CHANDLER MHM

# Newsletter

# THAILAND: OVERVIEW OF REGULATORY COMPLIANCE AND CATEGORIZATION OF MEDICAL DEVICES

### Introduction

In 2015, Thailand along with other ASEAN members ratified the ASEAN Medical Device Directive ("**AMDD**") in order to align regional regulations governing medical devices. To comply with the terms of the AMDD, Thailand has passed several amendments, regulations and notifications on the classification and registration requirements for medical devices. Importation and manufacture of medical devices has more recently increased due to the COVID-19 global pandemic. With an increasing interest in the life and health sciences sector, and a global need for medical devices and equipment, an understanding of Thailand's regulatory regime related to medical devices is important for business operators including importers and manufacturers, in Thailand.

### Background – Governing law

Medical devices in Thailand are generally regulated under the Medical Devices Act B.E. 2551 (2008) (the "**Medical Devices Act**"). The Medical Devices Act includes 3 broad categories of medical devices, as follows:

1. medical devices that require importers and manufacturers to obtain corresponding licenses from the Food and Drug Administration ("**FDA**");
2. medical devices that require importers and manufacturers to register with FDA; and
3. medical devices that require notification to the FDA by importers and manufacturers.

The Medical Devices Act, through subordinated regulations and notifications, further categorizes and imposes certain registration, notice and/or licensing requirements depending on the type of medical device. This briefing will provide an overview of these regulations.

### Medical device categories

Regulations on different categories of medical devices are laid out in a Notification issued by the Ministry of Public Health in 2019 (the "**MPH Notification 2019**"). The main factor in determining what category a medical device falls into, is the associated 'risk level' as determined by the Ministry of Public Health. The corresponding 'risk' assessment determines whether an importer or manufacturer of such a medical device is required to apply for a license, or whether that operator must register with or notify the FDA.

Under the MPH Notification 2019, risk is based on the potential impact on a person's body, the health, life of a person or on the public health system. The MPH Notification 2019 has classified medical devices into 1) In vitro diagnostic medical devices ("**IVD Medical Device**"); and 2) Non-in vitro diagnostic medical devices ("**Non-IVD Medical Device**"), The risk assessment criteria are as follows:

| IVD Medical Device | Non-IVD Medical Device | Registration/Notification/ Licensing Requirements for the Registrant of Medical Devices at the Place of Operation of the Manufacturer or Importer |
|---|---|---|
| Risk level 1: Low risk to a person and the public health system | Risk level 1: Low risk | Requires registration with the FDA |

## Key Contacts


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|---|---|---|
| Risk level 2: Medium risk to a person or low risk to the public health system | Risk level 2: Medium-low risk | Requires notification to the FDA |
| Risk level 3: High risk to a person or medium risk to the public health system | Risk level 3: Medium-high risk | Requires notification to the FDA |
| Risk level 4: High risk to a person and the public health system | Risk level 4: High risk | Requires a license from the FDA |

Detailed categorizations are described in a Notification of the Ministry of Public Health corresponding to each type of medical device. The General Secretary of the FDA is empowered to judge any issues arising from the categorization of the medical devices.

### Compliance requirements (notification, registration, and licensing)

In December 2020, the Ministry of Public Health issued several Ministerial Regulations to govern procedures for requests for issuance of licenses for the manufacture or importation of medical devices. The Ministerial Regulations also covered the registration and issuance of certifications of registration of medical devices. These notifications also included procedures for the notification of certain medical devices by the manufacturers or importers to the General Secretary of the FDA or the person authorized by the General Secretary of the FDA. In addition, the Ministerial Regulations regulate procedures for the issuance of the certification of notification of medical devices to the manufacturers or importers. (the "**MPH Regulations 2020**"). Furthermore, The Ministry of Public Health issued several notifications, which became effective on 15 February 2021, (the "**MPH Notifications 2020**") to prescribe the characteristics of each type of medical device and the criteria for the risk assessment of medical devices to enable medical devices to be categorised.

In addition to the above, to manufacture or import medical devices, the manufacturer or importer must register their place of operations with the FDA. Importers and manufacturers must also obtain a license for the manufacture or importation of medical devices as regulated by the Regulation of Ministry of Public Health 'Re: Request for and Issuing License for Manufacture or Importation of Medical Devices' which became effective on 18 March 2021. In order to sell certain medical devices (e.g., human blood containers, HIV test kits, etc.) sellers must also obtain a license granted by the FDA pursuant to the rules, procedures and conditions set forth under the regulations of the Ministry of Public Health. A seller is prohibited from selling medical devices that are not registered with, notified to, or licensed by the FDA.

### Conclusion

Operators, importers, and/or manufacturers engaging in a medical device business should familiarize themselves with the classifications and categorizations of medical devices regulated by the MPH Notifications 2020, including rules and procedures in relation to applications for and issuance of licenses, notifications or registration systems as regulated by the MPH Regulations 2020. Under the current interpretation of the FDA, any licenses, certificate of registration/notification issued under the Medical Devices Act cannot be transferred. As such, in cases of a change of control of a business, or merger and acquisition, licensing, notification/registration procedures may need to be repeated. If you require further information on the issues raise above, please contact the authors in the right-hand column.