Medical Device Regulation in Thailand

27th January 2021

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

Outline

- **Legislation**
  June – December 2020

Notification of Ministry of Public Health

01 Labeling and Instructions for use

02 Complaint channel and its record

03 Exemption of some advertising approval

04 Prohibiting of powder medical gloves

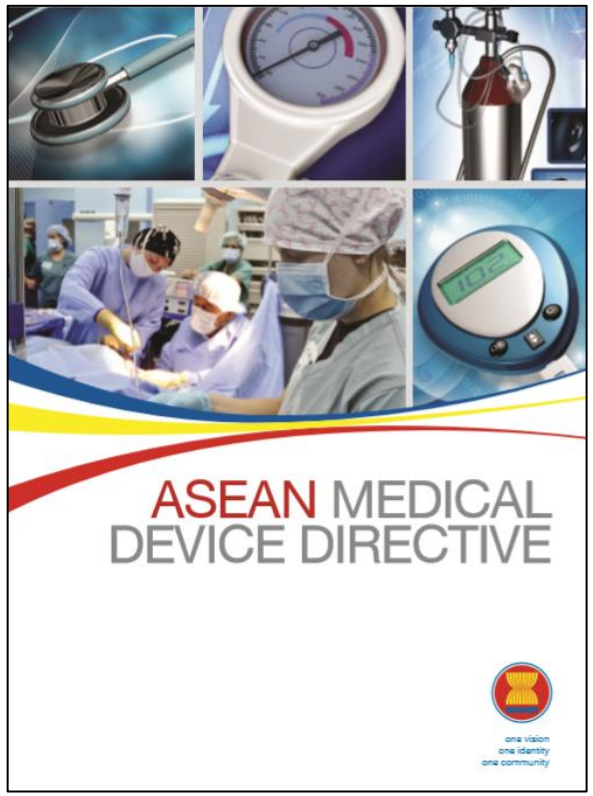
FDA Announcement

05 Covid-19 related medical devices

- **Upcoming regulation** in 2021

Ministerial Regulation
FDA Announcement

ASEAN Medical Device Directive (AMDD)



Legislation are align with AMDD.

ASEAN AGREEMENT ON MEDICAL DEVICE DIRECTIVE

Thailand submitted Instrument of Ratification on 19th January 2021

Instruments of Ratification

No.	Member State	Date	Document Type
1.	Cambodia	27 March 2019	Instrument of Acceptance
2.	Indonesia	26 December 2018	Instrument of Ratification
3.	Lao PDR	04 December 2015	Instrument of Acceptance
4.	Malaysia	24 July 2020	Instrument of Ratification
5.	Myanmar	06 September 2018	Instrument of Ratification
6.	Singapore	02 November 2015	Instrument of Ratification
7.	Thailand	19 January 2021	Instrument of Ratification
8.	Viet Nam	23 March 2016	Instrument of Acceptance

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 23, 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 notifications 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

01

Labeling and Instructions for use

Effective date on 31st October 2021

ARTICLE 10
LABELLING

(1) A medical device shall be labelled in accordance with the requirements of the Member State prior to placing on the market in that Member State.

(2) Member States may set the labelling requirements for a medical device in accordance with Annex 7 (Labelling Requirements) or as deemed appropriate by the Member States.

(3) Member States may set the requirement for having the label of a medical device in their national languages.

ANNEX 7

Labelling Requirements

1. DEFINITIONS

CLINICAL INVESTIGATION: Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device.

Explanation: This term is synonymous with 'clinical trial' and 'clinical study'. Clinical investigations include feasibility studies and those conducted for the purpose of gaining market approval, as well as nvestigations conducted following marketing approval.

Routine post market surveillance may not constitute a clinical investigation (e.g. investigation of complaints, individual vigilance reports, literature reviews).

Labeling

Home use medical device :

Must have Thai Language

Professional use medical device:

Thai or English Language

IFU

→ Paper-based

→ Electronic IFU

02

Complaint channel and its record

Effective date is 4th May 2021

ARTICLE 12
POST-MARKETING ALERT SYSTEM

(1) Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Agreement, regarding the incidents involving a medical device as mentioned below is recorded and evaluated when appropriate:

(a) any malfunction or deterioration in the characteristics or performance of a medical device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(b) any technical or medical reason in relation to the characteristics or performance of a medical device for the reasons referred to in subparagraph (a), leading to product recall of medical devices of the same type by the product owner, authorised representative, authorised distributor or person responsible for placing medical device into the market.

ANNEX 5

Post Marketing Alert System (PMAS) Requirements

3. COMPLAINT RECORDS

The records on complaints related to a medical device may include the following information:

- the medical device brand name, medical device registration number, model/catalogue number or bar code, control/serial/ lot number and any other means of identification of the medical device;
- the name(s) and address(es) of the dealer;
- records pertaining to the problem investigation.

All actions taken by dealers in response to the problems and complaints must be kept on record. These actions include any communications with the reporter/complainant, the evaluation of the problem/complaint, and any steps taken to correct the problem or prevent the recurrence of the problem. Such steps might include increased post-market surveillance of the medical device, corrective and preventive action with respect to the design and manufacture of

Establish Complaint channel

- Collect complaint records and effective handling system
  - Evaluation & Correct problem
  - Document Retention

03 Exemption of some advertising approval

- Direct advertising to healthcare professional are exempted from approval

Effective date is 2nd November 2020

- Advertisement characteristic which do not require approval
  - Trade name or
  - Trademark or
  - Trade logo

Effective date is 5th November 2020

04 Prohibiting distribution of Powder medical gloves

Effective date is 5th November 2020

Powder medical gloves are prohibited to **manufacture, import or distribute** in Thailand.

Manufacturing for exportation are allowed.

However, the specification and standards must meet requirement of the customer

Note: USFDA banned powder medical gloves since 18th January 2017

05

Covid-19 related medical equipment announcements

Increasing number of importer

Product	January 4, 2021	
	Before	After
Surgical Mask	11	590 (+579)
N95 Respirator	12	131 (+119)
Gown / Coverall	4	190 (+186)

Standard of Single-use Medical Mask
Effective date is 13th October 2020

Standard of Medical Gown and Coverall
Effective date is 21st December 2020

Increasing number of manufacturer

Product	January 4, 2021	
	Before	After
Surgical Mask	13	74 (+61)
N95 Respirator	1	6 (+5)
Gown / Coverall	5	45 (+40)

Standard of Single-use
N95 Medical Mask
Effective date is 1st December 2020

05

COVID-19 Diagnostic Test Kit

Classification : Class 4 (D), Licensed medical device

1.

Molecular test : RT-PCR, RT-LAMP, Other methods

72 approved products

2.

Antigen and Antibody : Rapid test, Reagent

Antibody:

38 approved products

Antigen:

3 approved products

Data as of 20th January 2021

Establishment License (Scope: Clinical Laboratory)

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Medical device exemption for Testing

↓

Technology Evaluation

Clinical Evaluation

5 Endorsed laboratories by Thai FDA

1. Department of Medical Sciences
2. Bamrasnaradura Infectious Diseases Institute
3. Faculty of Medicine Ramathibodi Hospital
4. Faculty of Allied Health Sciences, Chulalongkorn University
5. Faculty of Medical Technology, Mahidol University

Molecular test:

Item	Lab parameters	Values
1	Analytical Sensitivity	RT-PCR: Less than 1000 copies/ml RT-LAMP,CRISPR: Less than 4,000 copies/ml
2	specificity of primers and probes with SARS-CoV, MERS-CoV and other human corona 229-E such as NL-63, OC-43,229-E and HKU-1	No cross reactivity

Antibody test:

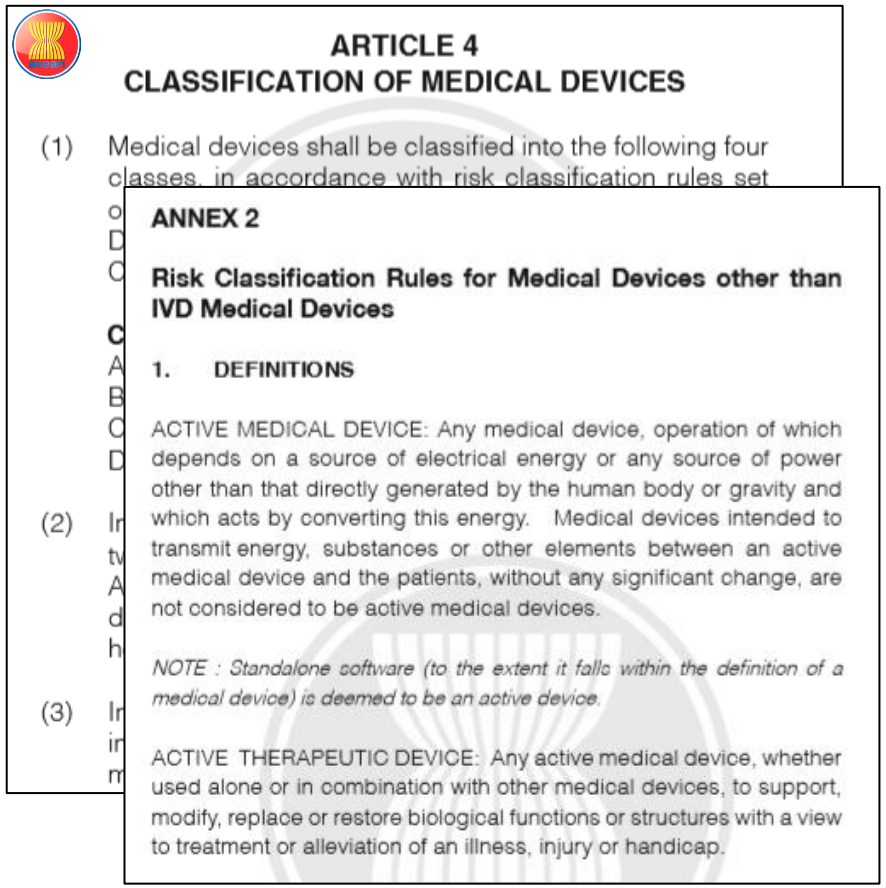
Item	Lab parameters	Values
1	Diagnostic Sensitivity	≥ 85 % , n ≥ 50
2	Diagnostic specificity	≥ 98 % , n ≥ 100
3	Non-specificity	≤ 10 % , n ≥ 20

Antigen test:

Item	Lab parameters	Values
1	Diagnostic Sensitivity	≥ 90 % , n ≥ 50
2	Diagnostic specificity	≥ 98 % , n ≥ 100
3	Non-specificity	≤ 10 % , n ≥ 20
4	Limit of Detection (if any)	

Upcoming Regulation in 2021

The new regulations are aligned with ASEAN Medical Device Directive (AMDD)



ARTICLE 4
CLASSIFICATION OF MEDICAL DEVICES

(1) Medical devices shall be classified into the following four classes, in accordance with risk classification rules set

(2)

(3)

ANNEX 2

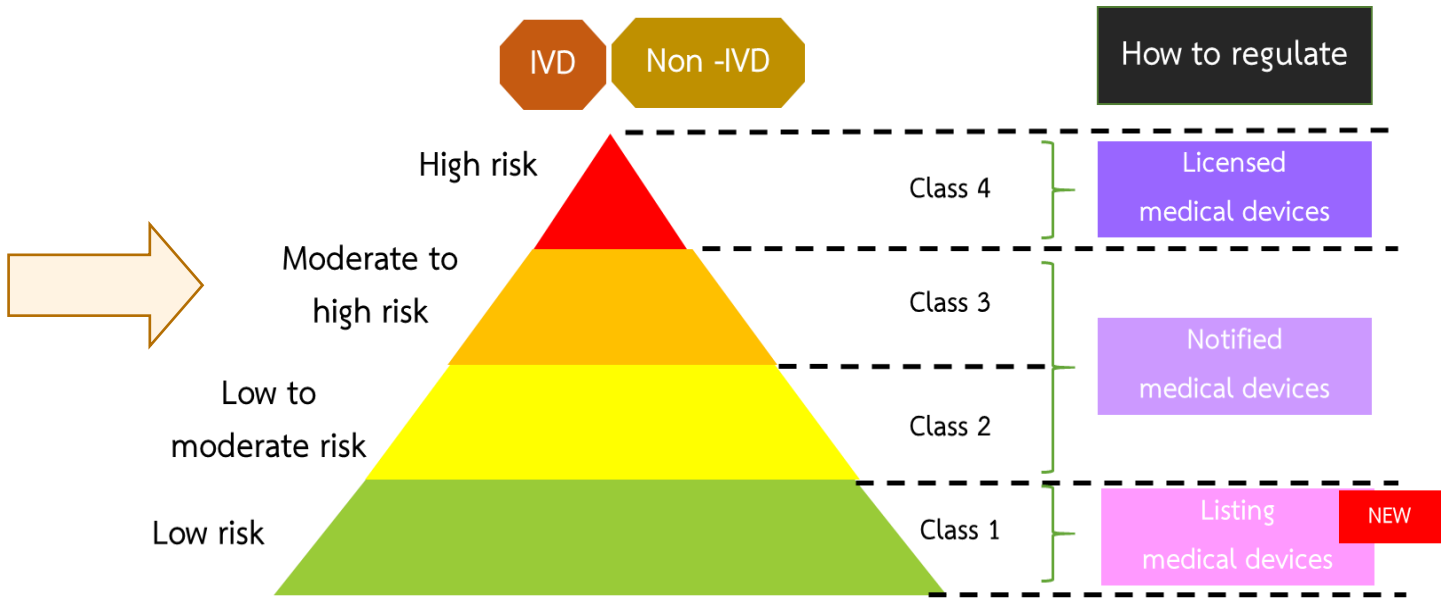
Risk Classification Rules for Medical Devices other than IVD Medical Devices

1. DEFINITIONS

ACTIVE MEDICAL DEVICE: Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patients, without any significant change, are not considered to be active medical devices.

NOTE : Standalone software (to the extent it falls within the definition of a medical device) is deemed to be an active device.

ACTIVE THERAPEUTIC DEVICE: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.



Medical Device Act B.E. 2551
And Medical Device Act (2nd edition) B.E. 2562

NEW Ministerial Regulation 2021

- Fee
- Licensed
- Notified
- Listing

Notification of Ministry of Public Health

- Categorized of Licensed MD → class 4
- Categorized of Notified MD → class 2,3
- Categorized of Listing MD → class 1+ Animal

FDA Announcement

Transition period of Manufacturer and Importer that have licenses

Class 1-4

Manufacturer/Importer that already have Establishment License + Certificate

Submit Application (Partial) → Before EXP. Date of Licenses

5 Years license

Submit Full application → Before EXP. Date of Licenses

Renewal 5 Years license


thank you.