

Thai Food & Drug Administration and Department of Internal Trade: Responses to COVID-19

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Outline

● Introduction

● Innovation related to COVID-19

- Innovation in the Pharmaceutical Industry
- Innovation in Engineering/Medical Devices

● FDA Regulatory Landscape

Update on Important Regulations from FDA/DIT

POST-Pandemic Era

Food Security

(Sustainable agriculture, food availability and supply, food safety)

Medicine and Vaccine Security???

Medical Device Security???



POTENTIAL COVID-19 DRUGS

Adalimumab

Tofacitinib

Anti-cytokine drug

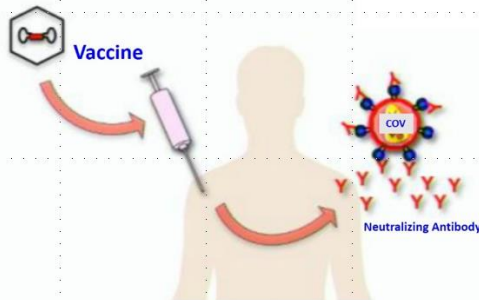
Anti-inflammatory drug

(Inhibit)

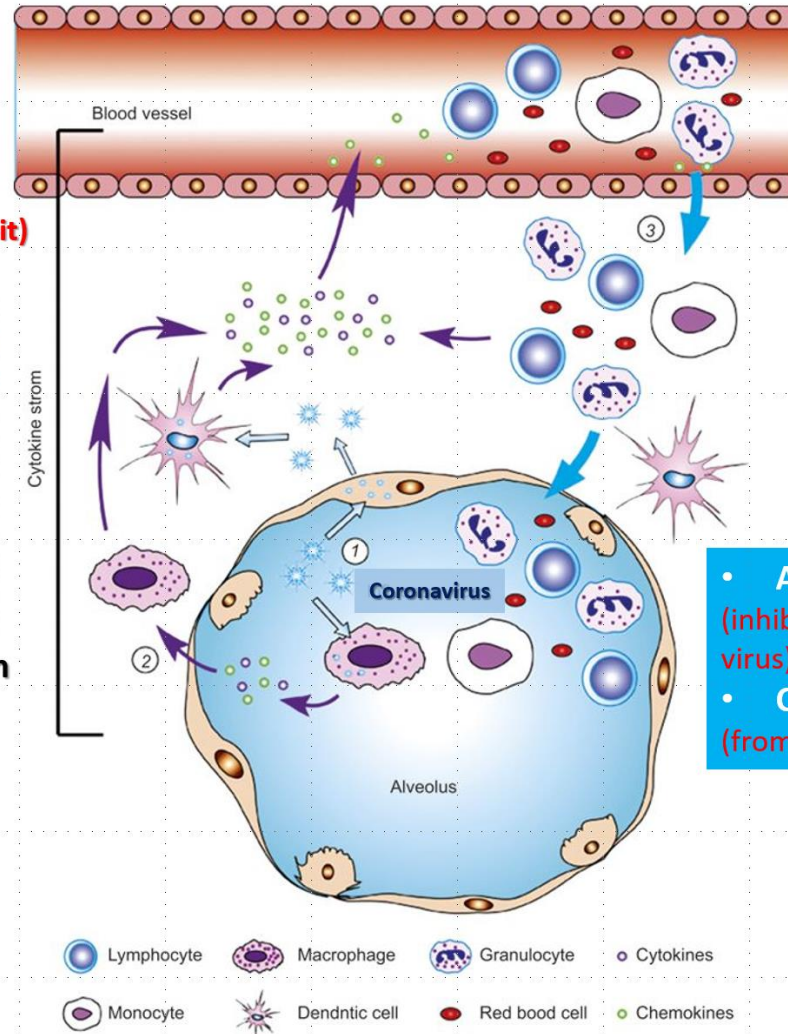
Severe Inflammation
Multiple Organ dysfunction



Cytokine Storm



Vaccination –the best approach



- Anti-viral drug (inhibit entry/ replication of virus)
- Convalescent serum (from recovery patients)

Famipiravir

Remdisivir

Ritonavir

Lopinavir

MSF calls for no patents or profiteering on COVID-19 drugs and vaccines

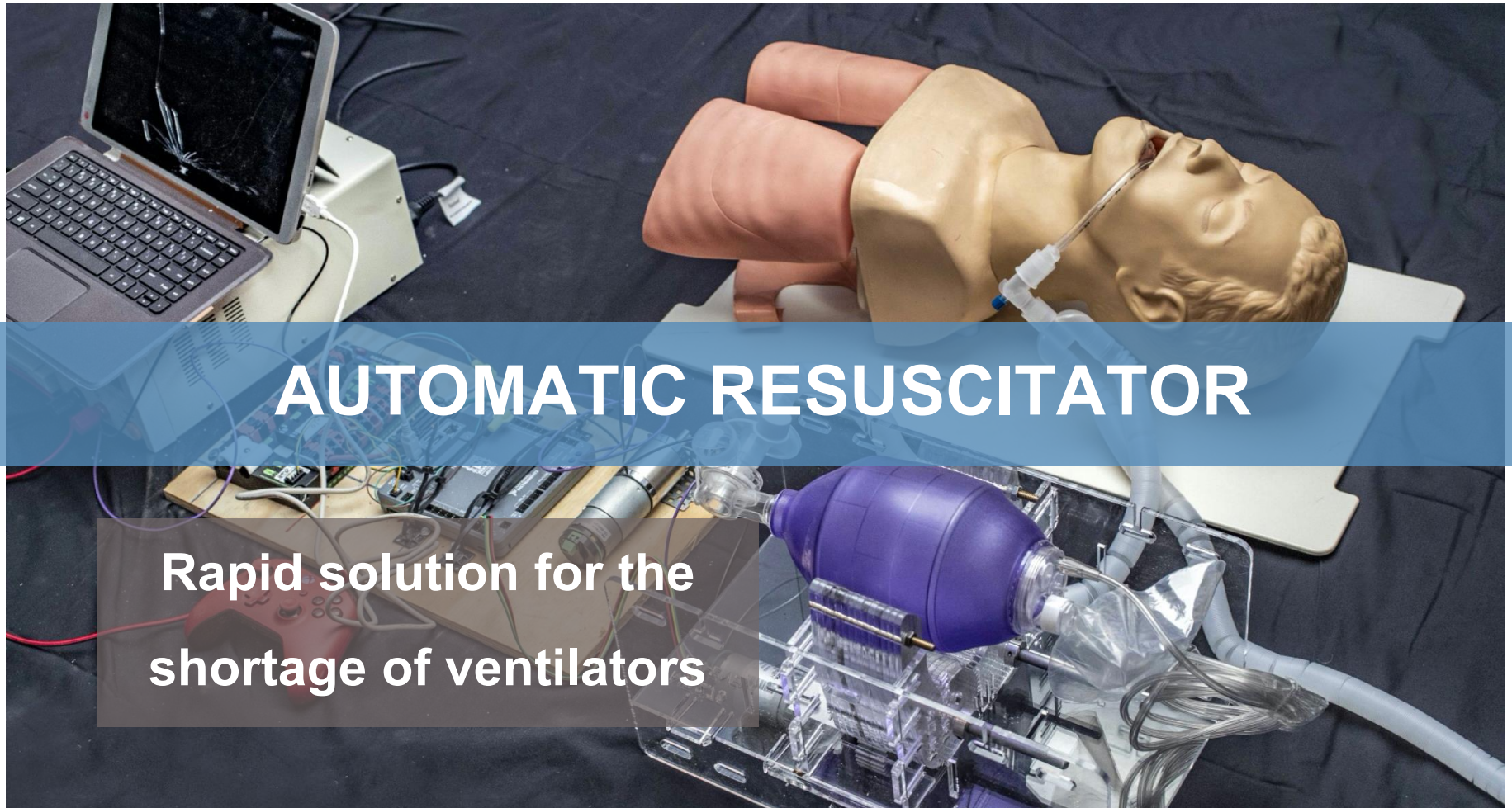
- **AbbVie to Allow Use of Intellectual Property for Coronavirus** Kaletra (lopinavir/ritonavir) as an experimental option for treatment of coronavirus
- Amazon, Facebook, Hewlett Packard Enterprise (HPE), IBM, Microsoft, and Sandia National Laboratories are joining the **“Open COVID Pledge”** by making all of their patents freely available to the public for use in the fight against COVID-19.

Offering to grant a temporary license for the public to utilize any of the pledgors' patents for R&D, deployment of medical equipment, network products, software solutions, etc., to assist in this urgent public health crisis.

INNOVATION CHALLENGE IN ENGINEERING

The prototype of this ventilator was invented by MIT

All of this information is freely available at e-vent.mit.edu.



AUTOMATIC RESUSCITATOR

Rapid solution for the
shortage of ventilators

INNOVATION CHALLENGE IN MEDICAL DEVICES

Cooperation between Honda and Vajira Hospital



Equipped With
HEPA Filter

NEGATIVE PRESSURE TRANSFER BED

INNOVATION CHALLENGE IN ENGINEERING

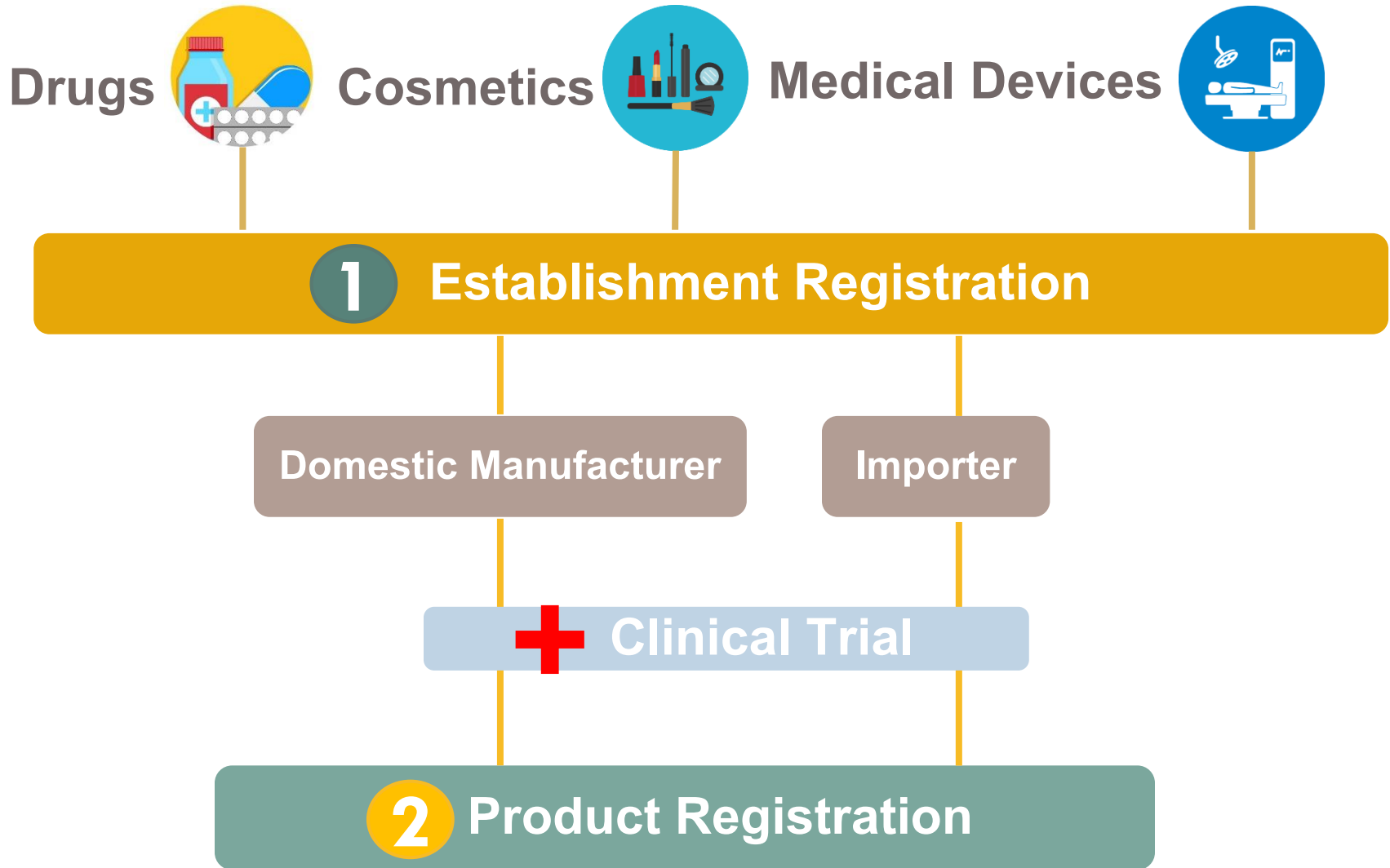
The testing booth was first developed in Korea, so that people with coronavirus symptoms can get tested without being in direct contact with medical staff.

CORONAVIRUS TESTING BOOTH

Inspired by
Telephone
Booths



FDA Regulatory Landscape and Requirements



สำนักงานคณะกรรมการ
อาหารและยา



FOOD AND DRUG
ADMINISTRATION

UPDATE ON REGULATIONS IMPLEMENTED BY **THAI FDA** & **DIT**

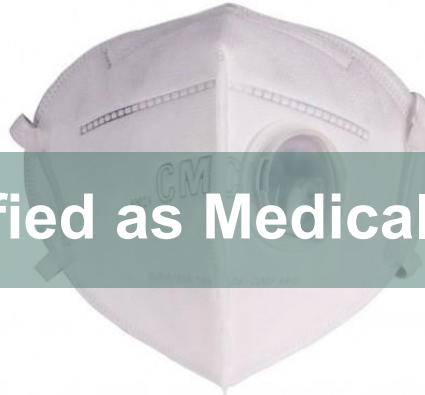


Department of Internal Trade
Ministry of Commerce

Face Mask Classification*



Surgical Mask



**Surgical Mask with
Valve**



N95 mask



Not Classified as a Medical Device



Cloth Mask

Mask for Industry



* แนวทางปฏิบัติเรื่อง แนวทางการพิจารณาหน้ากากอนามัย (Guidance Re Classification of Face Masks)

Trading of Hygienic Masks

Designated as Controlled Goods by the DIT

Medical Mask

Mask for Industry

Export Restriction: Exporter must obtain permission prior to exporting.

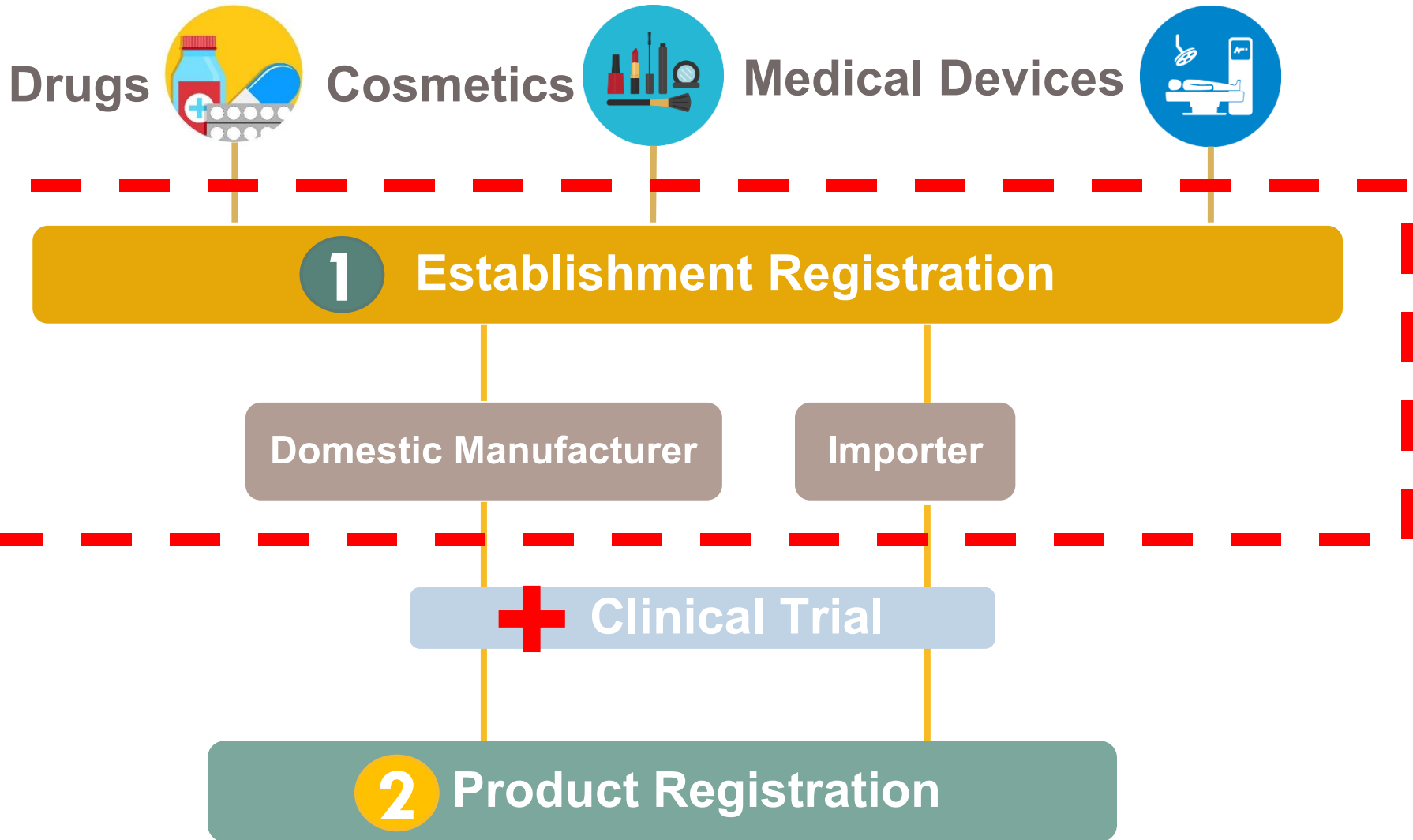
Retail prices of Domestic Surgical Masks must not exceed THB 2.50

Prices of other Face Masks are not controlled.

BUT! Manufacturers, Importers, Distributors and Exporters are required to:

- (i) **notify** the price and must not change the price prior to receiving approval.
- (ii) **submit** records of the cost price, sales price, import volume, production volume, export volume and stock volume.

FDA Regulatory Landscape and Requirements



Fast-Track Registration Pathway for

COVID-19 Medical Devices (General Medical Devices)

1. Surgical Masks

Controlled

2. N95 Masks

Goods

3. Surgical Gowns

4. Isolation Gowns

5. Equipment for Testing - SWABs

6. Personal Protection Equipment

7. Medical Gloves

(Not including surgical gloves)

8. Medical Thermometers

9. Medical Goggles

10. Medical Face Shields

11. Medical Hood Coverings

12. Medical Leg Coverings

13. Medical Caps

Medical Device Classification

The registration requirements are different depending on product classification

Licensed Medical Device

High Risk

- HIV Test Kits
- Contact Lenses
- Condoms
- Blood Bags
- Silicone Breast Implants*
- COVID-19 Test Kits*
- Injectable Hyaluronic Acid

Detailed Notification Medical Device

Moderate-High Risk

- Physical Therapy Devices
- Alcohol Detectors
- Methamphetamine Diagnostic Test Kits
- Concentrate for Hemodialysis

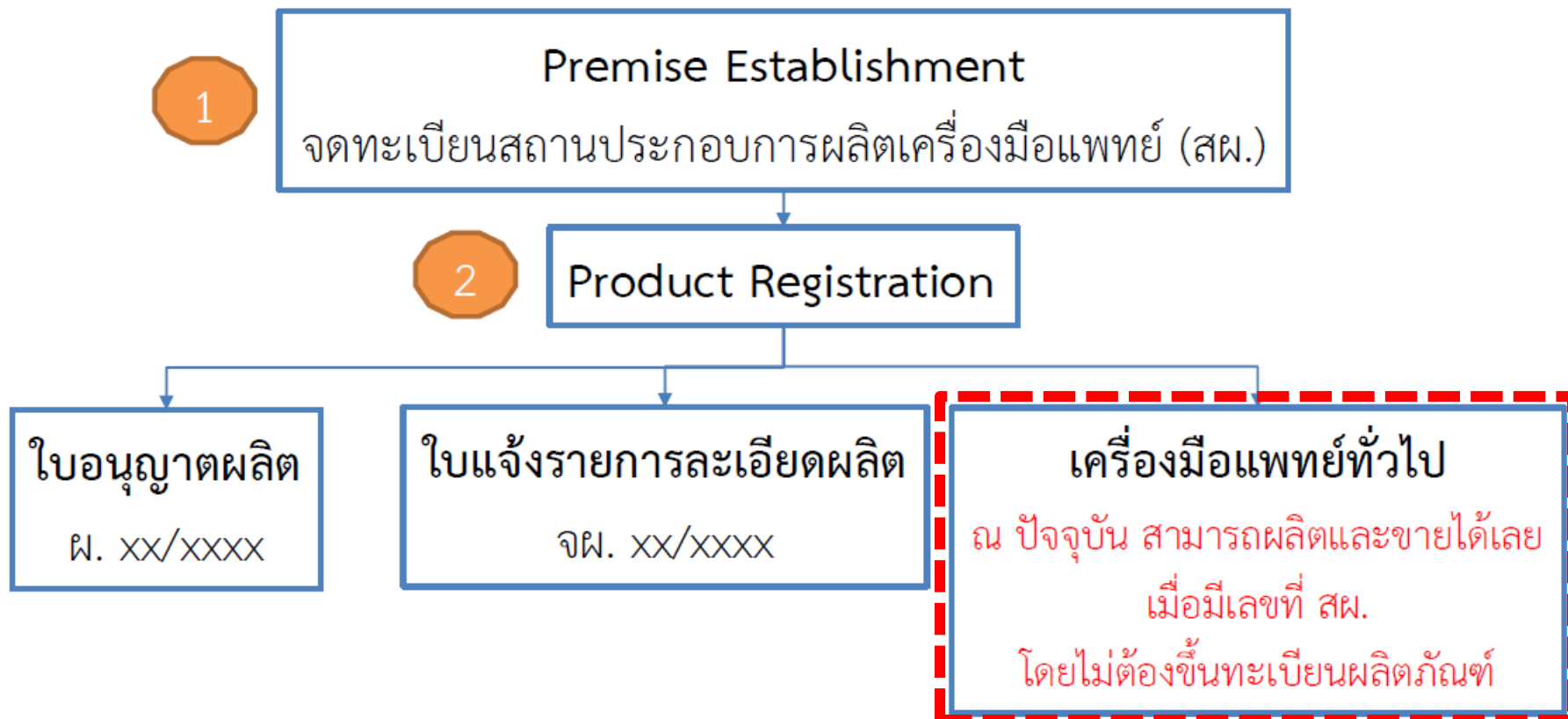
Notification (General) Medical Device

Low Risk

- Other Medical Devices not listed as a Licensed or Detailed Notification Medical Device

* ประกาศกระทรวงสาธารณสุข เรื่อง กลุ่มเครื่องมือแพทย์หรือเครื่องมือแพทย์ที่ผู้ผลิตหรือผู้นำเข้าต้องได้รับอนุญาต พ.ศ. 2563

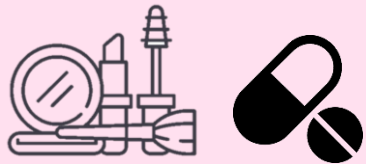
Medical Device Registration for Domestic Manufacturers



Alcohol-Based Hand Sanitizer



Lotion, Solution,
Cream, Gel, Foam, Spray



Originally, they are either

**Drugs or
Cosmetics**



For consumer safety,
the product is about to
become a

**Detailed Notification
Medical Device**
ความเสี่ยงปานกลาง



Owing to the COVID-19 outbreak,
the reclassification of Alcohol-
Based Hand Sanitizer as a medical
device is Cancelled.

Alcohol-Based Hand Sanitizer will
continue be classified as

Cosmetics

The Alcohol Concentration (Ethanol, Isopropanol, n-Propanol)
lower than 70 %v/v is now banned in Thailand.

Registration Requirements*

* แนวทางปฏิบัติและการแสดงฉลากเครื่องสำอางที่มีส่วนผสมของแอลกอฮอล์เพื่อขออนุญาตสำหรับมือ

Cosmetic Control Group Circular Re Procedure and Condition of the Registration of Alcohol-Based Hand Sanitizer

1 The Alcohol Concentration must greater than 65 %w/w.

2

Claims



Antibacterial, Reduce Microbial Load



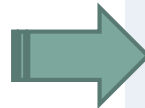
Any statement related to COVID-19, Coronavirus, *Escherichia coli*, *Pseudomonas aeruginosa*, Kill, Safe.

3

Drug Manufacturer

Herbal Medicine Manufacturer

Medical Device Manufacturer



Are allowed to register and produce alcohol-based hand sanitizer without having to become a cosmetics manufacturer.

Cosmetics Registration



ผู้ผลิตหรือผู้นำเข้าต้อง



1. จัดเตรียมสถานที่
อุปกรณ์ การจัดเก็บข้อมูล
ให้เป็นไปตามกฎหมาย
กำหนด



2. จัดแจ้ง
เครื่องสำอางก่อนผลิต
หรือนำเข้า
5 Business Days



3. เครื่องสำอางที่ผลิต
หรือนำเข้าต้อง
ไม่มีสารห้ามใช้ และ
ใช้สารตามที่กฎหมาย
กำหนด



4. ไม่มีจุลินทรีย์ที่ทำให้
เกิดโรค และมีจำนวน
จุลินทรีย์ที่ไม่ทำให้เกิดโรค
ไม่เกินกว่าที่กฎหมาย
กำหนด



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QUESTIONS ?