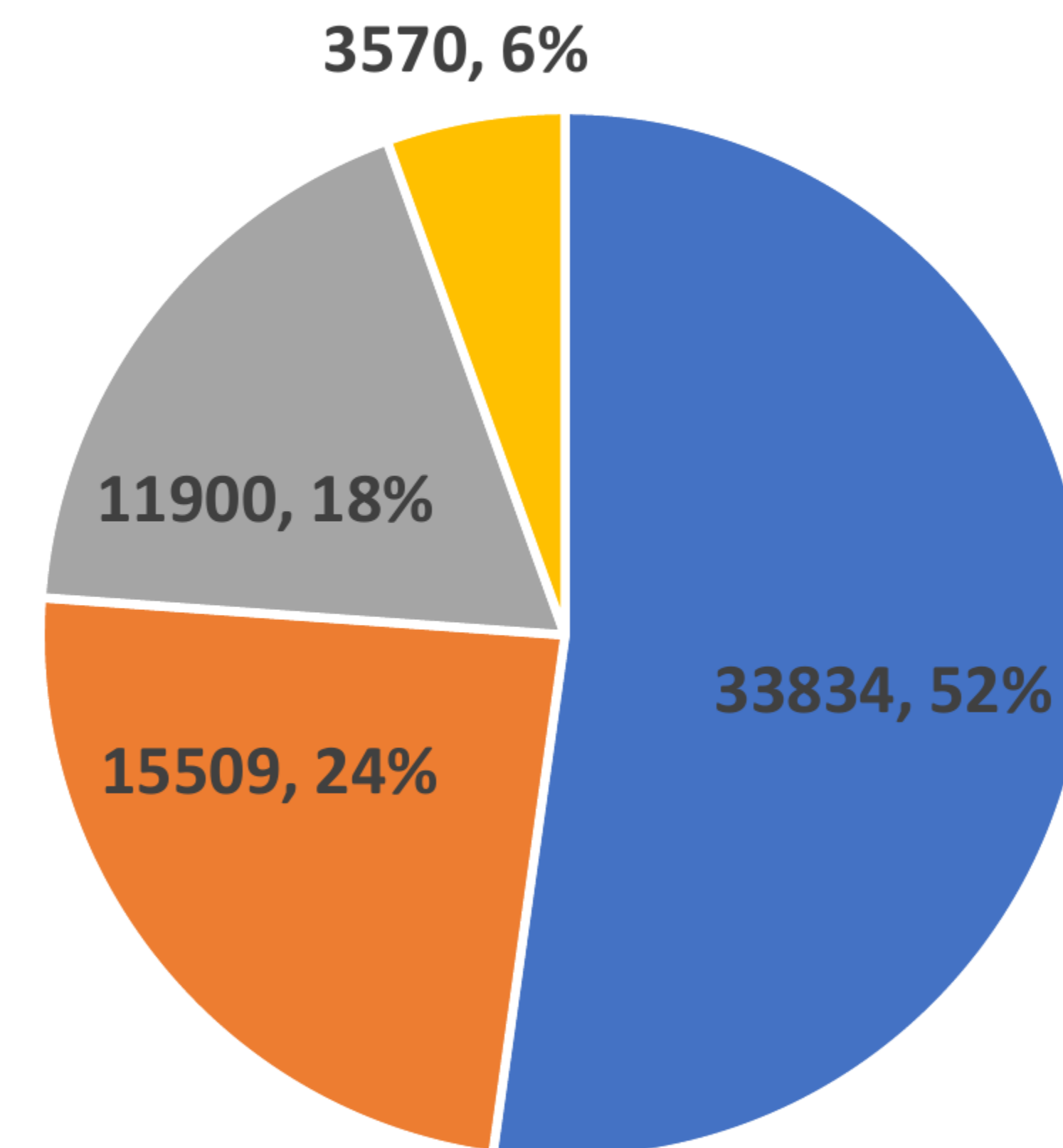
Overview of THAILAND registration database



■ import ■ local manufacture



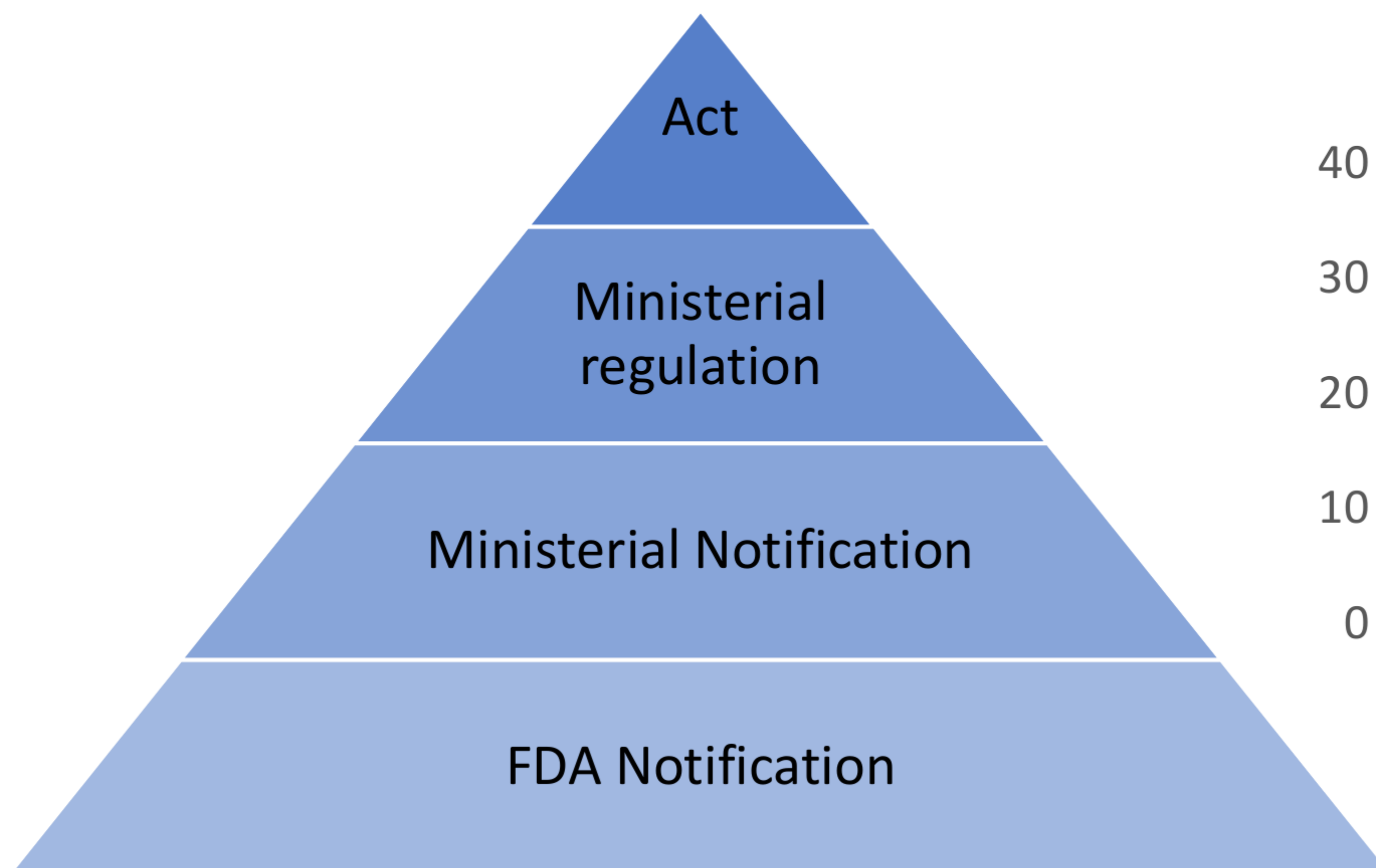
■ Non-IVD ■ IVD ■ Animal medical devices



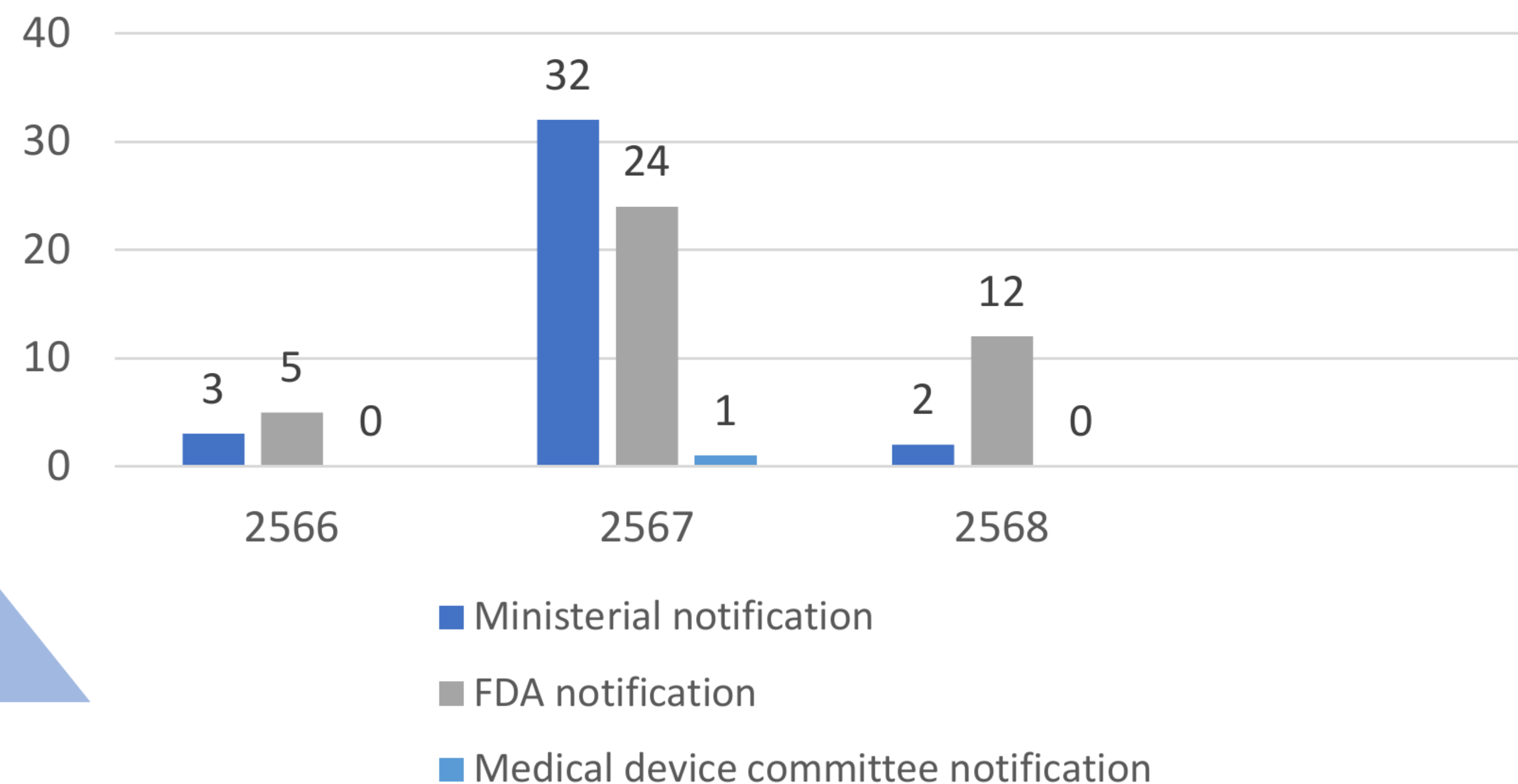
■ Class 1 ■ Class 2 ■ Class 3 ■ Class 4

As of 21st November, 2025

Overview of THAILAND regulation



Regulation Announcement in 2023 - 2025



• Key updated regulations

1. Notification of the Ministry of Public Health

RE: Quality Management System for Medical Device Manufacture B.E. 2566 (2023)

- Local Manufacturer
- Come into force 3 Jul 2024

For more information, please see



Notification of the Ministry of Public Health
Quality Management System
for Medical Device Manufacture B.E. 2566 (2023)
effective from 3 July 2024

**Establishment Registrants, Registrants as Manufacturers
of Licensed, Notified, or Listed Medical Devices**

shall control and supervise the manufacturing of medical device in accordance with the quality management system of medical devices to ensure product quality, standards compliance, and safety while minimizing risks to consumers.



Notification of MoPH

Medical devices Class 2 Class 3 Class 4

shall comply with one of the following requirements:

- 1 Good Manufacturing Practices for Medical Devices, as specified in Appendix A.
- 2 ISO 13485:2016 or later versions.
- 3 ISO 13485-2562 or later versions.

Medical devices Class 2 Class 3 Existing*

In case it is not feasible to comply with the above standards, manufacturers shall control and supervise the manufacturing process in accordance with the quality management system, as specified in Appendix B

Medical devices
Class 3

Comply with Appendix B

Deadline
31 Dec 2026

Medical devices
Class

Comply with Appendix B

Deadline
31 Dec 2027

* Existing: Establishment registrants as manufacturers before 3 July 2024.

Medical devices Class 1
or medical devices for animals

must comply with one of the following requirements:

- 1 Good Manufacturing Practices for Class 1 Medical Devices, as specified in Appendix C.
- 2 Good Manufacturing Practices for Medical Devices, as specified in Appendix A.
- 3 ISO 13485:2016 or later versions.
- 4 ISO 13485-2562 or later versions.

In the case of a medical device manufacturer producing devices with different risk classifications, the quality management system for the device with the higher risk classification shall be followed.

For example, if a manufacturer produces both Class 1 and Class 3 medical devices, the quality management system for Class 3 devices shall be followed

Non-compliance will result in penalties as stipulated under the Medical Device Act B.E. 2551 (2008) and its amendments, as outlined below:		
Section	Rate of Penalty	Involved Persons
100	Imprisonment ≤ 1 year Or a ≤ 100,000 baht fine, or both	<ul style="list-style-type: none"> Registrants as manufacturers of licensed medical devices Registrants as manufacturers of notified medical devices
100/1	Imprisonment ≤ 6 months Or a ≤ 50,000 baht fine, or both	<ul style="list-style-type: none"> Establishment registrants as manufacturers Registrants as manufacturers of listed medical devices

กองควบคุมเครื่องมือแพทย์
MEDICAL DEVICE CONTROL DIVISION

For more information, please contact qmsmdcd@gmail.com

• Key updated regulations

2. Notification of the Ministry of Public Health

RE: Quality Management System for Medical Device Import and Sale B.E. 2566 (2023)

- Importer and Seller Establishment Licensee
- Come into force 4 Jan 2025

For more information, please see



Notification of the Ministry of Public Health

Re: Quality Management System for Medical Device Import and Sale B.E. 2566 (2023)
effective from **5 January 2025**

Establishment registrants as **importers** and establishment registrants as **sellers** shall control and supervise the import and sale of medical devices to ensure product quality, standards compliance, and safety while minimizing the risks to consumers

Notification of MoPH

Quality Management System for Medical Device Import and Sale

shall comply with the Good Importing Practices or Good Selling Practices as specified in this notification, consisting of 4 clauses as follows:

Clause 1	Organization, management system, and responsibility assignment
Clause 2	Resource management
Clause 3	Supply chain and device specifications
Clause 4	Monitoring, follow-up, and surveillance

5 January 2025 New registrants * comply with two clause, i.e., Clause 2 and 3.

5 January 2026 Existing registrants ** comply with two clause, i.e., Clause 2 and 3.

1 January 2027 New registrants * and Existing registrants ** comply with three clause, i.e., Clause 2, 3, and 4.

1 January 2029 New registrants * and Existing registrants ** comply with four clause, i.e., Clause 1, 2, 3, and 4.

* New registrants refer to those who received approval of establishment registration as importers or sellers of medical devices from January 5, 2025, onward.
** Existing registrants refer to those who received approval of establishment registration as importers or sellers of medical devices before January 5, 2025.

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MEDICAL DEVICE CONTROL DIVISION

For more information, please contact: qmsmdcd@gmail.com

• Key updated regulations

3. Notification of the Ministry of Public Health

RE: The Use of Medical Devices for Clinical Research B.E. 2566 (2023)

- Importer, Manufacturer, Sponsor, Investigator
- Come into force: Depending on the risk classification of devices from 15 Jan 2025

For more information, please see



Notification of the Ministry of Public Health

Re: The Use of Medical Devices for Clinical Research B.E. 2566 (2023)

Published in Government Gazette on 15 January 2024

Objectives

- To protect the rights, safety, and well-being of subjects.
- To ensure that clinical research on investigational devices aligns with scientific principles and ethical standards for human research.
- To ensure that results of clinical research on investigational devices are of quality and reliability

Key Points

Clinical research standards: **Non-IVD** = ISO 14155:2020

Obligations and responsibilities of sponsors, researcher, manufacturers, and importers of investigational devices: **IVD** = ISO 20916:2019

Sponsors, researcher, manufacturers, and importers of investigational devices shall comply with this notification according to the following timelines

Investigational Devices

	Class 4	Class 3	Class 2	Class 1
New	15 Jan 2025	15 Jan 2026	15 Jan 2027	15 Jan 2028
Existing	15 Jan 2026	15 Jan 2027	15 Jan 2028	15 Jan 2029

Notes:

1. The effective date of this notification depends on the risk classification of the medical devices.
2. "Existing" refers to manufacturers and importers of investigational devices prior to the effective date of this notification who are in the process of conducting clinical research.

For more information: idthaifda@gmail.com

กองควบคุมเครื่องมือแพทย์
MEDICAL DEVICE CONTROL DIVISION

- **Key updated regulations – RELIANCE MECHANISMS**

4. Notification of the Thai Food and Drug Administration

RE: List of Reference Agencies for the Inspection or Certification of Medical Devices or Medical Device Establishments

List of Reference Agencies
Therapeutic Goods Administration: <u>TGA</u>
Health Canada: <u>HC</u>
European Union Notified Bodies: <u>EU NB</u>
Japan Ministry of Health Labour and Welfare: <u>MHLW</u>
US Food and Drug Administration: <u>US FDA</u>
WHO Prequalification of in Vitro Diagnostics (IVD)
Health Science Authority (HSA), Singapore

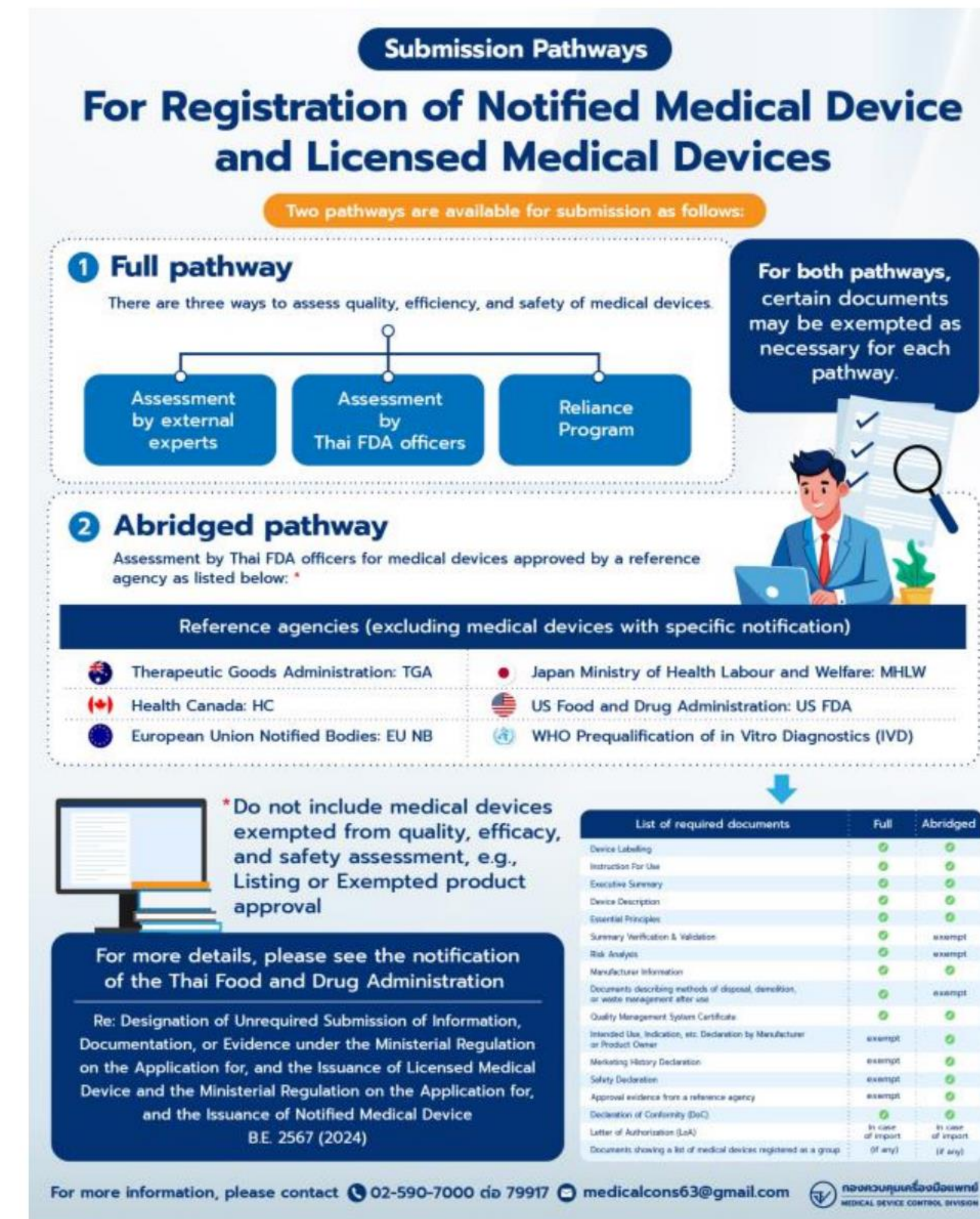
• Key updated regulations – RELIANCE MECHANISMS

5. Notification of the Thai Food and Drug Administration

RE: Designation of Unrequired Submission of Information, Documentation, or Evidence under the Ministerial Regulation on the Application for, and the Issuance of Manufactured or Imported Licensed and Notified Medical Device B.E. 2567 (2024)

Medical devices approved by reference agencies (*TGA, HC, EU NB, MHLW, US FDA, WHO PQ*) for ≥ 1 year are eligible for the “Abridged Pathway,” which reduces documentation, fees, and review time.

For more information, please see



- **FUTURE regulation**

Notification of the Ministry of Public Health

RE: Rules, Procedures, and Conditions for Labeling and Instructions for Use of Medical Devices B.E.

- ✓ Introduces electronic labelling (e-labelling) for software, applications, or other similar digital formats
- ✓ Aimed at increasing flexibility, accessibility, and reducing environmental impact.

THANK YOU