Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Country Update : THAILAND

29th GHWP Annual Meeting
4th Dec 2025

29th GHWP Annual Meeting and 29th GHWP TC Meeting, 1st - 4th Dec 2025
Bangkok, Thailand

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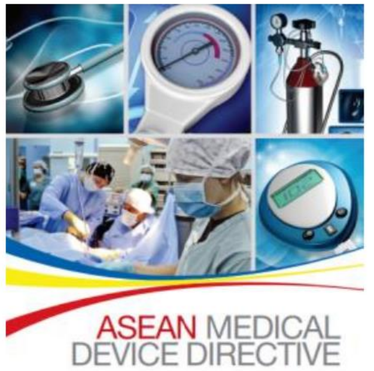
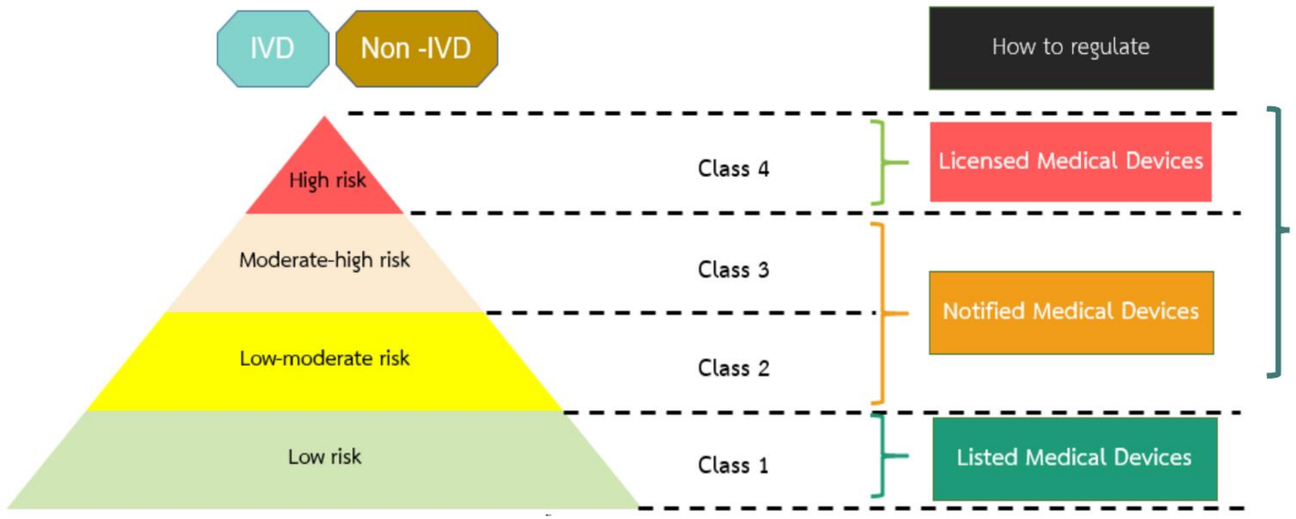
Overview of THAILAND regulatory framework

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





CSDT

ASEAN Medical Device Directive

The ASEAN Secretariat
Jakarta

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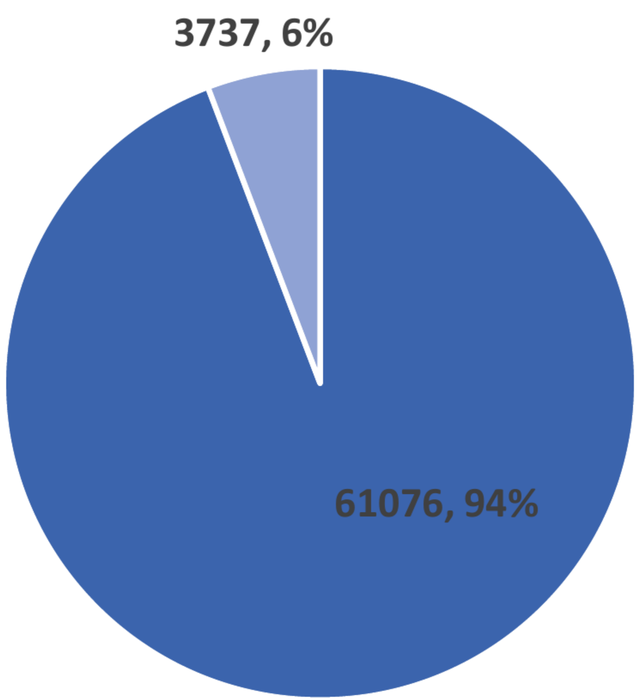
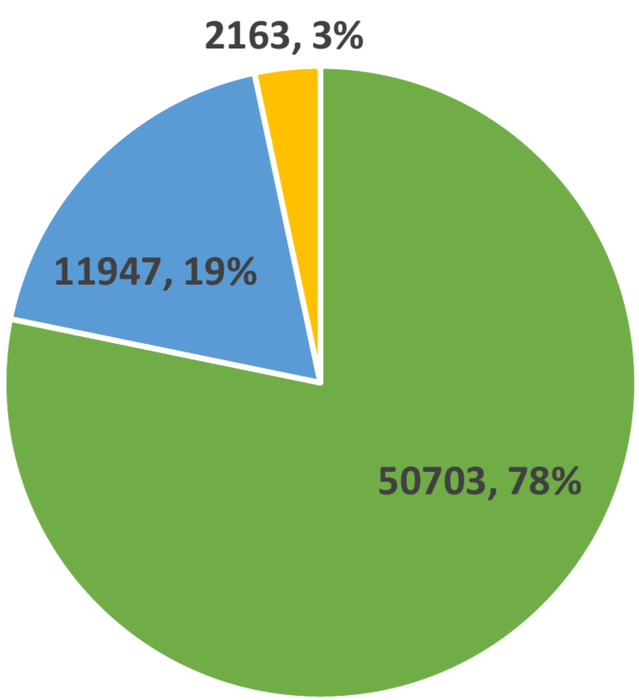
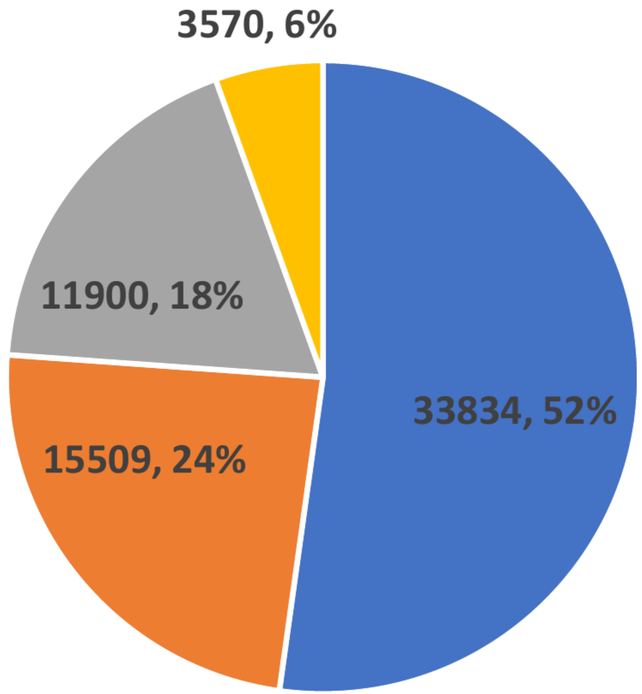
Overview of THAILAND registration database







As of 21st November, 2025

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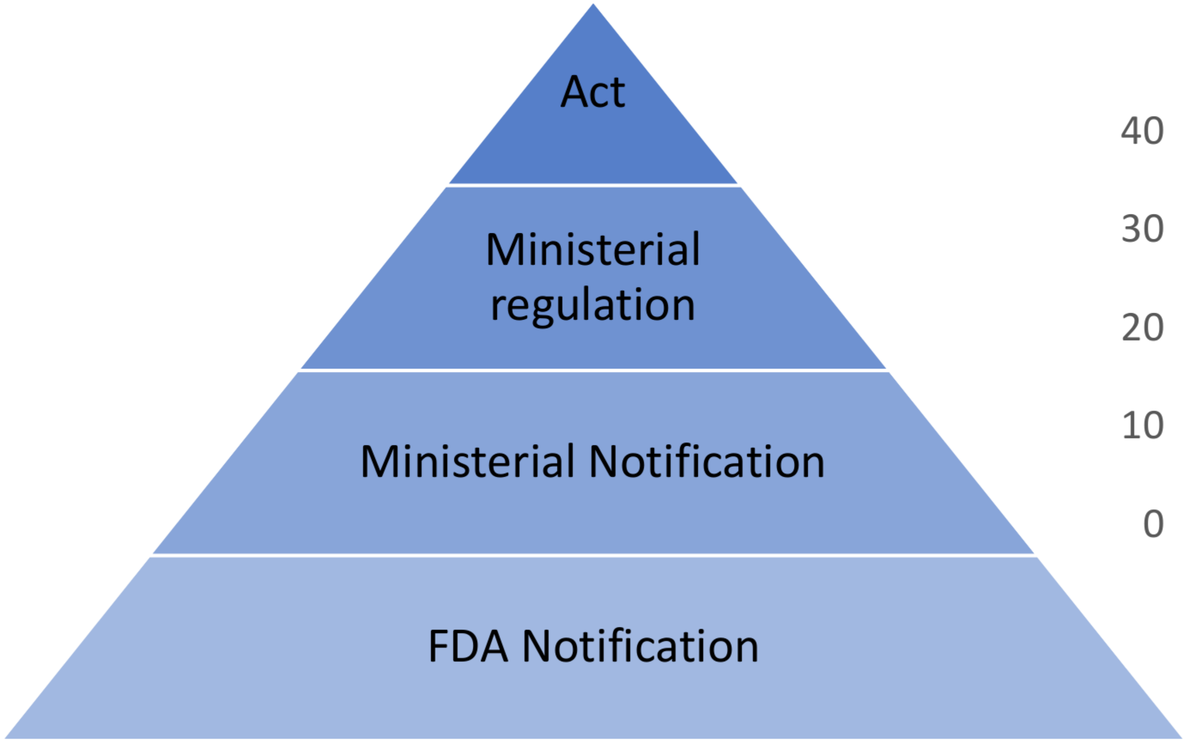
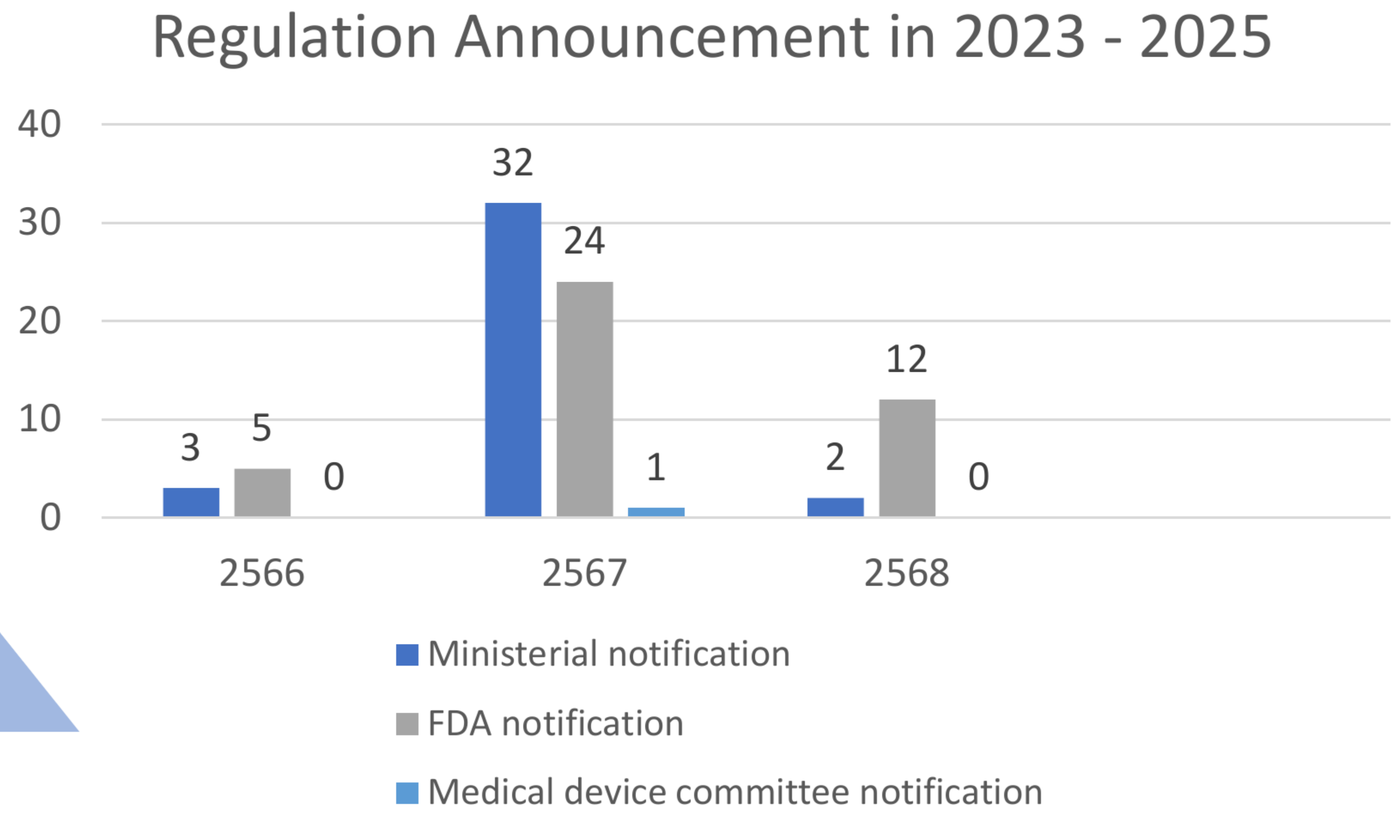
Overview of THAILAND regulation





- **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

• 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

• 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

- **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: **TGA**
Health Canada: **HC**
European Union Notified Bodies: **EU NB**
Japan Ministry of Health Labour and Welfare: **MHLW**
US Food and Drug Administration: **US FDA**
WHO Prequalification of in Vitro Diagnostics (IVD)
Health Science Authority (HSA), Singapore

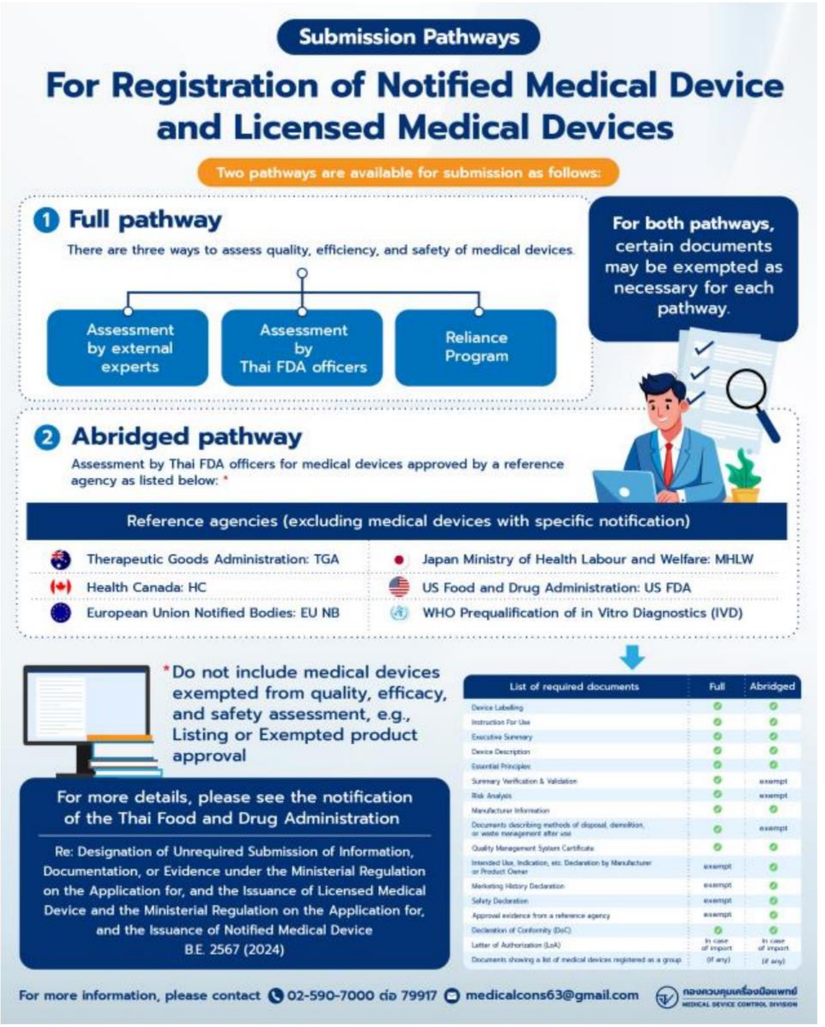
- **Key updated regulations – RELIANCE MECHANISMS**

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.

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THANK YOU

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