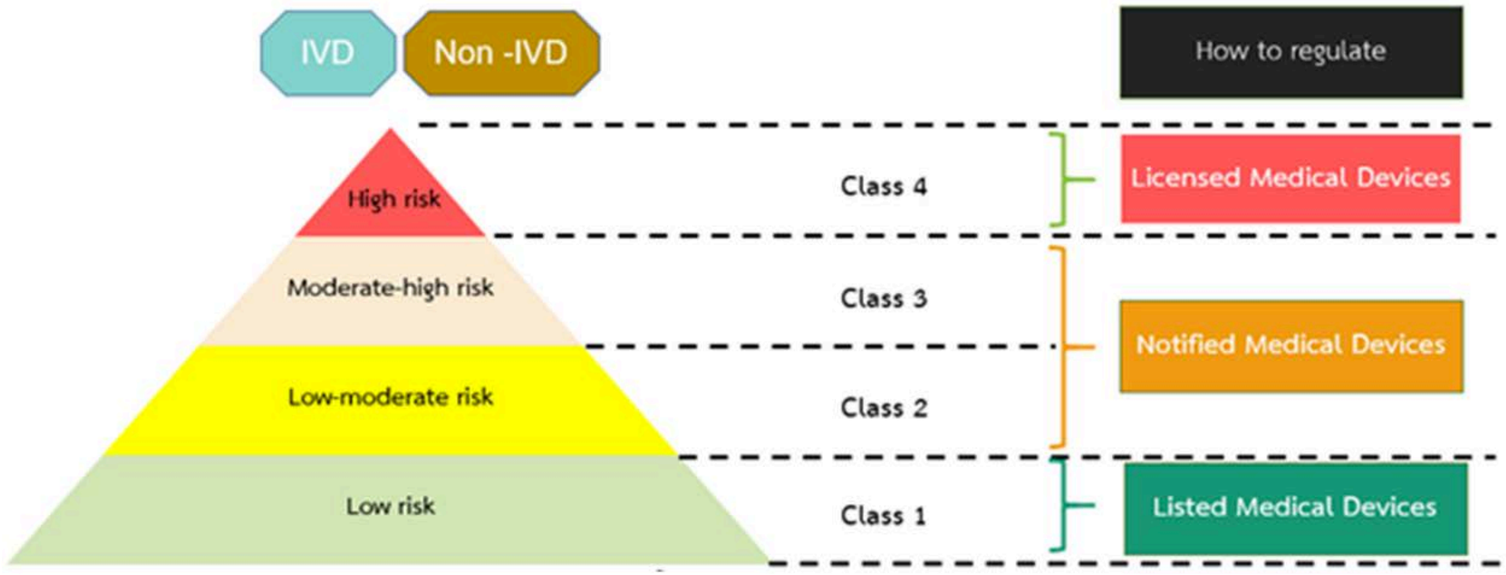
Medical Device Control Division
Food and Drug Administration, Ministry of Public Health

ABRIDGED PATHWAY REVIEW

FOR MEDICAL DEVICE REGULATION IN THAILAND

Determination of Medical Device Risk Classification

Medical devices in Thailand are classified into four risk-based categories.
This classification aligns with ASEAN Medical Device Directive (AMDD).



ThaiFDA provides an online medical device self-classification program

An establishment registrant who wishes to register a medical device in Thailand must first determine its risk classification, as registration requirements vary by each class.

Common Submission Dossier Template (CSDT)

Product registration documents preparation for Medical Devices Class 2 - 4

1 Registration Information

1. **Medical Device Name**
2. **Scope of Medical Device**
3. **GMDN Code**
4. **Name and Address of Product Owner**
5. **Name and Address of Physical Manufacturer** *(for importer)*
6. **Name and Address of Authorized Representative**
7. **Item Table**

2 Common Submission Dossier Template (CSDT) Documents

Common Submission Dossier Template (CSDT)

Product registration documents preparation for Medical Devices Class 2 - 4

1. **Medical Device Label**
2. **Instruction for Use (IFU)**
3. **Executive Summary**
4. **Device Description**
5. **Essential Principles**
6. **Summary verification & validation**
7. **Risk Analysis**
8. **Manufacturer Information**
9. **Document Describing Methods of Disposal, Demolition, or Waste Management after Use**
10. **Quality Management System Certificate** *e.g. ISO 13485*
11. **Declaration of conformity (DoC)**
12. **Declaration Letters**
    a. Intended Use, Indication etc. Declaration
    b. Market History Declaration
    c. Safety Declaration
    d. Approval Evidence from Reference Agency
13. **Letter of Authorization (LoA)** (for importer)
14. **List of Medical Devices and Grouping** (if any)
15. **Change Notification Approved from HSA**
16. **Regulatory Reliance Participating Letter**
17. **Approval Evidence from HSA**
18. **Consent form**

Submission Dossier for Class 2-4 Medical Devices

	Full pathway	Abridge pathway	Reliance pathway
1. Medical Device Label	✅	✅	✅
2. Instruction for Use (IFU)	✅	✅	✅
3. Executive Summary	✅	✅	✅
4. Device Description	✅	✅	✅
5. Essential Principles	✅	✅	✅
6. Summary verification & validation	✅	-	✅
7. Risk Analysis	✅	-	✅
8. Manufacturer Information	✅	✅	✅

Submission Dossier for Class 2-4 Medical Devices

	Full pathway	Abridge pathway	Reliance pathway
9. Document Describing Methods of Disposal, Demolition, or Waste Management after Use	(if any)	-	(if any)
10. Quality Management System Certificate *e.g. ISO 13485*	✅	✅	✅
11. Declaration of conformity (DoC)	✅	✅	✅
12. Declaration Letters			
Intended Use, Indication etc. Declaration	-	✅	-
Market History Declaration	-	✅	-
Safety Declaration	-	✅	-
Approval Evidence from Reference Agency	-	✅	-

Submission Dossier for Class 2-4 Medical Devices

	Full pathway	Abridge pathway	Reliance pathway
13. Letter of Authorization (LoA) *(for importer)*	✅	✅	✅
14. List of Medical Devices and Grouping *(In case of Grouped Medical Devices Application)*	(if any)	(if any)	(if any)
15. Change Notification Approved from HSA	-	-	✅
16. Regulatory Reliance Participating Letter	-	-	✅
17. Approval Evidence from HSA	-	-	✅
18. Consent form	-	-	✅

* Reliance pathway is for medical devices which have been registered by HSA, Singapore, and are agreed to be in the Regulatory Reliance Program

Submission Pathways for Registration of Notified Medical Device and Licensed Medical Device

Two pathways are available for submission as follow:

1 Full pathway

There are three ways to assess quality, efficiency, and safety of medical devices.

- Assessment by external experts
- Assessment by Thai FDA officers
- Reliance Program

For both pathways, certain documents may be exempted as necessary for each pathway.

2 Abridged pathway

Assessment by Thai FDA officers for medical devices approved by a reference agency as listed below: *

Reference agencies (excluding medical devices with specific notification)	
Therapeutic Goods Administration: TGA	Japan Ministry of Health Labour and Welfare: MHLW
Health Canada: HC	US Food and Drug Administration: US FDA
European Union Notified Bodies: EU NB	WHO Prequalification of in Vitro Diagnostics (IVD)

Abridge Pathway : With Reference Agencies

Not require an assessment by external experts

1 Full pathway

There are three ways to assess quality, efficiency, and safety of medical devices.

- Assessment by external experts
- Assessment by Thai FDA officers
- Reliance Program

For both pathways, certain documents may be exempted as necessary for each pathway.

2 Abridged pathway

Assessment by Thai FDA officers for medical devices approved by a reference agency as listed below: *

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Health Canada: HC	US Food and Drug Administration: US FDA
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Comparison : Abridge pathway vs Full pathway

List of required documents	Full	Abridged
Device Labelling	✓	✓
Instruction For Use	✓	✓
Executive Summary	✓	✓
Device Description	✓	✓
Essential Principles	✓	✓
Summary Verification & Validation	✓	exempt
Risk Analysis	✓	exempt
Manufacturer Information	✓	✓
Documents describing methods of disposal, demolition, or waste management after use	✓	exempt
Quality Management System Certificate	✓	✓
Intended Use, Indication, etc. Declaration by Manufacturer or Product Owner	exempt	✓
Merketing History Declaration	exempt	✓
Safety Declaration	exempt	✓
Approval evidence from a reference agency	exempt	✓
Declaration of Conformity (DoC)	✓	✓
Letter of Authorization (LoA)	In case of import	In case of import
Documents showing a list of medical devices registered as a group	(if any)	(if any)

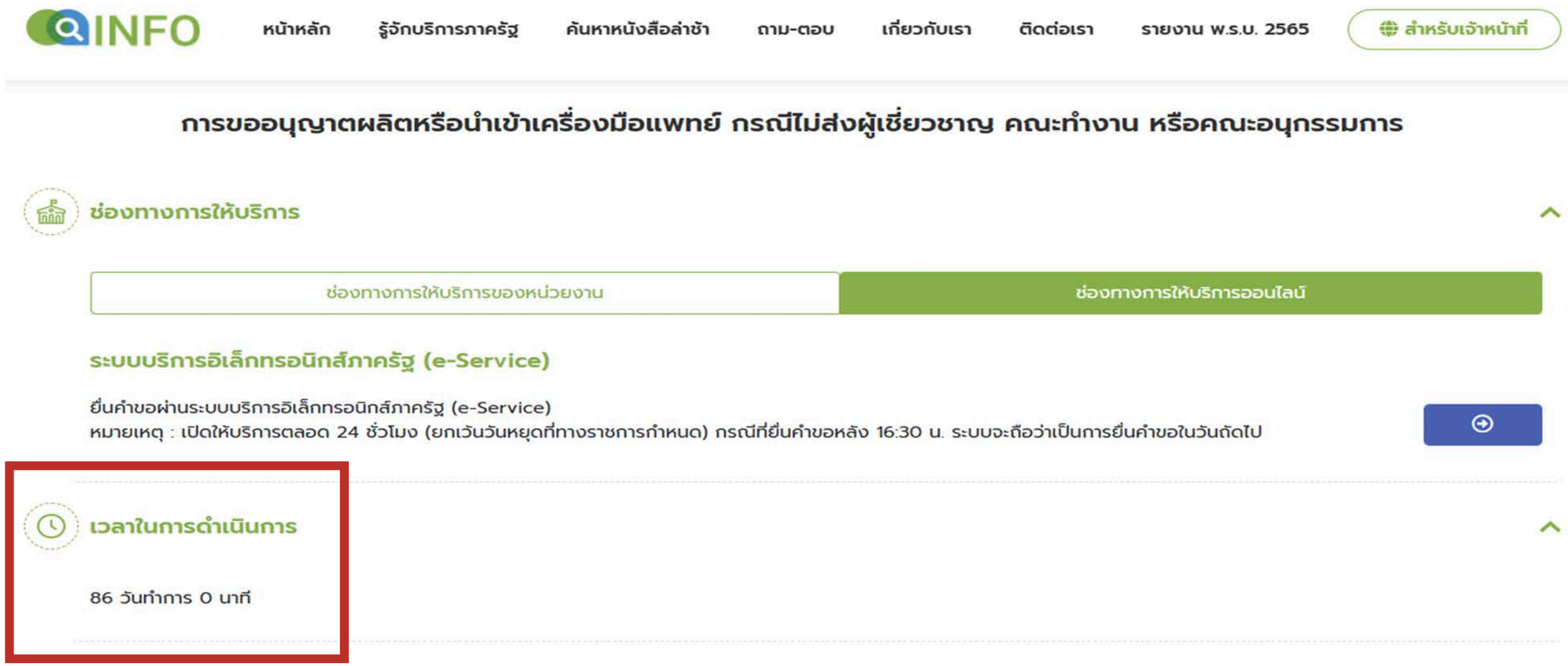
Medical Device Registration Fee

	Application fee	Document verification fee (for class 1)	Expert fee (for class 2-4)	Certificate fee	Total
Certificate of Listed Medical Device (Class 1)					
Local Manufacture	500 THB	300 THB	-	1,000 THB	1,800 THB
Import	500 THB	600 THB	-	2,000 THB	3,100 THB
Certificate of Notified Medical Device (Class 2-3)					
Local Manufacture	1,000 THB	-	30,400 THB	5,000 THB	36,400 THB
Import	1,000 THB	-	38,000 THB	10,000 THB	49,000 THB
Certificate of Licensed Medical Device (Class 4)					
Local Manufacture	1,000 THB	-	42,400 THB	10,000 THB	53,400 THB
Import	1,000 THB	-	53,000 THB	20,000 THB	74,000 THB

For Abridge pathway and Full (Concise), there will be no External expert fee for medical devices class 2-4

Registration Time Frame

In case of no require an assessment by external experts



Check for the time left for each registration

More Information

In case of no require an assessment by external experts

https://en.fda.moph.go.th/entrepreneurs-medical-devices/manufacture-import-commercialpurposes

Thank You