Outline

• Legislation
  June – December 2020

  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.

### Thailand submitted Instrument of Ratification on 19th January 2021

<table>
<thead>
<tr>
<th>Instruments of Ratification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No.</strong></td>
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<tr>
<td>1.</td>
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<td>7.</td>
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<td>8.</td>
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</tbody>
</table>
**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.
   
   **Evaluation:** 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 investigations conducted following market approval.
   
   **Routine post-market surveillance:** May not constitute a clinical investigation (e.g., investigation of complaints, individual vigilance reports, literature reviews).

**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 the 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 label, authorized representative, authorized 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, product group number, if any, container/packaging lot number with 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 the medical device.

**IFU**

- Paper-based
- Electronic IFU

**Establish Complaint channel**

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

Home use medical device:
Must have Thai Language

Professional use medical device:
Thai or English Language
Exemption of some advertising approval

- Direct advertising to healthcare professionals are exempted from approval

Effective date is 2\textsuperscript{nd} November 2020

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

Effective date is 5\textsuperscript{th} November 2020

Prohibiting distribution of Powder medical gloves

Effective date is 5\textsuperscript{th} 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

Medical device regulation in Thailand
Covid-19 related medical equipment announcements

**Increasing number of importer**

<table>
<thead>
<tr>
<th>Product</th>
<th>January 4, 2021</th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical Mask</td>
<td></td>
<td>11</td>
<td>590 (+579)</td>
</tr>
<tr>
<td>N95 Respirator</td>
<td></td>
<td>12</td>
<td>131 (+119)</td>
</tr>
<tr>
<td>Gown / Coverall</td>
<td></td>
<td>4</td>
<td>190 (+186)</td>
</tr>
</tbody>
</table>

**Increasing number of manufacturer**

<table>
<thead>
<tr>
<th>Product</th>
<th>January 4, 2021</th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical Mask</td>
<td></td>
<td>13</td>
<td>74 (+61)</td>
</tr>
<tr>
<td>N95 Respirator</td>
<td></td>
<td>1</td>
<td>6 (+5)</td>
</tr>
<tr>
<td>Gown / Coverall</td>
<td></td>
<td>5</td>
<td>45 (+40)</td>
</tr>
</tbody>
</table>

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

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

Medical device regulation in Thailand
Medical device regulation in Thailand

Classification: Class 4 (D), Licensed medical device

Establishment License (Scope: Clinical Laboratory)

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:

<table>
<thead>
<tr>
<th>Item</th>
<th>Lab parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Analytical Sensitivity</td>
<td>RT-PCR: Less than 1000 copies/ml RT-LAMP, CRISPR: Less than 4000 copies/ml</td>
</tr>
<tr>
<td>2</td>
<td>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</td>
<td>No cross reactivity</td>
</tr>
</tbody>
</table>

Antibody test:

<table>
<thead>
<tr>
<th>Item</th>
<th>Lab parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Diagnostic Sensitivity</td>
<td>≥ 85 %, n ≥ 50</td>
</tr>
<tr>
<td>2</td>
<td>Diagnostic specificity</td>
<td>≥ 98 %, n ≥ 100</td>
</tr>
<tr>
<td>3</td>
<td>Non-specificity</td>
<td>≤ 10 %, n ≥ 20</td>
</tr>
</tbody>
</table>

Antigen test:

<table>
<thead>
<tr>
<th>Item</th>
<th>Lab parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Diagnostic Sensitivity</td>
<td>≥ 90 %, n ≥ 50</td>
</tr>
<tr>
<td>2</td>
<td>Diagnostic specificity</td>
<td>≥ 98 %, n ≥ 100</td>
</tr>
<tr>
<td>3</td>
<td>Non-specificity</td>
<td>≤ 10 %, n ≥ 20</td>
</tr>
<tr>
<td>4</td>
<td>Limit of Detection (if any)</td>
<td></td>
</tr>
</tbody>
</table>

Data as of 20th January 2021

Antigen and Antibody: Rapid test, Reagent

Antigen: 3 approved products

Antibody: 38 approved products

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

72 approved products

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

Establishment License (Scope: Clinical Laboratory)
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

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.

IVD Non-IVD

High risk

Moderate to high risk

Low to moderate risk

Low risk

How to regulate

Class 4 Licensed medical devices

Class 3 Notified medical devices

Class 2 Listing medical devices

Class 1 NEW medical devices

Medical device regulation in Thailand
Medical Device Act B.E. 2551
And Medical Device Act (2nd edition) B.E. 2562

Ministerial Regulation

Fee
Licensed
Notified
Listing

Notification of Ministry of Public Health

Categorized of Licensed MD
Categorized of Notified MD
Categorized of Listing MD

class 4
class 2,3
class 1+ Animal

FDA Announcement

Transition period of Manufacturer and Importer that have licenses

Class 1-4
Submit Application (Partial)
Manufacturer/Importer that already have Establishment License + Certificate

5 Years license
Before EXP. Date of Licenses

Renewal 5 Years license
Before EXP. Date of Licenses

Medical device regulation in Thailand
thank you.