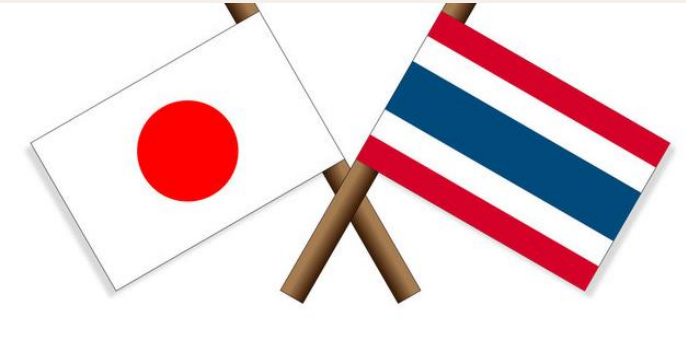
タイの医療機器産業の事業展開にかかる法規制

Laws and Regulations of Doing Business in The Medical Device Sector in Thailand



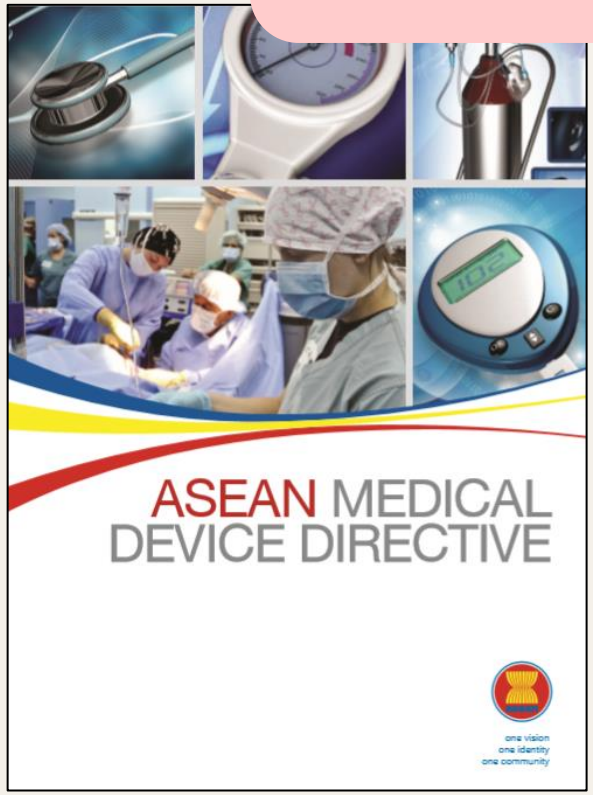
タイ保健省　食品・薬品委員会事務局(FDA)
医療機器管理部　シリンマー　カッチャマー(Ph.D)

2021年6月24日

講演概要／Outline

- タイにおける医療機器の法規制
  - -定義
  - - 統一申請様式(CSDT)
- 医療機器のタイ市場への進出

タイにおける医療機器の法規制
Medical Device Regulation in Thailand



同法律は
ASEAN 医療機器指令
（AMDD）に準じて
制定された

タイは2021年1月19日に批准書を提出

INSTRUMENT OF RATIFICATION

WHEREAS the ASEAN Agreement on Medical Device Directive was done at Bangkok, the Kingdom of Thailand, on 21 November 2014;

WHEREAS Article 22, paragraph 1 of the Agreement stipulates that this Agreement shall be subject to ratification and/or acceptance by Member States in accordance with their internal domestic requirements; and

WHEREAS Article 22, paragraph 3 of the Agreement stipulates that the Secretary-General of ASEAN shall promptly notify all Member States of the ratifications or deposit of each instrument of ratification and/or acceptance;

THE GOVERNMENT OF THE KINGDOM OF THAILAND, having considered the aforesaid Agreement, hereby confirms and ratifies the same and undertakes to faithfully perform and carry out all the stipulations contained therein.

IN WITNESS WHEREOF, this Instrument of Ratification is signed and sealed by the Deputy Prime Minister and Minister of Foreign Affairs of the Kingdom of Thailand.

DONE at the Ministry of Foreign Affairs, Bangkok, this [illegible] Day of December in the Year Two thousand Five hundred and Sixty-three of the Buddhist Era, corresponding to the Year Two thousand and Twenty of the Christian Era.

(Don Pramudwinai)
Deputy Prime Minister and Minister of Foreign Affairs
of the Kingdom of Thailand

医療機器とは？　What is medical device?

2019年医療機器法に基づいた医療機器の定義

(1) 製造者が、単独あるいは組み合わせにより、下記の特定の目的で人または動物に対し使用されることを意図した機器、器具、機械、インプラント、ラボ内外で使用される体外検査用試薬、材料、ソフトウェア、その他同等の製品

(a) 人または動物の病気の診断、予防、モニタリング、治療、除去

(b) 人または動物の怪我の診断、モニタリング、治療や補完

(c) 人または動物の解剖学や生理的プロセスにかかる
調査、置換、修正または補強

(d) 人または動物の生命の支援や維持

(e)人または動物の受精の制御または生殖医療支援

(f) 人または動物の障害に対する支援や補完

(g) 人または動物の検体の体外検査を通じた医療診断目的の
情報提供

(h) 医療機器の消毒

(2) (1)に伴う付属品

(3) 機器、器具、機械製品、その他の大臣が認可する

医療機器製品

人または動物の体における(1)の目的の達成は、薬理学的、免疫学的、代謝的方法を意図したものであってはならない

「付属品」とは製造者や製品の所有者が、医療機器類の目的の達成を可能にするか支援するために、特定の医療機器と併用の上、特別に使用を意図した物品、器具または製品

統一申請様式（CSDT）：付属文書4
Common Submission Dossier Template (CSDT): Annex 4

-準拠していることを示すための書式
-安全性と性能に関する基本原則（EPSP：Essential Principles of Safety and Performance)
-技術文書の要旨(STED: Summary of Technical Documentation)

ANNEX 4
ASEAN Common Submission Dossier Template

1. INTRODUCTION

The Common Submission Dossier Template (CSDT) should reduce the differences in documentation formats that presently exist in different ASEAN jurisdictions. The adoption of the CSDT in ASEAN should minimise the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different Regulatory Authorities.

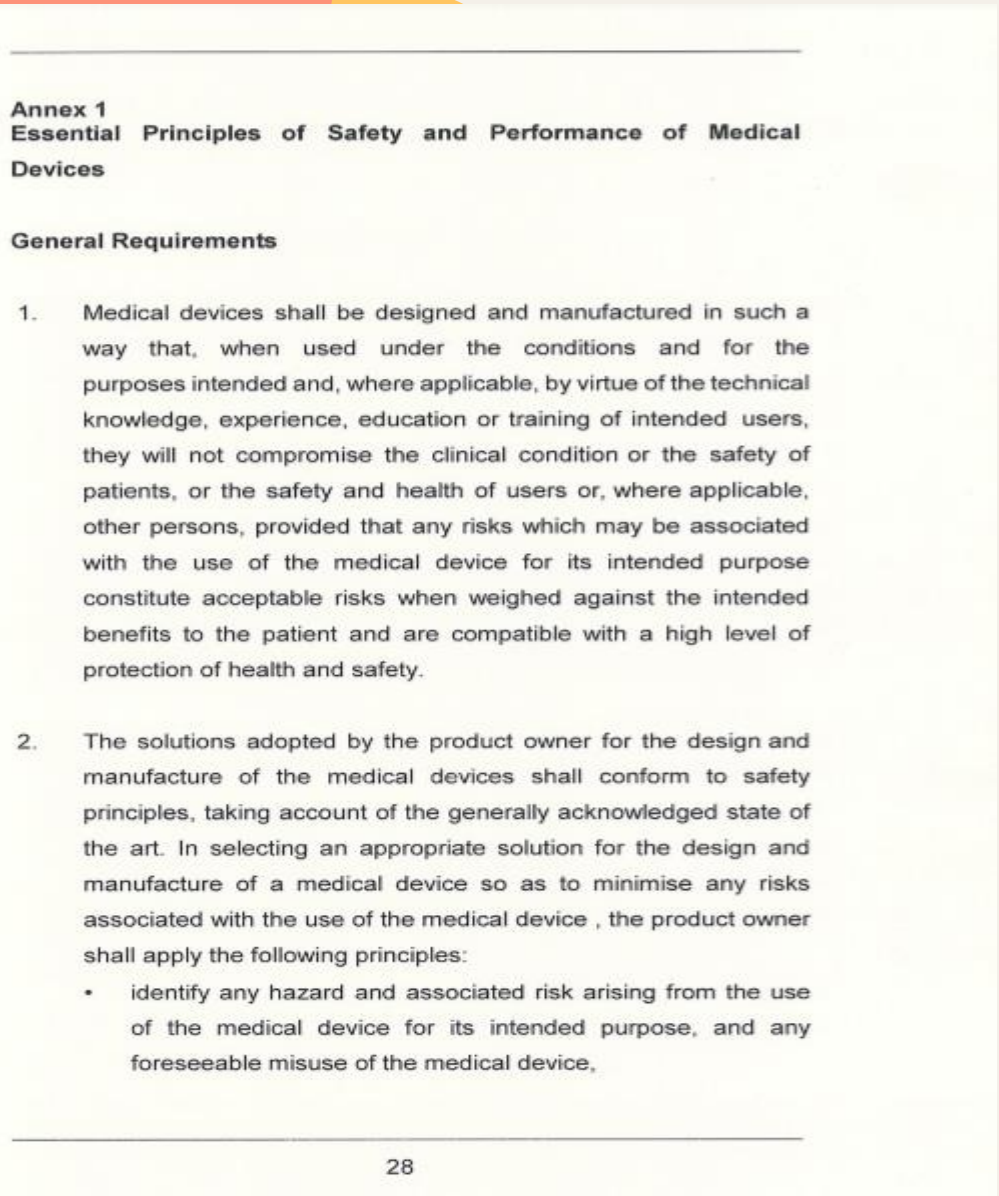
2. SCOPE

This CSDT is intended to apply to all medical devices. For IVD medical devices, the Regulatory Authority of the Member State may choose to adopt this CSDT or prescribe another format for regulatory submissions to that Member States. The depth and detail of the information contained in the CSDT will depend on:

- the classification of the subject medical device;
- the complexity of the subject medical device.

The format of the CSDT recommended herein is based upon the goal of both regulators and product owners to strive for the least burdensome means to demonstrate conformity to the Essential Principles for all classes of medical devices.

Where there are sections not applicable to the medical device, the reason for the non-applicability should be provided under the section heading. Requirements for post-market vigilance or adverse event reporting are outside the scope of this document.



Annex 1
Essential Principles of Safety and Performance of Medical Devices

General Requirements

1. Medical devices shall be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with the use of the medical device for its intended purpose constitute acceptable risks when weighed against the intended benefits to the patient and are compatible with a high level of protection of health and safety.

2. The solutions adopted by the product owner for the design and manufacture of the medical devices shall conform to safety principles, taking account of the generally acknowledged state of the art. In selecting an appropriate solution for the design and manufacture of a medical device so as to minimise any risks associated with the use of the medical device , the product owner shall apply the following principles:
   - identify any hazard and associated risk arising from the use of the medical device for its intended purpose, and any foreseeable misuse of the medical device,

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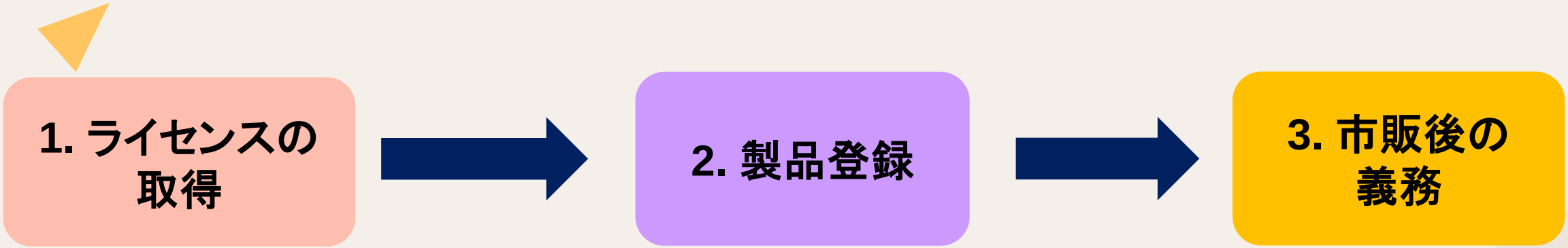
医療機器の安全性と性能に関する基本原則(EPSP)

Essential Principles of Safety and Performances of Medical Devices

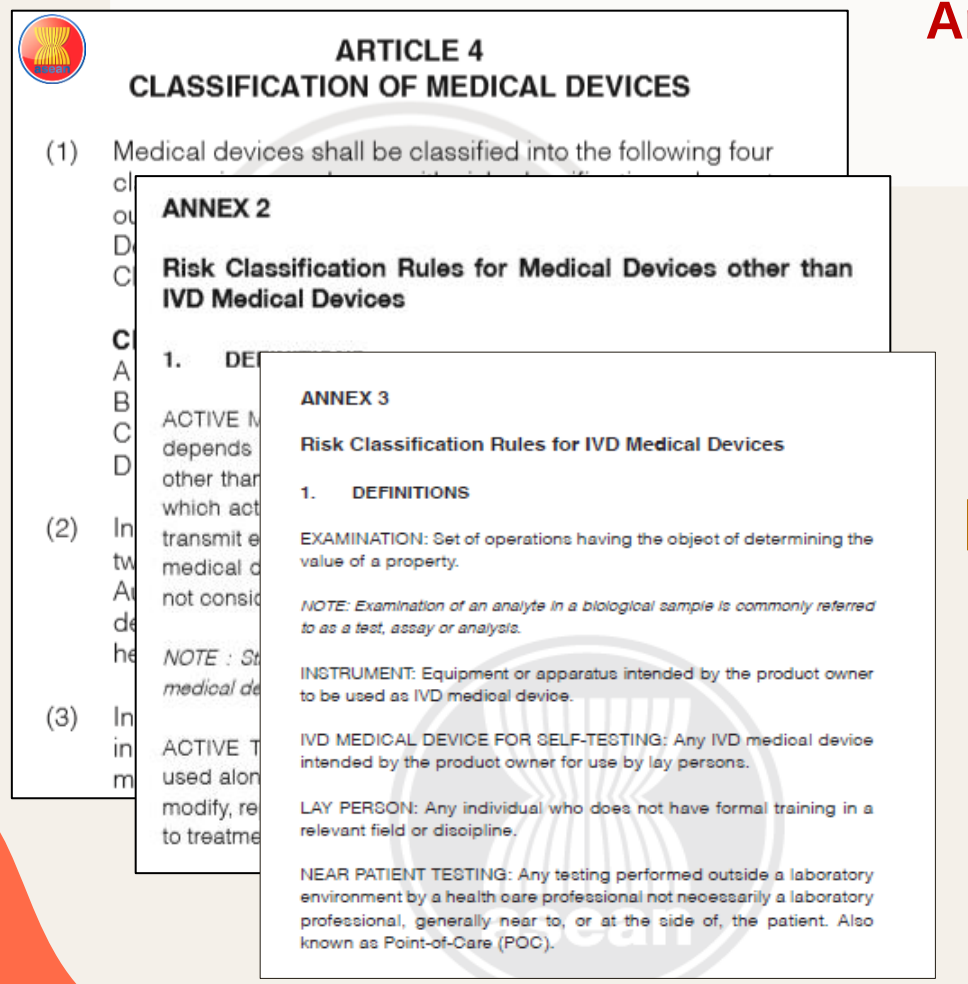
1. 一般的な要件
   General Requirements: 1-7
2. 設計と製造に関する要件
   Design and Manufacturing Requirements: 8-19

医療機器のタイ市場への進出
Placing Medical Device on Thailand Market



新しい規制はASEAN 医療機器指令（AMDD）第4条と付属文書2および3に準じて制定された

The new regulations are aligned with ASEAN Medical Device Directive (AMDD): Article 4 and Annex 2 and 3



ARTICLE 4
CLASSIFICATION OF MEDICAL DEVICES

(1) Medical devices shall be classified into the following four

ANNEX 2

Risk Classification Rules for Medical Devices other than IVD Medical Devices

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ANNEX 3

Risk Classification Rules for IVD Medical Devices

1. DEFINITIONS

EXAMINATION: Set of operations having the object of determining the value of a property.

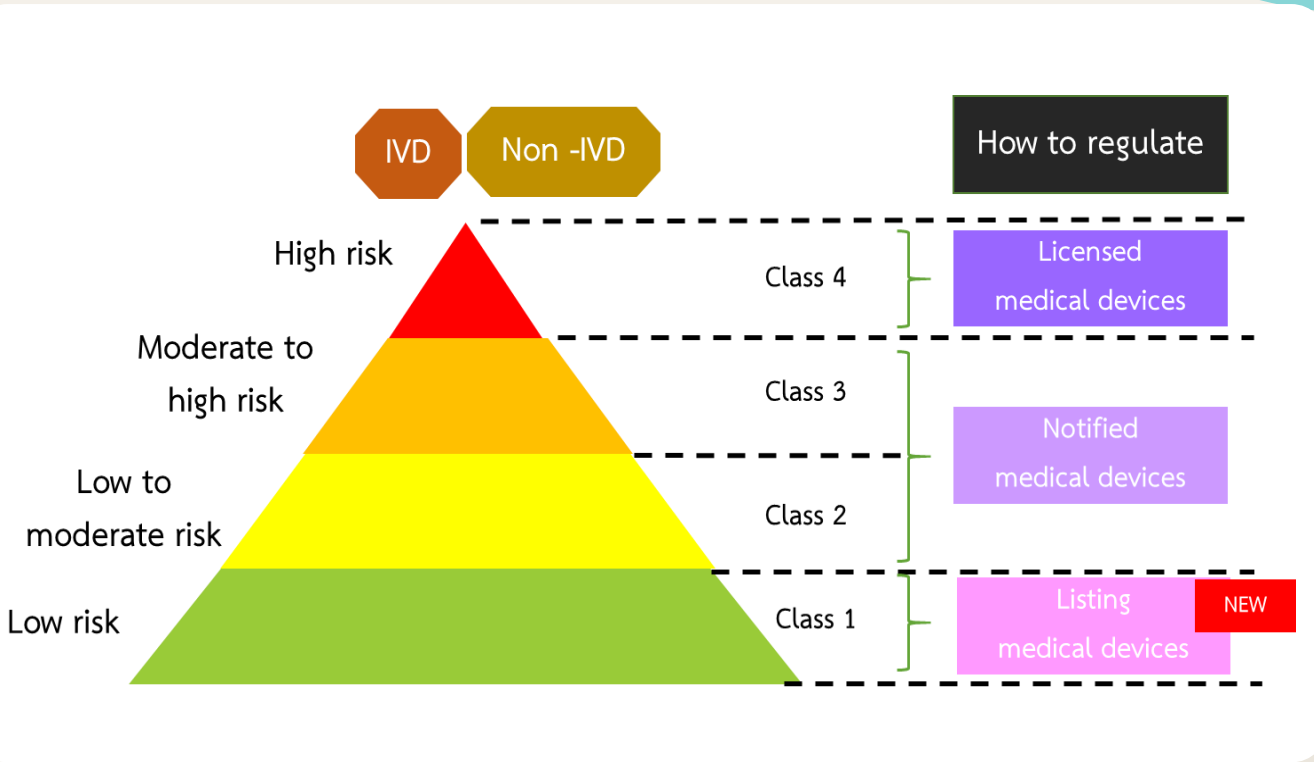
NOTE: Examination of an analyte in a biological sample is commonly referred to as a test, assay or analysis.

INSTRUMENT: Equipment or apparatus intended by the product owner to be used as IVD medical device.

IVD MEDICAL DEVICE FOR SELF-TESTING: Any IVD medical device intended by the product owner for use by lay persons.

LAY PERSON: Any individual who does not have formal training in a relevant field or discipline.

NEAR PATIENT TESTING: Any testing performed outside a laboratory environment by a health care professional not necessarily a laboratory professional, generally near to, or at the side of, the patient. Also known as Point-of-Care (POC).



タイムライン：医療機器認可申請の提出を円滑化　クラス1
Timeline: Facilitation for Medical Device Submission CLASS 1

提出日	規制
現在 2021年3月17日	最終的なリスト登録
	OR Partial 1 輸入ライセンスが2022年3月16日前に失効 または 2021年12月31日前に販売証明書類を添付して製造ライセンスを取得

特記事項: 同規制は更新には該当しない

タイムライン：医療機器認可申請の提出を円滑化　クラス2-4
Timeline: Facilitation for Medical Device Submission CLASS 2-4

提出日

2021年3月17日
-
2024年2月13日

2024年2月14日

規制

Partial 1

輸入ライセンスが
2022年2月14日**前**に失効
または
2021年12月31日**前**に販売証明書類を添付して
製造ライセンスを取得

OR

Partial 2

輸入ライセンスが
2022年2月14日**後**に失効
または
2021年12月31日**後**に販売証明書類を添付して
製造ライセンスを取得
または
新しい輸入者・製造者

統一申請様式

特記事項: 同規制は更新には該当しない

免除される広告の認可について
Exemption of some advertising approval

ヘルスケア分野の専門職に
対する**直接広告について**
認可を免除

2020年11月2日発効

認可が不要

- 商標名
- 商標
- ロゴ

2020年11月5日発効

お問い合わせ先
Further Information

月曜日–金曜日

営業時間　8.30 - 16.30

E-mail: mdcd1988@fda.moph.go.th

（15営業日）

連絡をいただく前に下記をご準備ください

1. 意図する医療機器の使途と表示
2. タイの医療機器規制
3. 米国、欧州（EU）、カナダ、オーストラリア、日本など他国の規制の歴史的経過
4. 貴社製品に関する特定の質問

Thank you!

ขอบคุณค่ะ!