Intellectual Property

# Guide to Medical Device Commercialisation in the Malaysia Market

## Introduction

During this Covid-19 pandemic, we frequently hear the term "ventilator" on the news as it is an important piece of medical equipment that assists in the case of respiratory failure due to Covid-19-related lung infections. It is undeniable that medical devices are important in safeguarding the well-being of the human population, and hence, they must be manufactured according to prescribed rules and regulations, and properly tested before they enter the market.

In Malaysia, medical devices are regulated by the Medical Devices Authority ("**MDA**"), which is a federal statutory agency under the Ministry of Health Malaysia to implement and enforce the Medical Device Act 2012 ("**Act**") and the Medical Device Regulation 2012 ("**Regulations**").

## Whether a Product is a Medical Device under the Medical Devices Act 2012

Under the Act, medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of –

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement or modification, or support of the anatomy or of a physiological process;
(d) support or sustaining life;
(e) control of conception;
(f) disinfection of medical device; or
(g) providing information for medical or diagnostic purpose by means of in vitro examination of specimens derived from the human body, which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means.

## Classification of a Medical Device

A medical device must then be classified and grouped. The classification of medical device is determined from:

(a) the manufacturer's intended purpose for the medical device; and
(b) a set of classification rules which can be found in the Regulations.

These rules will classify medical devices into one of four classes of medical devices. The purpose of risk-based classification to make sure that the regulatory controls apply to a medical device is proportionate to risk.

## Registration of Medical Device

A Manufacturer, or an authorised representative ("**AR**") appointed by a foreign manufacturer in the case of an imported medical device, needs to apply for medical device registration. A medical device must be registered with the MDA before it can be imported, exported or placed in the market.

A manufacturer must ensure that a medical device:

(a) conforms to the prescribed essential principles of safety and performance;
(b) is manufactured in accordance with good manufacturing practice; and
(c) is labelled, packaged and marked in accordance with the prescribed manner.

All medical devices shall be subjected to conformity assessment to demonstrate its conformity to the requirements specified in the Regulations. The manufacturer has to conduct conformity assessment and collect evidence of conformity.

Subsequently, a Registered Conformity Assessment Body ("**CAB**") must be appointed by the manufacturer to conduct the assessment on the conformity and validate the evidence of conformity. Thereafter, a certificate and a report of conformity assessment must be issued by the Registered CAB upon completion of conformity assessment.

An application for registration of medical device is filed with the MDA after the certificate of conformity and report of conformity are obtained. Such application must be submitted with the following documents:

(a) application fee;
(b) document or information as specified in forms determined by the MDA; and
(c) any other additional information on the application or sample of the medical device as may be required by the MDA.

## Licensing of Establishment

The Act has defined an establishment as a person who is either:

(a) a manufacturer;
(b) an AR appointed by a foreign manufacturer;
(c) an importer; or
(d) a distributor;

who is responsible for placing any medical device in the market, but does not include a retailer.

An establishment dealing with medical devices must apply for establishment licence under the Act. Such dealings include the import, export and placing of any registered medical devices in the market.

If the establishment is a manufacturer, it must conduct conformity assessment on quality management system based on ISO13485. An AR, an importer and a distributor shall conduct conformity assessment on quality management system based on Good Distribution Practice for Medical Devices (GDPMD).

Subsequently, a Registered CAB has to be appointed by the establishment to conduct the conformity assessment. Similarly, a certificate and a report of conformity assessment issued by the Registered CAB have to be obtained.

An application for an establishment licence is filed with the MDA. Such application must be submitted with the following documents:

(a) application fee;
(b) document or information as specified in forms to be determined by the MDA; and
(c) a certificate and a report of conformity assessment.

## New Regulations

There are two new relevant regulations which will come into operation on **1 July 2020.** They are as follows:

(a) the Medical Device (Advertising) Regulations 2019 which prescribe the matters relating to the contents and conditions for advertising of medical devices, and provide that approval must be obtained to advertise a registered medical device; and

(b) the Medical Device (Duties and Obligations of Establishments) Regulations 2019 which prescribe the manner, criteria, conditions and procedures relating to the post-marketing activities of medical device establishments.

## Conclusion

Businesses should be aware of all the compliance and approval requirements before manufacturing and/or putting medical devices for sale in the market, to avoid getting penalised. Failure to comply with the licensing or the registration requirement will attract a hefty penalty of a fine up to RM200,000.00 and/or imprisonment for a term not exceeding three years.

Visit our COVID-19 Resource Centre for views from our lawyers across the region on common issues and legal implications brought about by COVID-19. For specific inquiries, please reach out to your relationship partner or send an email to our COVID-19 Legal Team.

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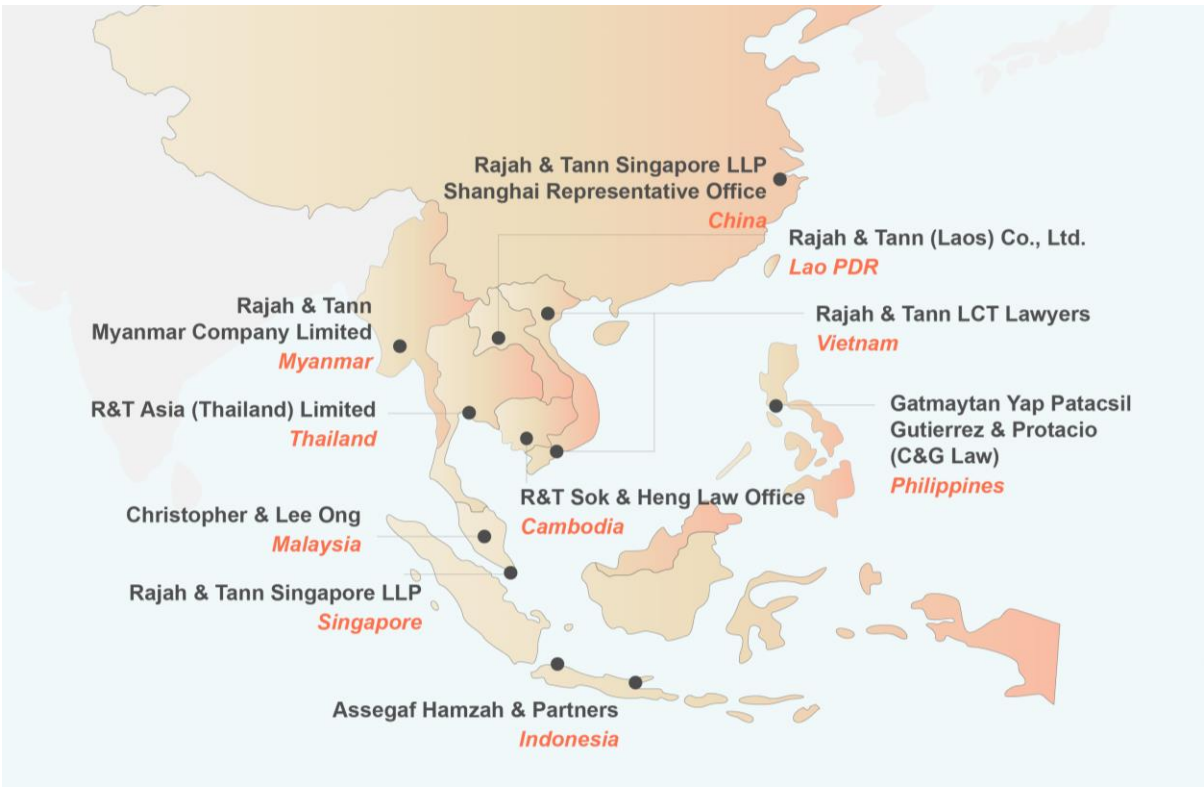


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