ASEAN MEDICAL DEVICE Directive ("AMDD") Agreement should be beneficial to Thailand's medical device business and standards

By

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An independent study paper submitted in partial fulfillment of the requirements for the degree of Master of Laws LLM. International Business Law

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ABSTRACT

Thailand has enacted the Medical Device Act 2008, which developed from the Medical Device Act 1988, to protect the public from substandard and dangerous medical devices, as well as advertisements for such devices. This Act has been established by the Thai Food and Drug Administration (hereinafter refer to as “TFDA”) in order to monitor, cover and control the manufacturers, importers, and distributors of medical devices within the territory of Thailand. The TFDA has duties under the law to enact regulations and monitor medical devices on their own initiative. Moreover, the TFDA also establishes and publishes the process by which entrepreneurs must register medical devices. The TFDA’s mission under the Act is to prevent circumstances that would result in harm to the public.

However, Thailand be part and parcel of the ASEAN Economic Community in the year 2015. ASEAN has set up a working schedule for the Medical Device Product Working Group (hereinafter referred to as “MDPWG”) and the ASEAN Consultative Committee for Standards and Quality (hereinafter refer to as “ACCSQ”) to brainstorm and draft the ASEAN Agreement on Medical Device Directive (hereinafter referred to as “AMDD”) to enforce and monitor medical devices in ASEAN member states. The objectives of this agreement are to promote cooperation, harmonization and mutual recognition of standards, and certification of medical devices. In 2015, the AMDD will be finalized and enforced, and the agreement will be honored and implemented by all ASEAN member states. Each member state may have to amend its internal laws, or enact new ones, to bring itself into compliance.

In conclusion, it can be asserted that the AMDD should be beneficial to Thailand. It can promote medical devices' business, and enhance the devices' standards. This will make the Thailand entrepreneurs more competitive, and this may be able to compete with other entrepreneurs in the world.
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Chapter 1
Introduction

1.1 Background and General Statement of the Problems

Every day sees dynamic new developments in science and technology. These significant innovations mean that human societies have new equipment, gadgets and devices that make our lives easier. These advances have affected our livelihood, entertainment, transportation and health. Everyone acknowledges that “health is more important than wealth.” Thus, new methods have been discovered to protect and expand human lifespans. In this regard, medical devices are an important means of helping people maintain their health and cure many diseases. However, medical devices are also able to injure or cause damage to people as well, if such devices are not good enough in their design or process. For this reason, governments should enact laws regarding medical devices to safeguard the public.

Thailand has enacted the Medical Device Act 2008 (hereinafter referred to as “MDA 2008”), which developed from the Medical Device Act 1988 (hereinafter referred to as “MDA 1988”), to protect the public from substandard and dangerous medical devices, as well as advertisements for such devices. This Act has been proposed by the Thai Food and Drug Administration (hereinafter refer to as “TFDA”) in order to monitor, cover and control the manufacturers, importers, and distributors of medical devices within the territory of Thailand. The TFDA has duties under the law to enact regulations and monitor medical devices on their own initiative. Moreover, the TFDA also establishes and publishes the process by which entrepreneurs must register medical devices. The TFDA’s mission under the Act is to prevent circumstances that would result in harm to the public.

MDA 2008 has clear definitions of medical devices and their manufacturers, importers and distributors in Thailand, but its implementation and enforcement are still ineffective. For example, a product such as an “elastic ankle support” is a medical device within the definition of MDA 2008, but it is not considered to be such a device in the opinion of the Thai FDA.
Another significant problem with MDA 2008 is that the Act has not clarified the quality standards for medical devices. Therefore, some entrepreneurs take advantage of the gap in the law to reduce their costs and earn more profits without concern for the health and safety of users and patients.

However, Thailand be part and parcel of the ASEAN Economic Community in the year 2015. ASEAN has set up a working schedule for the Medical Device Product Working Group (hereinafter referred to as “MDPWG”) and the ASEAN Consultative Committee for Standards and Quality (hereinafter referred to as “ACCSQ”) to brainstorm and draft the ASEAN Agreement on Medical Device Directive (hereinafter referred to as “AMDD”) to enforce and monitor standard for medical devices in ASEAN member states. The objectives of this agreement are to promote cooperation, harmonization and mutual recognition of standards, and certification of medical devices. In 2015, the AMDD will be finalized and enforced, and the agreement will be honored and implemented by all ASEAN member states. Each member state may have to amend its internal laws, or enact new ones, to bring itself into compliance.

The main issue of medical devices is that, at the present time, there is no universally accepted standard for them. Most countries around the world have their own standards, and their own laws for enforcing harmonization of standards, mutual recognition of standards and compliance. On the other hand, some countries have no standards at all. Nevertheless, the World Health Organization (“WHO”) has undertaken to create and promote universally accepted standards for medical devices by creating the Global Harmonization Task Force (“GHTF”) to perform this task. However, the GHTF’s contribution is only to provide a guideline standard for states to follow voluntarily. Consequently, the objective of achieving universally accepted standards is difficult, if not impossible, to achieve.

1.2 Hypothesis of the Study

There are also some attempts within the ASEAN region to standardize the definition of medical devices by establishing the AMDD, which calls for member states to define the standard of such products within their countries according to the

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rules and regulations of the AMDD. But the significant differences between the member countries make this difficult to accomplish. For example, ASEAN member states include developed countries, developing countries and underdeveloped countries with major differences in their economic and technological progress, expertise and funding. Consequently, while ASEAN has succeeded in reaching the AMDD Agreement, and agreed to implement it at the beginning of 2015, there are serious difficulties remaining.

Therefore, it is the hypothesis of this Individual Study that AMDD will enhance Thailand standards of medical device. However, there must be good preparation on Thailand local laws.

1.3 Objectives of the Study

The objectives of the study are to analyze the standard of medical devices as provided in the GHTF’s Guideline, the Community European Mark (“CE Mark”), the AMDD and MDA 2008, in order to understand their nature, their similarities and their differences, and to prove that the AMDD which is the ASEAN standards is enhance Thailand standard of medical device.

1.4 Study Methodology

1. To study and compare MDA 2008, AMDD and CE Mark for medical devices.
2. To study and analyze the AMDD.
3. To analyze the impact and enforcement of the AMDD.
4. To analyze the ways to improve MDA 2008.

1.5 Scope of the Study

This paper has focused on documentary research and analysis of the concept and theory of the standardized medical device. This research will analyze the MDA
2531 and MDA 2008, the AMDD and CE MARK regulations to identify ways to improve the MDA 2008.

1.6 Expectations of the Study

1. To provide information for medical device manufacturers, importers and distributors and prepare for implementation of the AMDD, which will be enforced beginning in the year 2015.

2. To assess the problems of MDA 2008 and the AMDD.

3. To understand the definition of “Medical Device” in MDA 2008, the AMDD and CE MARK.

4. To clarify the differences between MDA 2008, AMDD and CE Mark for medical devices.

5. To present the methods of protocol of the manufacturers, importers and distributors under the AMDD.

Chapter 2

Thailand and International Standards of Medical Devices

2.1 Thailand Medical Device Law and Regulation for Medical Device Standard

Prior to 1988 there was no specific law about medical devices and related equipment in Thailand. If a dispute arose as to whether a medical device had any harmful defects, the Ministry of Public Health would resolve the problem by applying the Medicine Act.

During that period, the manufacturers, importers and distributors of medical devices were rather free to advertise their medical products by informing the public about their benefits and efficacious. However, there was usually no evidence to support the claims made in the advertisements. If a device had an undesirable effects, it shall be subject to the provisions of the Medicine Act, as if it is a medicine.

In 1963, a Thai court ruled that certain medicinal bracelets, rings and necklaces were medicine under the definition contained in the Medicine Act because these medical devices were intended to prevent and cure prevent diseases. However, the application of the Medicine Act to medical devices and related equipment was inappropriate. The application of the Medicine Act, mutatis mutandis, to medical devices is not reliable because it is based upon interpretation of the Act which may be varied and inconsistent, and thus may cause confusion among interpreters.

The medical sciences have continued to make significant advances, and medical devices and other equipment intended to cure and protect humans have become integral features of daily life. The application of the Medicine Act to medical devices is no longer appropriate. It is necessary to enact specific laws to regulate medical devices. These laws should maintain safe standards to protect human health and livelihood, and prevent the manufacturer, importers and distributors from

2 Thai Food and Drug Administration, Instruction for the new medical device entrepreneur (Nonthaburi, 2012.) (Unpublished manuscript).
engaging in wrongful or dangerous conduct. This was the reason for the enactment of the Medical Device Act 1988 ("MDA 1988"), which entered into force on 24 April 1988.

However, the MDA 1988 was repealed when Thailand subsequently enacted the Medical Device Act 2008 ("MDA 2008"), which entered into force on 6 March 2008. There were four main reasons to enact the MDA 2008. First, the new Act was intended to improve the weak points of the MDA 1988, which had been in force for 20 years. Second, significant advancements had occurred in the area of medical devices. Third, efforts to reform government services led to changes in the system for monitoring and controlling medical device makers. Fourth, the government desired to upgrade the quality of medical devices manufactured in Thailand to meet international standards. These four aims of the new Act were expected to provide additional protection for consumers.

MDA 2008 classifies medical devices into categories similar to those defined in MDA 1988. But Article 4 contains some additional relevant definitions of medical devices. The first category is medical devices for which a manufacturer or importer must obtain a license (hereinafter referred to as "LMD"). The Act contains rules, procedures and conditions for the manufacture and import of LMDs. Entrepreneurs, manufacturers or importers of LMDs need to receive approval from the regulator under the Act, which is the Ministry of Public Health (hereinafter referred to as the "MPH"). The MPH is charged with publishing notice to the public regarding which medical devices must obtain such approval. To date, the MPH has published such notification regarding condoms, surgical equipment, diagnostic reagents and test kits related to HIV, and contact lenses.

These medical devices must be of the appropriate standard and quality under the law. Although MDA 2008 does not define the required standard and quality of medical devices, it gives the MPH authority to establish standards for categories of medical devices. This means that entrepreneurs, manufacturers and importers must obey the notifications issued by the MPH.

The second category is medical devices for which a manufacturer or importer must declare the specifications, procedures and conditions for manufacturing or importing the device (hereinafter referred to as "SMD"). They must disclose the specifications to the MPH before engaging in commercial transactions. The MPH has
devices,\textsuperscript{4} including certain types of medical devices that are prohibited from being manufactured, imported, sold or advertised.\textsuperscript{5}

notified the public of several medical devices that it has assigned to this category, including equipment or devices related to physical therapy, alcohol meters, silicone breast implants, and equipment or devices for lifting or tightening breasts.

The third category is called “General Medical Devices” (hereinafter referred to as “GMD”). Manufacturers of GMD must register their businesses before manufacturing such devices for commercial transactions. And importers of GMD must obey the published notifications of the MPH regarding the import of these devices into Thailand.

\textsuperscript{4} Article 4 of MDA 2008 contains the following definitions:

“Medical device” means:

(1) an 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 one or more of the specific purpose(s) of:

(a) clinical practice of medicine, medical practice, nursing and midwifery practice, dental practice, medical technology practice, physical therapy practice and veterinary practice under the laws governing the respective professions or other medical or public health practices as prescribed by Notification of the Minister;

(b) diagnosis, prevention, monitoring, treatment, alleviation or cure of human or animal disease;

(c) diagnosis, monitoring, treatment, alleviation or cure of human or animal injury;

(d) investigation, replacement, remedy, modification, or support of the anatomy or of a physiological process of human or animal body;

(e) supporting or sustaining life of human being or animals;

(f) control of conception or promotion of human or animal fertility;

(g) aid or compensation for disabled or handicapped of human or animal;,
(h) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human or animal body;

(i) disinfection or sterilization of a medical device;

(2) an equipment or constituent of an instrument, apparatus, machine, product or object under (1); (3) other instrument, apparatus, implement, machine, product or object as prescribed by Notification of the Minister. The achievement of its primary intended action stated in (1) which occurs in or on the human or animal body must not be the result of a pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

"Manufacture" means to make, assemble, devise, repackage separately or collectively, improve, transmute, modify or sterilize.

"Distribute" means sell, dispense, dispose of, exchange, lend, lease, lease on hire purchase, or transfer of right or possession to another person for commercial purposes including possession for sale.

"Import" means to bring or order into the Kingdom.

"Export" means to bring or send out of the Kingdom.

"Advertisement" means an act by any means which exposes the public to sight, sound or acknowledgment of a statement for commercial purposes and shall also include a sales promotion.

"Licensee" means a licensee under this Act; in the case where the licensee is a juristic person, it shall also include a person appointed or designated by the juristic person to administer operations.

"Specifications provider" means the recipient of a specifications declaration receipt under this Act; in the case where a juristic person is the recipient of a specifications declaration receipt, it shall also include a person appointed or designated by the juristic person to administer operations.

"Establishment registrant" means the recipient of a registration certificate for an establishment under this Act; in the case where the recipient of a registration certificate for an establishment is a juristic person, it shall also include a person appointed or designated by the juristic person to administer operations.
MDA 2008 imposes certain duties upon the manufacturers, importers and sellers of medical devices. Manufacturers must apply for a license to manufacture general medical devices and detailed medical devices. Importers must apply for a license to import general medical devices and detailed medical devices. Sellers must apply for a license to sell general medical devices and detailed medical devices.

Sections 56 through 60 of MDA 2008 also contain provisions regulating the advertising of medical devices offered for commercial sale, including prohibiting their direct sale and specifying certain diseases, such as paralysis and palsy, that cannot be the subject of advertising. The Act provides that the claims made in advertising for

"Licensor" means the Secretary-General of the Food and Drug Administration or a person designated by the Secretary-General of the Food and Drug Administration.

5 The following medical devices are prohibited from being manufactured, imported or advertised:

1. Counterfeit medical devices
2. Medical devices not in conformity with standards
3. Medical devices unsafe for use
4. Medical devices manufactured or imported that do not conform to a license or declared specifications
5. Medical devices for which a license or specifications declaration has been revoked under section 70

Anyone who manufactures, imports, distributes or advertises such medical devices shall be subject to imprisonment for a term not exceeding five years or a fine not exceeding five hundred thousand baht, or both.

6 Section 56 Medical Device Act 2008. No person shall advertise a medical device under section 6(11) or a medical device under section 46.

Section 57 Subject to section 56, the advertisement of a medical device must first be licensed by the licensor. A license shall be valid for a period of not more than three years as from the date of issue. A license application, licensing and license validity period under paragraph one shall be in accordance with the rules, procedures and conditions prescribed by the licensor provided that the licensor may also prescribe
medical devices must not be overstated or exaggerated. It also prohibits the offering of prizes, lucky drawings or other similar promotions based on chance to boost the sales of medical devices. Anyone violating these regulations is subject to being imprisoned or fined.

specific conditions of advertisement and restrictions on advertising media. The provisions of section 33 shall apply *mutatis mutandis* to the consideration of advertisement licensing or the consideration of a change, amendment or modification of an item in the advertisement license.

Section 58 In the case where an advertisement license is lost, destroyed or damaged, the advertisement licensee shall submit an application for a replacement within fifteen days as from the day of knowledge of the loss, destruction or damage. An application for a replacement advertisement license shall be in accordance with the rules, procedures and conditions prescribed by the Secretary-General as published in the Government Gazette.

Section 59 A medical device advertisement must:

(1) not be a false or exaggerated representation of the benefits, quality, quantity, standard, constituent or origin of the medical device;

(2) not represent any person’s endorsement or commendation of the medical device’s benefits;

(3) not offer a prize conditional upon the taking of chance by any means;

(4) not represent benefits in regard to the prevention, treatment, relief or cure of a disease or symptom of a disease of which advertisement is prohibited under a Notification published by the Minister;

(5) Not contain a misleading statement on an essential substance in relation to the medical device.

Section 60 In the case where the licensor finds that an advertisement is in violation of section 57 or section 59, the licensor shall have the power to issue any of the following orders: (1) to make changes to the content or means of advertisement; (2) to prohibit the use of certain statements or means appearing in the advertisement; (3) to suspend the advertisement. In an order under paragraph one, the licensor may also order the advertisement of correct information.
Sections 77 through 80 of MDA 2008 define civil liabilities under the Act. These provisions impose liability on manufacturers, importers, distributors and users of medical devices for damage incurred in the use of those devices, unless they can prove that such damage resulted from force majeure and not from any defects in such devices or from the mistakes of the user. The prescription period is three years from the acknowledgment of the damage or the charging of those persons from whom compensation is sought, but it should not exceed ten years from when the damage occurred.

However, MDA 2008 does not prescribe any standard regulating how

7 Section 77. A manufacturer, importer or vendor of medical device must be responsible for injury arising from the use of medical device unless it can be proven that the injury was caused by force majeure, or was not caused by a defect in the medical device, or was caused by the fault of the injured person.

Section 78. A person who uses or enables the use of medical device on another person thereby causing death or injury to the body or health must be responsible for the such person’s injury arising from the use of such medical device unless it can be proven that precautions have been taken in conformity with technical standards, or that the injury was caused by force majeure, or was caused by the fault of the injured person. The provisions of paragraph one shall apply to psychological injury arising as a consequence of injury to the injured person’s body or health.

Section 79. The limitation period of a claim for damages under this Chapter arising from a medical device or use of a medical device shall expire upon the lapse of three years as from the day the injured person acquired knowledge of the injury and 30 knowledge of the person liable for damages, provided that such period shall not be more than ten years as from the day the injury occurred due to the medical device or use of the medical device.

Section 80. A liable person under section 77 or section 78 who has paid damages to the injured person shall have the right to seek indemnification from a person who has contributed to the cause of injury. The right to seek indemnification shall be exercised within three years as from the day of payment of damages. The person seeking indemnification, however, may only seek indemnification for the proportion exceeding his/her own liability.
manufacturers of medical devices should provide consumers with information regarding their qualities and capabilities, such as the types of labels or technical attachments which the manufacturers should provide. There are no rules imposing safety standards to reassure consumers, no statement of the essential principles governing medical devices, and no means of conformity assessment. These shortcomings cause many problems, such as the marketing of unqualified or unsafe products that cause harm to the public.

2.2 Introduction for International Medical Devices Standards

According to my researched and studied found that at present, the medical device regulations in any given country are different from those in other nations. Some countries have specified the definition of such devices in their domestic legislation, while others have not. Still other countries have no medical device legislation at all.

In the year 2012, global revenue from the sale of medical devices reached $321 billion. It is estimated that this revenue will increase by five to nine percent by the year 2017, reaching $398 billion.\(^8\) This increase in revenue should motivate new entrepreneurs to start businesses relating to medical devices in the global market.

New entrepreneurs who would like to start medical device businesses should learn and follow the relevant regulations pertaining to medical devices in their respective countries. On the other hand, exporters of medical devices need to acknowledge and follow the medical device regulations in the countries to which they will export their devices. Yet some countries do not have any laws or regulations regarding medical devices in their own territories. Thus, there are no international standards by which to monitor and control medical devices around the world.

2.3 The Three Core Pillars of Medical Device Regulation

From my researched and studied, every medical device regulation in the world has three core pillars: a Quality Management System (hereinafter referred to as “QMS”), Safety and Effectiveness, and a Vigilance and Post-Market System, as shown in the following illustration:

Three core pillars of medical device regulation

First, QMS is a system for managing the quality of medical devices. It is intended to reduce, and eventually eliminate, non conformance with applicable standards, and to meet customers’ expectations efficiently and cost-effectively. A QMS can be created by a provision of law, by a regulation or by other means. In Thailand, the QMS is defined in MDA 2008, but in the European Union, the QMS is described in the CE Mark for medical devices. The ASEAN Medical Device Directive Agreement also establishes a QMS with which every member will have to comply once the agreement becomes enforced. In addition, the International Standard Organization (hereinafter referred to as “ISO”) has a developed a standard for QMS.

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for medical devices known as ISO 13485.\textsuperscript{10} Entrepreneurs who intend to manufacture and sell medical devices may apply the QMS most suitable for their own products.

Second, Safety and Effectiveness is a registration process by which regulatory authorities may consider and approve medical devices pursuant to a QMS. The process differs in every country, depending on each country’s policies. For example, in Japan, medical devices must be registered in order to assure the quality and safety of such devices. This approach to risk management may require up to two years before approval of the registration. In contrast, Thailand has no requirement of risk management, and the time frame for registration is shorter than in Japan. Some countries require a clinical trial of medical devices to determine whether they are safe for public use before approving their registration. Regardless of the particulars, this risk management and registration process is essential for quality assurance and public safety.

Finally, a Vigilance and Post-Market System (hereinafter referred to as “VPS”) is a process by which the regulator authorized by the QMS monitors whether medical devices already introduced into the consumer market have the quality claimed for them, or whether they pose any risks for their users. The QMS can be enforced through the legislation of the state concerned. Consequently, the effectiveness of a country’s QMS will depend on the domestic legislation of that state, which may be different from the laws found in other states.

\section*{2.4 Global Harmonization Task Force ("GHTF")}

The World Health Organization (hereinafter referred to as “WHO”) and the International Medical Device Regulators Forum, a voluntary organization comprised of representatives of medical device regulators from countries around the world (hereinafter referred to as “IMDRF”), have attempted to harmonize the national legislation of various states to bring them into conformity. The IMDRF’s main instrumentality in this effort is the Global Harmonization Task Force (hereinafter

\textsuperscript{10} ISO 13485:2003, Medical devices, Quality management systems requirement.
referred to as “GHTF”). The IMDRF or GHTF will establish standards for medical devices to serve as a model law that states may follow when enacting laws regarding standards for medical devices.

The GHTF encourages the convergence of regulatory systems for medical devices at the global level to facilitate trade while preserving the right of participating members to protect public health by the most suitable regulatory means. The primary goal of the GHTF is to protect the health of users of medical devices. The GHTF has tried to create guidelines for countries to use when developing their own medical device laws so that each will employ the same standards. Some countries have adopted the GHTF’s model law as their own domestic law when enacting legislation suitable for their own circumstances.

The fundamental keys of the GHTF guidelines are to control risks before launching medical devices in the marketplace, and to regulate and monitor those devices afterward. These risk control procedures also cover the devices’ usage cycle. Other important factors include the use of compatible definitions, the registration of manufacturers and the listing of medical devices to assess the result of their usage, certificates to identify the usage cycle, and labels providing necessary information for users. All of these elements should be adjusted to make them compatible with the rules and regulations pertaining to medical devices in each

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13 According to the GHTF guidelines, the cycle of medical device usage consists of:

1. Pre-market: The starting point, from the design, development, production, packaging, and labeling of medical devices.

2. Placement in the market: The process of introducing medical devices into the market, consisting of advertising and sale.

3. Post-market: The use of medical devices after their launch into the market, and their return if there is any error or defect in such devices.
ASEAN member state. Each country is able to appoint the authority to conduct such operations within their own country.

Moreover, the GHTF has provided a definition of medical devices,\textsuperscript{14} together with some related wording, to be used as a master template and adjusted for use in

\textsuperscript{14} ‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

In Vitro Diagnostic (IVD) Medical Device

‘In Vitro Diagnostic (IVD) medical device’ means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
each country. They have also categorized medical devices by grouping them according to their risks of usage:

- **Class A**: Low risk from using medical devices.
- **Class B**: Low to medium risk from using medical devices.
- **Class C**: Medium to high risk from using medical devices.
- **Class D**: High risk from using medical devices.

### 2.5 Medical Device Standards around the World

Australia has adopted the GHTF Guidelines for monitoring medical devices for use in their own territory. The Australian authority responsible for regulating medical devices is the Therapeutic Goods Administration, and the law that regulates medical devices is the Therapeutic Goods Act of 1989\(^{15}\), which contains a definition of the term “medical device”\(^{16}\) and a classification of medical devices. Australia has

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Note 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Note 2: In some jurisdictions, certain IVD medical devices may be covered by other regulations.

\(^{15}\) The Therapeutic Goods Act of 1989.

\(^{16}\) medical device is:

- any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
  - investigation, replacement or modification of the anatomy or of a physiological process;
separated medical devices into five classes: Class I, which involves the lowest risk; Class IIa; Class IIb; Class III; and Active Implantable Medical Devices (“AIMD”), which involves the highest risk. On the other hand, In-Vitro Diagnostic Medical Devices (“IVD”) are separated into four classes: Class I, Class II, Class III and Class IV. These classes are divided based on the public health risk, meaning that Class I involves the lowest risk and class IV involves the highest risk.

The medical device law in the United States\textsuperscript{17} is significantly different from the GHTF Guidelines. The main difference between U.S. law and the GHTF Guidelines is that the U.S. definition of medical device in much broader in scope. The U.S. also classifies medical devices differently than the GHTF Guidelines. The United States is the largest medical device market in the world, with GDP per capita in 2009 totaling $44,871.78. The U.S. Food and Drug Administration’s Center for Devices and Radiological Health is the regulatory authority, and it has issued a definition of the term “medical device.”\textsuperscript{18} It classifies medical devices based on their risks and has divided them into three classes, as follows:

\begin{itemize}
  \item - control of conception;
  \item and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
  \item a) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or
  \item b) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or
  \item b. an accessory to such an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).
\end{itemize}

\textsuperscript{17} Federal Food Drug & Cosmetic Act 2010.

\textsuperscript{18} medical device is:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:"
Class I, General Controls, are the lowest risk medical devices. This class has minimal potential to harm the user and is often simple in design. Examples include elastic bandages and examination gloves.

Class II, Special Controls, are moderate risk medical devices. Examples of devices in this class include powered wheelchairs and surgical drapes.

Class III are the highest risk medical devices. This class is subject to the strictest regulatory requirements.

The medical device law in Japan is similar to the GHTF Guidelines. Japan is one of the largest producers of medical devices in the world, with GDP per capita in 2009 totaling $39,864.35. The Pharmaceutical and Food Bureau and the Pharmaceutical and Medical Devices Agency (hereinafter referred to as “PMDA”), acting on behalf of the Ministry of Health, Labor and Welfare (hereinafter referred to as “MHLW”), is the regulatory authorities responsible for announcing policy regarding medical devices and for the registration of medical devices. The Japanese law regulating medical devices is called Japan’s Pharmaceutical Affairs Law\textsuperscript{19}. It contains a definition of the term “medical device” and a classification of medical devices. The Japanese classification of medical devices is very strict and complicated. It separates medical devices into four categories: Class I, General Medical Devices; Class II, Controlled Medical Devices; and Classes III and IV, Specially Controlled Medical Devices. Conversely, IVD medical devices are only classified as either Class I or Class IV within the Japanese categories.

• recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

• intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

• intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

\textsuperscript{19} Japan's Pharmaceutical Affairs Law 2009.
Canada, which had GDP per capital in 2009 totaling $39,795.41, has adopted the GHTF Guidelines to monitor medical devices in their territory. However, there are some significant differences, because Canada defines medical devices differently than the GHTF Guidelines. The regulatory authority authorized to oversee medical devices in Canada is the Medical Devices Bureau of the Therapeutic Products Directorate, a division of the Health Products and Food Branch of Health Canada. The law regulating medical devices in Canada is the Medical Devices Regulations SOR/98-282. This law contains a definition of the term “medical device”, and a classification of medical devices. Canada classifies medical devices and IVD devices separately. However, both types of medical devices are classified based on the risk associated with their use. They are divided into four classes; Class I is the lowest risk, and Class IV is the highest risk.

India is one of the four largest markets for medical devices in Asia, and ranks in the top 20 of medical device markets worldwide. In the past, India had no laws to specifically regulate and monitor medical devices. Any medical devices made elsewhere in the world could be freely imported to India without any regulatory control. During that period, India construed its regulations regarding drugs to also

20 Medical Devices Regulations SOR/98-282.

21 Canada defines “medical device” as follows:

“active device” means a medical device that depends for its operation on a source of energy other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device. (instrument actif)

“active diagnostic device” means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity. (instrument diagnostique actif)

“active therapeutic device” means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating an illness or injury or a symptom of an illness or injury.
apply to medical devices, and classified medical devices into two classes: lifesaving medical equipment and non-life saving medical equipment. However, India developed its own legislation and enacted the Medical Device Regulation Bill of 2006\textsuperscript{22}, which entered into enforcement in 2009. The Department of Health under the Ministry of Health and Family Welfare has the authority to regulate and monitor medical devices within India. Under this new law, India has defined\textsuperscript{23} and classified medical devices based on the GHTF Guidelines.

\textsuperscript{22} Medical Device Regulation Bill of 2006.

\textsuperscript{23} 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

i) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the–diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

- investigation, replacement, modification, or support of the anatomy or of a physiological process,

- supporting or sustaining life,

- control of conception,

- disinfection of medical devices,

- providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;

p) 'Medical device intended for clinical investigation' means any medical device intended for use by a duly qualified medical practitioner or by a person authorized to use the same by virtue of his professional qualifications for conducting investigations in an adequate human clinical environment;
q) ‘medical device testing laboratory’ means any medical device laboratory or Institute established by the Central or a State Government or any other agency and accredited to the National Accreditation Board for Testing and Calibration Laboratories (NABL) or an equivalent accreditation agency and/or recognized by MDRA;

r) ‘misbranded product’ means an article of medical device of any of following categories where it purports, or is represented to be, or is being –

(1) offered or promoted for sale with false, misleading or deceptive claims either upon the label of the package, or through advertisement, or where it is sold by a name which belongs to or is misleadingly similar to another article of medical device or product ; or offered or promoted for sale under the name of a fictitious individual or company claiming to be the manufacturer or the producer of the article as borne on the package containing the article or the label on such package;

(2) where it is sold in package which have been sealed or prepared by or at the instance of the manufacturer or producer bearing his name and address but the article is actually an imitation of, or is a substitute for, or resembles in a manner likely to deceive a person to believe that it is another article of medical device marketed under the name under which it is sold, and is not plainly and conspicuously labeled so as to indicate its true character; or the package containing the article or the label on the package bears any statement, design, or device regarding structure of the product contained therein, which is false or misleading in any material particular, or if the package is otherwise deceptive with respect to its contents; or the article is offered for sale as the product of any place or country which is false;

(3) if the article with in the package contains any component which is not mentioned in the declarative label, or the package is not labeled in accordance with the requirements of this Act, or contravenes any of the provisions of this act, or the rules and regulations made thereunder; or is offered for sale for special uses, unless its label bears such information as may be specified by rules and regulations as might be prescribed , concerning its components in order sufficiently to inform its purchaser as to its value for such use;
2.6 The Main Problem with the International Standard for Medical Devices

A comparison of the rules and regulations governing medical devices in a variety of leading countries shows that there are differences, either in the terms used in the definitions or in the categories of medical devices. Thus, there is no universal standard employed to define and regulate such products internationally. Although the GHTF has tried to encourage the development of a consistent standard by providing a master template of laws, rules and regulations known as the GHTF Guidelines, there is no requirement that countries adopt this template. It is only a pattern for countries to adopt voluntarily, and it can be amended or adjusted for use in each particular country. As a result, there are differences in the standards for medical devices around the world, which is the chief obstacle that must be overcome to encourage every country to use a single, universal standard.

The problem of different standards for medical devices affects the level of trust consumers have in the quality and reliability of such products in the international marketplace. Every country has their own rules and regulations based on their own legal traditions, social beliefs, economic conditions and other factors. Some countries have laws or rules and regulations that are very strict, and it is therefore to be expected that the quality and safety standards of the medical devices made in those countries will be higher. It is logical to conclude that the higher the standard for medical devices, the greater consumer confidence in and demand for those devices will be. Therefore, countries that have the strictest laws or rules and regulations are able to export more of their medical devices and obtain greater sales revenue. They are also able to charge higher prices because of the greater reputation of their devices. Although the prices may be high, demand for them remains strong because safety is a key selling point of medical devices. No matter how high the price, consumers are willing to pay more for the perceived safety and effectiveness of medical devices manufactured to a high standard.

On the other hand, there are still some countries that do not yet have efficient laws or rules and regulations to define and control medical devices in their countries. These countries will encounter problems because their products are manufactured under weaker standards, or under no standards at all. This leads to a lack of
confidence in the use of such products, both in their own country and in others. They will struggle to sell products in their country or to export them to the global market. Due to this lack of confidence, their products cannot compete with those manufactured in countries with high standards for medical devices. Although their weaker standards may enable them to produce medical devices at lower cost, they find it difficult to market and sell such devices because of the lack of consumer confidence.

2.7 The Means to Resolve the Problem of the International Standard for Medical Devices

Due to the aforementioned problems, each country has tried to amend their laws to ensure high safety standards. Some countries have amended their laws using the laws of certain leading countries as models. Other countries have used the GHTF Guidelines as their yardsticks. For instance, Indonesia did not previously have any laws regarding the standard for medical devices in their country, but they subsequently used the GHTF Guidelines as the model to enact such standards.

Moreover, countries that have already enacted strict laws or rules and regulations frequently revise their rules to keep up with the current situation in their countries. For example, Japan, the leading manufacturer of medical devices, is currently in the process of revising their rules and regulations to provide more safety for consumers. Because medical science and technology is constantly progressing, it leads to the launching of useful new products almost every day. Some of these products may not fit within any of the previous definitions contained in the established rules. In addition, some manufacturers have tried to circumvent the existing standards by means of advertising.

Thus, GHTF has tried to encourage every country to enact the same standard for medical devices all over the world. They inform every country that it is necessary to have laws or rules and regulations to define the standards for medical devices. However, GHTF's standard is only a guideline for countries to follow, and it contains no enforcement mechanism. GHTF does not have the power to force any country to conform. This is why many countries still do not consider it necessary to
do anything about their standards for medical devices. Moreover, there is no
organization other than GHTF that handles the standards for such products. These
obstacles are the main reason that no one has been able to make the standard for
medical devices the same in every country.

2.8 Medical Devices in the European Union

Although most countries have different laws, rules and regulations based on
their unique social and economic conditions and other factors, the European Union
("EU") is the only group of countries that has adopted the same laws. The EU has
issued a standard for commercial products called the CE Mark, which is intended to
prevent any risks that may occur to people living within the EU region. The 28
member countries of the EU have reached a consensus to use CE Mark as the safety
standard for such products within their region. In addition to those EU countries, there
are some other non-member countries that have adopted CE Mark for use as the
standard for such products in their countries.

CE Mark also covers certain medical devices, which is known as “CE Mark
for Medical Devices.” It establishes a standardized process using test results to
provide proof of quality. It is designed to control risks throughout the lifespan of
medical devices, from their initial design through their end-use by consumers. It also
regulates the manufacturers, requiring them to produce their products under the ISO
standard, to conduct safety tests and provide evidence of actual use, and to report any
unintended or adverse consequences that may affect patients or other users due to the
use of such products. This regulatory scheme leads to having the same standard for
medical devices throughout the EU. CE Mark is also accepted in other countries
around the world, since any medical devices approved under, and marked or labeled
with, the CE Mark are guaranteed to be safe when used as intended.

CE Mark for Medical Devices (hereinafter referred to as “CE Mark”) is the
standardized regulation and symbol of medical device safety in the EU. Moreover, CE
Mark not only act the standard for medical devices, but also regulates other products
within the territory of the EU. CE Mark establishes the classifications of medical
devices such as pressure equipment, in vitro diagnostic devices, and implantable
devices. Any products obtaining approval may be labeled with the CE Mark, which demonstrates that they are safe. These directives constitute the European Union law governing medical devices, by which its members must abide. Not only has the CE Mark been accepted by EU members, but its reputation has been recognized worldwide. This chapter will explain Directive 93/42/EEC and 2007/47/EC, because they clearly define general medical devices for EU members.

While EU members are obligated follow the CE Mark regulations, countries outside the EU can also get the CE Mark applied to their own products if they have met all of its requirements. Once this has been verified, manufacturers of medical devices located outside the EU may place their products bearing the CE Mark into the EU markets.

As there are some similarities between the CE Mark and other medical device regulations discussed in this thesis, this chapter will first consider whether medical devices are “products” within the meaning of Directive 93/42/EEC. Article 1 of the Directive defines the term “medical device” as follows:

“medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of;

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,”

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;”

According to this definition, medical devices include such things as syringes, condoms, infusion pumps, massage chairs, implant fangs, and implant bone respirators. In the EU, medical devices are grouped according to the purposes for
which they will be used, namely general purpose, in vitro diagnostic purpose, medical purpose, and implanting purpose. A manufacturer should have clear objectives as to how its devices will be used, and should design their products in accordance with the relevant standard set forth by the Directive.

According to Annex IX of Directive 93/42/EEC, the classifications of medical devices covered by the CE Mark regulations are separated into three classes:

Class I are general medical devices that can be divided into two categories, those not requiring sterilization and those requiring sterilization.

Class II devices are divided into two categories, those intended for short-term implantation into the body and those intended for long-term implantation.

Class III are medical devices with indefinite implementation involving high risk that can be implanted into the body permanently, or that involve the nervous system or circulatory system.

The classifications of medical devices under the CE Mark regulations take several factors into consideration, including the duration of use, which is separated into three categories:

Step 1 is transient use, lasting less than 60 minutes;

Step 2 is short-term use, lasting more than 60 minutes but not more than 30 days; and

Step 3 is long-term use, involving continuous use for more than 30 days.

The Directive also requires the formation of an organization, called the Notified Body, to approve medical devices and monitor their compliance with the standards. The Notified Body consists either of personnel from the relevant government authority, or of any private firm appointed by the government to take responsibility for the consideration and registration of medical devices within the EU. The Notified Body is responsible for monitoring the standard of such medical devices. If a device is approved, the Notified Body will issue a standardized certificate and allow such device to be labeled with the CE Mark.

Annex II through Annex VII of the Directive establish the Conformity Assessment Procedure and contain regulations which govern the procedure for verification and approval of medical devices.

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Chapter 3
ASEAN Member's State Legislation

3.1 Introduction

Through a member of ASEAN instruments, such as ASEAN Vision 2020 (1997), Bali Concord II (2003), ASEAN Economic Community Blueprint (2007), and the ASEAN Charter (2008), the Asean Economic Community (AEC) is scheduled to achieved by the end of 2015. In so far as medical devices are concerned, some ASEAN countries have their own laws or rules and regulations governing medical devices in their territory using the GHTF Guidelines as a template, while others have laws or rules and regulations derived from other countries. Still other countries do not have any laws or rules and regulations governing medical devices at all. Such differences in standards result in the circumstances discussed below.

3.2 ASEAN Members Having Laws or Regulations Establishing Standards for Medical Devices

**Singapore:** Medical devices in Singapore are regulated by the Centre for Medical Devices (CMD), an organization under the control of the Health Sciences Authority (HSA). The CMD is responsible for supervising all medical devices manufactured in Singapore, either through a registration procedure or by testing and monitoring the devices. The CMD also has authority to commence legal proceedings against those who violate the 2007 Health Product Act.

Prior to 2007, there was little regulation or monitoring of medical devices in Singapore. However, the enactment of the 2007 Health Product Act gave the CMD more authority to regulate medical devices. In drafting this Act, Singapore worked together with several leading medical devices organizations from around the world, such as the U.S. Food and Drug Administration and the European Medical Devices

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Agency. The Act follows the master template from the GHTF Guidelines for medical devices, incorporating both the definitions and the categories of medical devices.

**Malaysia:** Medical devices in Malaysia are regulated by the Medical Devices Bureau (MDB), an organization under control of the Ministry of Public Health. The MDB was established in 2005 and is responsible for regulating and monitoring the production of medical devices in accordance with the law. The authority of the MDB derives from the Medical Device Bill26, which was most recently revised in 2008. Malaysian law is based on the GHTF Guidelines and establishes the essential principles governing medical devices, such as categorizing medical devices and establishing rules for safety, risk management, labeling and packaging, and assessment of conformity with applicable standards. Moreover, the MDB is also responsible for developing appropriate standards for medical devices that conform to the ISO and AEC standards, and manufacturers of medical devices in Malaysia are obligated to comply with such standards. The definitions, categories, and other rules and regulations governing medical devices in Malaysia are all based on the GHTF Guidelines.

**The Philippines:** Medical devices in the Philippines are subject to Republic Act No. 3720 (the Food, Drug and Cosmetics Act)27, which was first enacted in 1963 and revised in 1987. In 1992, Memorandum Circular 007s 1992 indicated that some medical devices needed to be registered. The two authorities responsible for regulating medical devices in the Philippines under the Act were the Bureau of Food and Drugs (BFAD) and the Bureau of Health Devices and Technology (BHDT). The BFAD was responsible for the registration of the developers and manufacturers of medical devices, while the BHDT was responsible for the registration of medical devices.

In 2009, the Food, Drug and Cosmetics Act was revised in accordance with a plan to promote the further development of medical devices in the Philippines over the next five years. The name of the revised act was changed to the Food and Drug

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26 Medical Device Bill 2008.
Administration (FDA). Medical devices are now controlled by the Centre for Device Registration, Radiation Health and Research. The revised Act is based on the GHTF Guidelines with respect to both the definitions and the categories of medical devices.

**Vietnam:** Medical devices in Vietnam are regulated by the Department of Medical Equipment and Health Works (DMEHW), which operates under the control of the Ministry of Public Health. The Ministry of Science and Technology (MOST) is also involved in any proceedings involving rules and regulations related to medical devices in the country.

Vietnam has not adopted any comprehensive definition of medical devices, nor have they attempted to categorize medical devices. They only define certain medical devices used in or imported into the country. Moreover, the procedure for registration of medical devices produced in the country is different from the procedure for registration of medical devices imported into the country. Medical devices manufactured in Vietnam must be registered with the DMEHW, while importers of medical devices must obtain a license. Moreover, Vietnam law did not comply with the GHTF Guideline.

**Indonesia:** Indonesia has had its own specific law regulating medical devices since 1976. This law has been constantly revised and developed. The latest enactment, called Ministerial Regulation No. 1184/Menkes/Per/X/2004\(^{28}\), is enforced by the Directorate of Regulation for Production and Distribution of Medical Equipment (Dirjin Pom), which is under the control of the Ministry of Public Health. Dirjin Pom is responsible for issuing licenses to manufacturers and distributors, assessing medical devices before their launch into the market, monitoring the devices after marketing, and assessing any advertising or promotions related to medical devices.

Indonesia has its own definitions of medical devices. The Indonesian authorities maintain that their definitions were adopted from the GHTF Guidelines, but they are not exactly the same as GHTF’s. Indonesia has adopted the U.S. system

\(^{28}\) Ministerial Regulation No. 1184/Menkers/Pex/X/2004.
of categorizing medical devices, which groups medical devices according to the risks of usage:

- **Class I**: General control of medical devices – Low risk
- **Class II**: Special control of medical devices – Medium risk
- **Class III**: Special control of medical devices – High risk

**Thailand**: The law regulating medical devices in Thailand is called the Medical Devices Act 2008 (MD 2008). The Act designates the Medical Device Control Department as the responsible authority responsible under the Act. It operates under the supervision of the Ministry of Public Health. Thailand uses its own definitions of medical devices, which are contained in Section 4 of the Act; moreover, the categories of medical devices found in the Act are completely different from those used by any other country in ASEAN. Medical devices in Thailand are classified into three categories: general medical devices, descriptive medical devices and licensed medical devices. The Ministry of Public Health is responsible for identifying the category to which any particular medical device belongs.

### 3.3 ASEAN Members without Laws or Regulations Establishing Standards for Medical Devices

Laos, Brunei Darussalam, Cambodia and Myanmar do not have any specific laws regulating the standards for medical devices in their countries. They apply certain international laws related to medical devices when appropriate. Each country has designated an authority responsible for regulating medical devices, as follows:

- **Laos**: the Food and Drug Department for consumable medical devices and the Curative Medicine Department for durable medical equipment (both agencies are under the control of the Ministry of Public Health)

- **Brunei Darussalam**: the Ministry of Public Health

- **Cambodia**: the Department of Food and Drugs
Myanmar: the Food and Drug Administration

Brunei Darussalam and Laos do not have any laws or rules and regulations requiring manufacturers of medical devices to register their devices or obtain permission to market them. Myanmar’s National Medicine Act provides that condoms, syringes and blood bags must be registered. Cambodian law provides that any medical devices imported into the country must be certified by the exporting country as to their source of origin.

3.4 The Method for Developing a Standard for Medical Devices within ASEAN

ASEAN consists of Brunei Darussalam, Cambodia, Indonesia, Lao, Malaysia, Myanmar, Philippines, Singapore, Thailand and of Vietnam. These countries shall be integrated into the ASEAN Economic Community (by the ASEAN instruments aforesaid. The main purposes of the AEC are to eliminate tariffs among ASEAN members; allow the free movement of capital and professionals within ASEAN; adopt streamlined customs clearance procedures; and eliminate non-tariff barriers to trade through the harmonization of standards, technical regulations and conformity assessment procedures.

The foregoing purposes should force the ASEAN member states to improve their capacity to build a strong community. Every community in the world should take care of its population’s health, because the health of the population is one of the most important parts of any community. Medical devices, which are directly related to the population’s health are, therefore, very important. ASEAN members should establish regulations to protect their populations from medical devices that may harm public health. Consequently, the ASEAN Member States had negotiated the ASEAN Agreement on the Medical Device Directive (hereinafter referred to as “AMDD”) during 2010 to 2013 and finally adopted it in 2014. This agreement will raise all ASEAN members’ standards for producing medical devices to an equal level, one that will enable them to compete in the international market for medical devices.
ASEAN members implemented the ASEAN common submission dossier template (hereinafter referred to as "CSDT"). This document is the form of a checklist and contains the relevant essential principles of safety and performance for medical device. The AMDD provides that the ASEAN Members States shall complete their respective constitutional and requirements, including the enactment of implementing legislation by the end of 2014 so that the Agreement shall enter into force at the beginning of 2015.

The main purpose of the AMDD is to regulate medical devices within ASEAN by setting up harmonized as uniform standards. ASEAN Member States shall comply with this agreement by enacting or modifying their respective local laws regulating medical devices in their own territories, to conform to the standard set by the AMDD. The AMDD seeks to protect ASEAN patients, users and consumers from unsafe medical devices. The AMDD shall accomplish this aim by providing information to the public regarding the safety of a medical device before they can purchase and use it. A secondary purpose of the AMDD is to motivate the ASEAN medical device market to adopt and employ the same standards as the international medical device market.

Achieving the goals of the AMDD will require ASEAN members to take several actions pursuant to its terms. First, the AMDD will develop the CSDT for the approval of medical devices in ASEAN territories. Second, the AMDD will explore the feasibility of allowing bench marked countries or recognized regulators to approve medical devices, explore the feasibility of adopting a harmonized system for placing devices into ASEAN medical device markets, and formalize a post-marketing alert system for defective or unsafe medical devices. Third, all ASEAN members should consider joining the Asian Harmonization Working Party (hereinafter referred to as "AHWP") and work in parallel with GHTF on efforts to harmonize technical regulations.29

The AMDD consists of 24 articles and 8 Annexes. There are several interesting points contained in this Agreement which merit further discussion.

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29 Institute of Medicine, M. Gropp, "Strengthening Regulatory Systems in Developing Countries," Overview of the Global Harmonization Task Force for Medical Device Regulation and Related Initiatives.
Article 1 contains general provisions, including a requirement that member states undertake all necessary measures to ensure that all medical devices marketed in their territories conform to the standards established by the agreement. Any person responsible for placing a medical device in the market of a member state, or their authorized representative, must be licensed by the regulatory authority of that state, and must register the medical device with that authority. Each ASEAN member shall appoint a regulatory authority to manage and monitor medical devices in their territories.

Article 2 contains the definitions of medical devices and their accessories. Medical devices are defined as follows:

“medical device” shall mean any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article:

(i) intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(c) investigation, replacement, modification, or support of the anatomy or of a physiological process;
(d) supporting or sustaining life;
(e) control of conception;
(f) disinfection of medical devices; and
(g) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

(ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.”

Under this definition, a medical device is something intended for human use only.

Article 2 also provides separate definitions of medical devices and in vitro diagnostic (IVD) medical devices. In addition, it defines such terms as accessory,
custom-made medical device, device intended for clinical investigation, refurbished medical device, person, sponsor, product owner, physical manufacturer, authorized representative, authorized distributor, Regulatory Authority, manufacture, register, intended purpose, placing on the market, putting into service, adverse event and Field Safety Corrective Action (hereinafter referred to as “FSCA”).

Article 3 states the essential principle of safety and performance of medical devices. This is the crucial, core principle of the AMDD. Medical devices produced in member states shall meet the essential principles set forth in Annex 1 (Essential Principals of Safety and Performance of Medical Devices) that may be applicable to such devices. This means that medical devices need not comply with all of the essential principles; rather, manufacturers shall comply with those principles that apply to their products, taking into account their intended purpose.

Article 4 of the AMDD sets forth the system for classifying medical devices and IVD devices in accordance with the risk classification rules contained in Annexes 2 (Risk Classification Rules for Medical Devices other than IVD Medical Devices) and 3 (Risk Classification Rules for IVD Medical Devices). Article 4 divides medical devices into four classes:

- Class A: Low Risk
- Class B: Low – Moderate Risk
- Class C: Moderate – High Risk
- Class D: High Risk

The risk classification rules for medical devices are laid out in Annex 2 of the AMDD, which contains 16 specific and detailed rules for classifying the risks associated with particular types of medical devices.

On the other hand, the risk classification rules for IVD devices are set forth in Annex 3, which contains seven rules for classifying the risks associated with IVD devices.  

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30 ASEAN Agreement on Medical Device Directive Annex 2 (Risk Classification Rules for Medical Devices other than IVD Devices), 21 November 2014.

These devices are divided into four classes:

- **Class A**: Low Individual Risk and Low Public Health Risk
- **Class B**: Moderate Individual Risk and/or Low Public Health Risk
- **Class C**: High Individual Risk and/or Moderate Public Health Risk
- **Class D**: High Individual Risk and High Public Health Risk

The possibility that a medical device could be assigned to more than one class under Article 4 has the potential of creating confusion among entrepreneurs, users and patients regarding the proper classification of device. Therefore, the article provides that in the event a medical device could be assigned to two or more classes under the rules, the regulatory authority shall assign such device to the class representing the highest health risk to end users. For example, if a device could be assigned to Class B, C or D of IVD devices, such a device shall be assigned to Class D under this article, as it represents the highest risk.

In circumstances where a medical device is designed to be used in combination with another medical device, each of the devices shall be classified separately. If a medical device has more than one intended purpose, it shall be assigned to the class appropriate for its most critical intended purpose. If a dispute arises regarding the proper classification of a medical device, the regulatory authority of the member state that is classifying the disputed device shall decide which classification is proper, and their decision shall be final. However, ASEAN Member States can classify medical devices differently from under the AMDD by submitting notification to the ASEAN Medical Device Committee (hereinafter referred to as “AMDC”). Such notification should include the reasons underlying the classification.

The classification of medical devices and IVD devices under the AMDD is based upon four main criteria. The first of these is the duration of use. This criterion is divided into three categories:

1. **Transient**, encompassing medical devices that are used for less than 60 minutes
2. **Short-term**, encompassing medical devices that are used for a period up to 30 days
3. **Long-term**, encompassing medical devices that are used for a period of more than 30 days
The second criterion is the location of use of the device. This criterion is also divided into three categories:

1. Medical devices used in the central circulatory system
2. Medical devices used in the central nervous system
3. Medical devices not included in either of the above categories

The third criterion is the level of invasiveness, which is divided into four categories:

1. Non-invasive medical devices
2. Invasive medical device inserted through bodily orifices
3. Surgically invasive medical devices
4. Implantable medical devices

The fourth criterion is the source of the device’s energy supply, which is separated into two categories:

1. Non-active medical devices
2. Active medical devices

Article 5 of the AMDD provides that member states must conduct conformity assessments of medical devices. This means that the regulatory authority in each member state must conduct an assessment of each medical device that is intended to be marketed in that state to determine whether it conforms and complies with the requirements of the AMDD. The articles states that the regulatory authorities may conduct the conformity assessment themselves, or appoint other bodies or organizations to do so.

Article 6 regulates the registration of medical devices and their placement in the market. The regulatory authority responsible for regulating medical device in each member states shall establish a registration system for medical devices. Each device that has been assessed and found to be in conformity with the AMDD under Article 5 must then be registered with the regulatory authority of each member state where it will be marketed before being placed in the market of those states. However, member states can choose to exempt certain medical devices from the registration requirement under appropriate circumstances. In addition, custom-made medical devices are also exempt from registration.
Article 7 of the AMDD concerns the licensing of persons responsible for placing medical devices in the markets of member states. Each person who is responsible for placing medical devices on the market must be licensed by the regulatory authority in each member state where the devices are marketed, and member states must establish an appropriate system for licensing such responsible persons. Product owners, manufacturers, importers and distributors, or their authorized representatives, should be local individuals or registered businesses under the local law in each member state. If the product owners are foreigners, they must appoint a local authorized representative to manage their businesses in each member state where they do business.

Article 8 identifies common technical documents relating to medical devices, and requires each member state to adopt and implement these documents. The article refers to three technical documents, each of which is contained in one of the annexes to the AMDD. The first of these is the ASEAN Common Submission Dossier Template (hereinafter referred to as “CSDT”), which is set forth in detail in Annex 4 (ASEAN Common Submission Dossier Template). The CSDT takes the form of a checklist and contains the relevant essential principles of safety and performance for medical devices; risk management recommendations; a summary of design verification and validation documents, including performance tests, biological tests, clinical tests, clinical data evaluation, literature searches, clinical experience and clinical investigation; guidelines for medical device labeling and manufacturer information.

The second technical document is Post Marketing Alert System (hereinafter referred to as “PMAS”) Requirements, which is set forth in Annex 5 (Post Marketing Alert System (PMAS) Requirements). PMAS documents include importation and/or distribution records, complaint records, adverse event reporting criteria and format, and field safety corrective action reporting format. The third technical document is the Harmonized Set of Elements for a Product Owner’s or Physical Manufacturer’s Declaration of Conformity, the details of which are set forth in Annex 6 (Components


Elements of a Product Owner's or Physical Manufacturer's Declaration of Conformity (DOC)).  

Under AMDD, it is necessary for medical devices to be accompanied by the proper technical documents. These documents shall specify the status of the device after its safety and capacity have been assessed. They shall identify the essential principles of safety and performance that are applicable to the device, and identify the general method used to demonstrate compliance with each such principle. If none of the essential principles apply to a particular medical device, the entrepreneur must clarify the reasons why such device is not covered by the principles on that list. The technical documents also need to specify the design, manufacture and objective of the medical device. These documents shall be written in English unless the regulatory authority approves the use of another language. Moreover, the technical documents shall always include the ASEAN CSDT, the PMAS requirements, and the product owner or physical manufacturer's Declaration of Conformity.

The Declaration of Conformity is a document issued by the product owner or physical manufacturer of a medical device and submitted with other forms to register such device with the regulatory authority in any ASEAN member state. It corroborates that the device conforms to and complies with the standards of the AMDD. The original form of the Declaration of Conformity with the proper authorized signature should be prepared and submitted to regulatory authority.

The AMDD requires that a CSDT be prepared for every medical device. However, the details that must be included in the CSDT depend on the class and the complexity of the medical device. Every section in the CSDT must be completed; if any section is not applicable to the medical device, the reasons why it does not apply need to be clarified. The CSDT shall be prepared in English unless the regulatory authority approves the use of other languages. The CSDT shall specify the surveillance to be carried out after the medical device is placed in the market, and an entrepreneur shall report any unexpected circumstances which are not defined in the CSDT.

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34 ASEAN Agreement on Medical Device Directive Annex 6 (Components Elements of a Product Owner's or Physical Manufacturer's Declaration of Conformity (DOC), 21 November 2014.
Academic papers analyzing the AMDD have identified the following documents that should be developed and prepared regarding a medical device:

1. ASEAN CSDT, as defined in Annex 4 (ASEAN Common Submission Dossier Template)

2. PMAS, as defined in Annex 5 (Post Marketing Alert System (PMAS) Requirements)

3. Harmonized set of elements for a Product Owner’s or Physical Manufacturer’s Declaration of Conformity, as specified in Annex 6 (Components Elements of a Product Owner's or Physical Manufacturer's Declaration of Conformity (DOC))

4. Component Elements of a “Dear Healthcare Professional” Letter, as specified in Annex 7 (Rebelling Requirements)

5. Sample Template of Letter of Authorization, as set forth in Annex 8 (Clinical Investigation)

Article 9 provides two ways in which medical devices may be deemed to comply with the essential principles referenced in Article 3 and set forth in Annex 1: either by conforming to the relevant technical standards recognized by the AMDC, or by conforming to other technical standards that have been accepted by the regulatory authority of the member state in which the device will be marketed. Article 9 also authorized the AMDC to revise, by consensus of the member states, the list of recognized technical standards.

Article 10 sets rules for the labeling of medical devices. All medical devices manufactured in ASEAN member states must be labeled and accompanied by additional attached documents in accordance with the rules and regulations of each country. ASEAN members may adopt the labeling requirements set forth in Annex 7 of the AMDD, or set their own standards. Each member state may require that its national language be used for the label and attached documents of any medical device marketed in its territory.

Article 11 requires member states to monitor the actual efficacy of medical devices to determine whether they live up to the claims made for them. There must be substantial evidence to corroborate the claimed benefits for a device, and the labels and attachments must certify the device’s composition, formulation or
preparation. The evidence supporting any claimed quality or benefit must be documented, with references provided according to the terms of Annex I of the AMDD.

Article 12 establishes a Post-Marketing Alert System that requires the relevant regulatory authority to report, record and evaluate any incidents involving medical devices in the market with respect to malfunctions, deterioration in performance, injuries, side effects or other dangers posed by those devices.\footnote{Article 12 of 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 labeling 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 sub paragraph (a), leading to product recall of medical devices of the same type by the product owner, authorized representative, authorized distributor or person responsible for placing medical device into the market.

(2) After carrying out an assessment, if possible together with the product owner, a Member State shall inform the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.

(3) Each Member State shall require that any person who is responsible for the manufacture or placing the medical devices on the market of that Member State, to:

(a) keep all relevant records pertaining to the tractability of the medical device, for such period and format as the Regulatory Authority in the Member State may stipulate;

(b) produce such records for inspection when required by the Regulatory Authority in the Member State;
Article 13 requires member states to establish an appropriate system for conducting clinical investigation of medical devices. It refers to the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and any subsequent amendments or revisions to this Declaration by the World Medical Association. It is acknowledged that all measures relating to the protection of human subjects are required to be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results, which may include the following requirements:

1. In the case of medical devices intended for clinical investigation, the Regulatory Authority of the Member State may require the product owner, or his authorized representative, or the sponsor of the clinical investigation in a Member State, as the case may be, to follow the procedure referred to in Annex 8 (Clinical Investigation) and register with the Regulatory Authority of that Member State in which the investigations are to be conducted.

2. The Regulatory Authority of the Member State may require that the clinical investigations be conducted in accordance with the provisions of Annex 8 (Clinical Investigation).

3. The Regulatory Authority of that Member State may require the product owner or his authorized representative, or the sponsor of the clinical investigation in a Member State, as the case may be, to submit or make available on
Declaration, adopted by the 18th Medical World Assembly in Helsinki, Finland in 1964, which sets ethical and professional medical standards for conducting clinical trials involving human subjects.

Article 14 establishes the ASEAN Medical Device Committee (AMDC), which is tasked with the overall responsibility of coordinating, reviewing and monitoring the implementation of the AMDD. The AMDC consists of at least one representative from the Regulatory Authorities of each ASEAN member. It may receive support from the ASEAN Consultative Committee for Standards and Quality (ACCSQ) and the ASEAN Secretariat in carrying out its duties. It may also establish an ASEAN Medical Device Technical Committee (AMDTC) to assist the AMDC in reviewing technical and safety issues relating to medical devices.

Article 15 is intended to safeguard the health and safety of patients and other users of medical devices in ASEAN. Medical devices marketed in member states must not compromise or harm the health or safety of patients, users or other persons when used in normal or reasonably foreseeable ways. If a regulatory authority determines that a medical device is harmful to health or safety despite being properly installed, request, as deemed appropriate, the report referred to in Annex 8 (Clinical Investigation).

(4) Where a clinical investigation is refused or halted by a Member State, that Member State may communicate its decision and the grounds thereof to all Member States and the AMDC. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State may inform all Member States and the AMDC concerned about its actions and the grounds for the actions taken.

(5) The Regulatory Authority of a Member State may require the product owner or his authorized representative, or the sponsor of the clinical investigation in a Member State, as the case may be, to notify of the end of the clinical investigation, with justification(s) in case of temporary suspension or of early termination. In the case of early termination of the clinical investigation on safety grounds, this notification may be communicated to the Regulatory Authority of all Member States where the clinical investigation is carried out.
maintained and used as indicated for its intended purpose, that authority shall take all appropriate action, including withdrawing the device from the market, prohibiting it from being marketed or limiting the scope of its use. In addition, the regulatory authority must immediately inform the other member states of such measures and the reasons they were taken. They must indicate whether their action is based on the medical device failing to meet the essential principles of Annex 1, on incorrect application of the technical standards referenced in Article 9, or on shortcomings in the technical standards themselves.

Article 16 governs confidentiality, and provides that all parties involved in implementing the AMDD shall keep secret all confidential information obtained while carrying out their responsibilities. There are, however, exceptions for disclosures by member states to other states as required by the agreement, for disclosures made in the course of administering or enforcing the agreement, for the dissemination of warnings or other information in the public interest, and the disclosure of information in the course of an investigation, criminal prosecution or other legal proceeding.

Article 17 contains a list of special circumstances that create exceptions to the general rules and requirements of the AMDD. For example, even though a medical device complies with the terms of the AMDD, member states may refuse to register that device, prohibit its marketing in their territory, or subject it to special controls or conditions for reasons related to religious or cultural sensitivity. Member states may also elect to refuse to register or prohibit the marketing of refurbished medical devices even though they otherwise comply with the requirements of the AMDD. Member states that restrict or ban specific medical devices must inform the other members of such actions and the reasons therefor, and provide a copy of the notice to the AMDC.

Article 18 pertains to implementation of the AMDD, and provides that member states must undertake appropriate measures to implement the agreement, including measures to ensure that the necessary technical infrastructure is put in place. Member states must modify their national laws as necessary to bring them in line with the provisions of the AMDD, and shall provide texts of any laws they adopt regarding medical devices to other member states, with a copy to the ASEAN Secretariat, who will in turn notify the AMDC. Furthermore, member states must establish post-marketing surveillance regimes to monitor medical devices after they
are introduced into the market, and are given full authority to take legal enforcement actions against any medical devices found not to comply with the AMDD.

Article 19 allows for revisions, modifications and amendments to the AMDD. Such changes may be made by the written agreement of all member states.

Article 20 governs dispute settlement, and states that any dispute concerning the interpretation or implementation of the agreement shall be resolved under the provisions of the ASEAN Protocol on Enhanced Dispute Settlement Mechanism.

Article 21 prohibits member states from making reservations with respect to any provision of the AMDD.

Article 22 states that the agreement is subject to ratification or acceptance by the member states according to their internal legal requirements. It shall enter into force on 1 January 2015, but shall be in force only among those members who have ratified or accepted it.

Article 23 provides that any annex attached with the agreement is an integral part of the AMDD. Finally, Article 24 states that the original agreement shall be deposited with the Secretary-General of ASEAN, who will provide certified copies to all member states.

From this review of the AMDD, it can be seen that the agreement follows the master template of the GHTF Guidelines. GHTF was established in 1993 to voluntarily regulate and control international trade in medical devices. The main purpose of GHTF is to provide model rules and regulations for medical devices and to promote the adoption of a single worldwide standard to ensure that all medical devices are safe for patients and other users. GHTF provides information and advice to countries wishing to use its Guidelines as a template to prepare rules and regulations for medical devices in their countries.

3.5 The Problem of Enacting the AMDD and Achieving Its Goals

A comparison of the terms of the AMDD with the internal rules and regulations governing medical devices in each ASEAN member country shows that Laos, Brunei, Cambodia, and Myanmar are the countries most affected by the AMDD, as they do not have any specific rules and regulations relating to medical devices. It
will be necessary for them to use the AMDD as a master template in drafting their own laws. They will also need to create rules and regulations to establish the standards and qualifications set forth in the AMDD. However, it is possible that their lack of existing laws may simplify their task, as enacting new laws may prove easier than amending old, established ones.

Vietnam, Indonesia, and Thailand are the second group of ASEAN countries affected by the AMDD. These countries have some rules and regulations for medical devices that differ from the AMDD. Some of the most obvious differences are found in their definitions and categories of medical devices. They will have to modify their definitions of medical devices to conform to the AMDD, and reclassify medical devices to match the categories contained in the AMDD. They will also need to conduct a thorough review of their existing laws to determine whether any of the provisions required by the AMDD are missing.

The countries least affected by the AMDD are Singapore, Malaysia and the Philippines. These countries already have their own rules and regulations based on the GHTF Guidelines, which means their internal laws contain little if any deviation from the terms of the AMDD. This is likely because the AMDD is itself adapted from the GHTF Guidelines.
Chapter 4
Analysis and Comparison of ASEAN National Legislations in Light of the AMDD

4.1 A Comparison of Thailand's Medical Devices Act B.E. 2008, CE Mark for Medical Devices and ASEAN Medical Device Directive.

Having reviewed Thailand's medical device regulations, which are found in MDA 2008, a comparison of those regulations with the CE Mark and AMDD reveals both similarities and differences between the three regulatory schemes.

The most obvious difference between these three regulations is their definition of medical devices. Section 4 of MDA 2008 defines medical devices as devices intended to be used in providing healthcare for both humans and animals. On the other hand, the CE Mark and AMDD define medical devices as intended for use in human healthcare only. This difference indicates that the scope of Thailand's regulation of medical devices is broader than the other two regulations. The definitions of medical devices and accessories in the CE Mark and AMDD are similar to one another. The wording “intended for use in healthcare” states a critical purpose for considering something to be a medical device. Yet the consideration of which devices or equipment will be deemed medical devices under each of these three regulations depends on the judgment of the regulator authority in each country.

For example, the Thailand Food and Drug Administration (“TFDA”) is the regulatory authority in Thailand under MDA 2008. The TFDA has decided that fashion contact lenses are medical devices within the meaning of the Act. Yet the definition of medical devices in MDA 2008 specifies that such devices are intended to be used for healthcare, and fashion contact lens are only used for cosmetic appearance, not for healthcare. But the TFDA announced that fashion contact lenses are medical devices under section 4(3) of MDA 2008 because such devices could

37 Section 4 (3) of Medical Devices Act B.E. 2008.
harm public health. The details of this announcement were provided in the Ministry of Public Health’s announcement regarding contact lenses.\(^{38}\)

On the other hand, the CE Mark considers prescription contact lenses for vision care to be medical devices, but does not consider fashion contact lenses to be medical devices. The application of the CE Mark’s definition of medical devices is based on the intended use of the devices usage and the risk of harm to public health. Obviously, the intended use of fashion contact lens is for fashion, not for healthcare. This principle has led to the same decision in other countries around the world. For example, the GHTF has also concluded that fashion contact lenses are not medical devices, and so has the AMDD. However, the AMDD has authorized the regulatory authority in each member state to establish their own safeguards or regulations within their own territories. It is an interesting question whether the Thai regulatory authority will change their opinion about fashion contact lenses.

Moreover, the medical device regulations in Thailand do not provide any guidance regarding medical devices that are intended to be used in combination with other medical devices. The AMDD covers such combination products by providing that each of the devices shall be classified separately. On the other hand, the CE Mark’s regulatory treatment of devices intended to be used in combination is based on the product’s primary mode of action. The CE Mark directives do not apply cumulatively.

Another significant difference between the regulations is their system of classifying medical devices. MDA 2008’s classification of medical devices in Thailand depends on the performance of those devices under actual use by the public. If a medical device damages or harms the public, the TFDA, who is the responsible authority, will give notice to the public that such device falls into one of three classes: general medical devices, descriptive medical devices and licensed medical devices.

On the other hand, the AMDD and CE Mark use similar classification systems based on the nature of the risk of using a medical device. This approach is different from the system used by the MDA 2008. For example, if a medical device is determined to pose a high level of risk to society, it will be classified as a high risk

medical device, as defined in the AMDD and CE Mark regulations. The makers of medical devices must follow the AMDD and CE Mark regulations appropriate for the level of risk associated with their product before placing it in the market. However, the AMDD and CE Mark have different numbers of classes for medical devices. The AMDD follows the GHTF template for classification, while the CE Mark separates medical devices into more classes than the GHTF template.\(^{39}\)

A third significant difference between the Thai regulations, the AMDD and the CE Mark is that Thai law does not specify any essential principles for medical devices. In Thailand, the TFDA may determine such essential principles according to their own opinions. The AMDD and CE Mark, on the other hand, specify such essential principles for owners, manufacturers and importers to follow. This enumeration of principles can help make medical devices in ASEAN and the EU more standardized and safer for patients and public users.

A fourth difference is that Thailand's medical device law does not specify the manufacturing standards that makers of medical devices should follow. It is not currently necessary for the manufacturers of medical devices in Thailand to comply with any such standard. If a manufacturer wishes to certify their production methods, they must hire an auditor to audit their manufacturing plant, machinery and processes to approve and certify their quality. This requires entrepreneurs to incur significant expenses. On the other hand, the AMDD and CE Mark specify that manufacturers must follow recognized international standards such as ISO 13485. Any medical device manufacturers who intend to operate within EU territories know they must obtain ISO 13485 certification.

Fifth, the regulatory authorities charged with enforcing these regulations have different names and, to some extent, they also have different duties under the respective laws. Thailand has appointed the Medical Device Control Division of the Thai Food and Drug Administration, a subdivision of the Ministry of Public Health, to monitor medical devices in Thailand. Their main responsibilities are to register and

\(^{39}\) For detailed descriptions of the various classifications of medical devices contained in these regulations, please refer to Section 2.3, p. 8 (GHTF), Section 2.7, p.15. (CE Mark), Section 3.2, p.19 and Section 4.1, p. 32 fn. 29 (MDA 2008), and Section 3.4, pp. 23-25 (AMDD), above.
issue medical device licenses and to regulate the manufacture, import, sale and advertisement of medical devices to ensure that such devices are safe and effective for use by consumers.\textsuperscript{40}

The AMDD gives member states the authority to appoint their own regulatory authorities to monitor medical devices in their territories and to enforce the provisions of the AMDD to ensure that such devices meet the required standards. Moreover, these regulatory authorities have the power to enact such additional regulations for medical devices as they deem appropriate, and to appoint a third-party auditor to conduct the conformity assessment process.

On the other hand, CE Mark separates regulatory authority into two separate bodies, the Competent Authority and the Notified Body. The Competent Authority is a government agency or other entity legally empowered to control the use or sale of medical devices within its territory. The Competent Authority has the ability to initiate enforcement actions to ensure that medical devices marketed in their territory comply with the CE Mark requirements. It is responsible for inspecting and notifying the Notified Body, monitoring the medical device market, gathering and evaluating market surveillance data and taking suitable enforcement actions.\textsuperscript{41} This factor is the key difference between the AMDD and CE Mark.

The Notified Body is a certified organization authorized by the member state’s Competent Authority to perform the conformity assessment tasks specified in the AMDD.\textsuperscript{42} The Notified Body can be either a government organization or a third party, but in practice the member states have appointed third parties as the Notified Body because the private sector has more experience and specialized expertise than the government.

A sixth difference relates to licensing. Under the AMDD and Thailand’s Law, the manufacturer or his authorized representative should register and notify the regulatory authority of the member state.\textsuperscript{43} On the other hand, CE Mark states that the manufacturer must inform the Competent Authority to register his or her business. Foreign manufacturers must appoint authorized representatives located in Europe.

\textsuperscript{40} Jack Wong and Raymond K.Y. Tong, “Handbook of Medical Device Regulatory Affairs in Asia,” 37.2, Medical Device Regulations and Regulators, p. 526.

\textsuperscript{41} Ibid., at 21.8.3, Competent Authority, p. 246.

\textsuperscript{42} Ibid., at 21.8.4, Notified Body: Conformity Assessment Body, p. 247.

\textsuperscript{43} Ibid., APPENDIX, Regulatory Summary Table, ASEAN.
The authorized representative will then perform all acts on behalf of the owner under each state's laws and regulations.

A seventh difference exists in the registration process. Thailand relies on manual submission of registration documents by the owner or manufacturer. Under the AMDD, member states must establish a system to assess medical devices. Such devices shall be assessed by the regulatory authority of the member state, or any firms appointed by the member state. To be approved, the devices must conform to the requirements of the AMDD, as well as any other relevant statutes of the member state. Under the CE Mark, however, low-risk medical devices or IVD devices can be self-tested and self-certified by the manufacturer as passing the requirements of the CE Declaration of Conformity. Moderate- and high-risk medical devices or IVD devices, on the other hand, must be certified by the Notified Body's conformity assessment procedure, and the technical documentation must be reviewed by the Notified Body. The Notified Body also has a duty to audit the quality management system of the manufacturer. After passing through this entire process, the manufacturer will obtain a CE certificate and be permitted to operate in the EU territories.  

An eighth difference concerns the documentation required and the language to be used in such documents. In Thailand, all documents shall be in Thai. The list of required documents includes the original Certificate of Free Sale or Certificate of Guarantee, a letter of authorization, a product catalogue and a copy of the application for an import license.  

Under the AMDD, the application form shall be in English unless a member state specifies that the local language be used instead. The required documents include the demonstration of compliance with the essential requirements and the common submission dossier template (CSDT). The details of these requirements are very similar to the CE Mark.  

Under the CE Mark, all applications shall be in English, unless a member state specifies use of its local language. If a medical device is a low- or moderate-risk

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44 Jack Wong and Raymond K.Y. Tong, Ibid., APPENDIX, Regulatory Summary Table, Europe.

45 Ibid., APPENDIX, Regulatory Summary Table, Thailand.

46 Ibid., APPENDIX, Regulatory Summary Table, ASEAN.
device, the required technical documents include the essential requirements checklist, the risk management file and the clinical evaluation report. For high-risk devices, the design file shall be submitted along with the foregoing documents.\textsuperscript{47}

Finally, there are also differences in the post-market monitoring of medical devices. Thailand’s regulations require the medical device makers to report adverse events and undertake product recalls.\textsuperscript{48} The AMDD, on the other hand, authorizes the regulatory authority to prepare appropriate measures to monitor the post-market performance of medical devices. The regulatory authority has a duty to inform the other member states about the details of its post-market monitoring system.\textsuperscript{49}

CE Mark has a stricter post-market system for addressing adverse developments than the other two regulatory schemes. In a case posing a serious threat to public health, the maker of a medical device shall report the problem to the Competent Authority within 48 hours after its occurrence. If a medical device causes the death of a user, the device’s maker shall report the death to the Competent Authority within 10 days. In other circumstances, the maker of a medical device shall report adverse consequences to the Competent Authority within 30 days of such occurrence.\textsuperscript{50}

\textbf{4.2 Advantages and Disadvantages after Enactment of the AMDD}

As AMDD will become effective to All of ASEAN members. ASEAN members have duty to amendment or enactment their local Law related to AMDD. There are several advantages and disadvantages after Enactment of the AMDD as follows;

\textbf{4.2.1 Advantages after the AMDD is enacted}

First, the AMDD will require the governments of ASEAN member states to enact or modify their own laws regarding medical devices. These new local medical device laws in each of ASEAN’s member states will force local

\textsuperscript{47} Jack Wong and Raymond K.Y. Tong, Ibid., APPENDIX, Regulatory Summary Table, Europe.

\textsuperscript{48} Ibid., APPENDIX, Regulatory Summary Table, Thailand.

\textsuperscript{49} Ibid., APPENDIX, Regulatory Summary Table, ASEAN.

\textsuperscript{50} Ibid., APPENDIX, Regulatory Summary Table, Europe.
manufacturers, or foreign entrepreneurs who intend to locate their production facilities within an ASEAN territory, to improve the quality of their medical devices to meet the standards specified by the local medical device law. Thus, the process will result in an increase in the quality of the medical devices manufactured in each of the ASEAN member states. This will in turn provide users of medical devices with better guarantees of safety and legal protection. In addition, medical devices originating within the ASEAN community will develop a better reputation in the global market.

Second, the standards for medical devices in ASEAN territories will be improved. The AMDD dictates that ASEAN members must enact local laws to enforce extensive regulations of medical device manufacturing. Any manufacturers producing medical devices in ASEAN territories must have processes for producing those devices that meet international standards. As a result, manufacturers will need to increase their efficiency and technical skills, including the development of human resources capable of producing medical devices in compliance with the standards defined by the new local laws. This trend will help to protect users and the general public from medical device manufacturers who try to increase their profits by investing the least cost into research, quality control and employee training.

Third, the new local laws in each ASEAN member state will make foreign investors more confident about long-term investments in the medical device industry in ASEAN. Because these laws require foreign investors in medical device businesses to appoint an authorized representative in each ASEAN member state in which they choose to invest, these local representatives of foreign investors can help build business networks within ASEAN. Furthermore, these local representatives can export their own medical devices to other ASEAN countries without facing tariff barriers.

Fourth, once the AMDD is in force and each ASEAN member has enacted their own laws to regulate medical devices, such devices originating in ASEAN territories will conform to international standards and will be recognized as safe, reliable, high-quality products in the international market. Entrepreneurs producing medical devices within ASEAN will be able to sell more of their products at higher prices, and thus make more profits from their businesses. Because the AMDD is adapted from the GHTF template, which is widely recognized around the world, medical devices that meet the standards defined by the AMDD will comply
with the GHTF standards as well. Consequently, countries that use the GHTF standard will be more confident about importing such medical devices from ASEAN.

Fifth, the main objective of establishing the ASEAN Economic Community is to build a strong bloc that can negotiate with other countries and regions in the international marketplace to eliminate tariff barriers. If all ASEAN members can enact local laws in accordance with the AMDD, the standard of medical devices will be improved, and medical device makers in ASEAN will be able to compete with some of the bigger producers of medical devices in the international market. A strong point for ASEAN members is their low cost of living, which means that manufacturers enjoy low labor costs. ASEAN territories also have plentiful natural resources for producing medical device without the need to import raw materials from abroad. These advantages will enable medical device makers in ASEAN to have lower costs than their international competitors in the medical device industry. Thus, medical devices produced in ASEAN territories will be of equal standard with devices in the international market, but at a lower price. This can help medical device manufacturers located in ASEAN compete with other leading medical device companies in the international sector.

Sixth, a major problem for medical device makers around the world is the inconsistent definition of medical devices. Some countries define medical devices differently than others. Consequently, some devices may be treated as medical devices in one country, but not in another. The AMDD contains a clear definition of medical devices that provides ASEAN members with a standard provision to be used in each country, subject to appropriate adaptation to local law. Thus, ASEAN members will enact or modify their own local laws to set standards equal to or higher than those defined in the AMDD. This can solve the problem of inconsistent interpretations of whether a product constitutes a medical device in ASEAN territories.

4.2.2 Disadvantages after the AMDD is Enacted

The ASEAN community is comprised of developed countries, developing countries and undeveloped countries. Most ASEAN members are developing or undeveloped countries. These members will incur financial costs in developing their own medical device standards in accordance with AMDD, particularly in developing or acquiring the infrastructure and technology needed to comply with those standards. The protocol for medical device standard requires
significant financial cost and modern technology. However, if a state fails to adopt such standards, they will be excluded from the ASEAN medical device market because they cannot achieve compliance with the standards set by the AMDD.

Second, it is not only developing and undeveloped countries that face the problem mentioned above. Small and midsize enterprises operating in the medical device sector, even those located in developed countries, will also face significant financial burdens. These entrepreneurs may have lower costs than larger enterprises, but they do not have sufficient capital or financial resources to invest in making the necessary upgrades to their business to comply with the AMDD. They may be forced out of the medical device industry because they cannot adapt and raise the standards of their business to comply with the new industry-wide standards for medical devices.

Third, after the AMDD enters into force and ASEAN members enact local laws, the protocols for registering and placing medical devices in the ASEAN market will be more complicated. The AMDD will force the regulatory authorities to be strict in regulating and monitoring medical devices in their territory. New investors who intend to launch medical device businesses will face a more complicated and costly process. As a result, investors may hesitate to establish new medical device businesses in ASEAN territories. This may cause the ASEAN medical device market to become smaller in the future than it is at present.

Fourth, the AMDD authorizes ASEAN members to appoint their own regulatory authorities to regulate and monitor medical devices in their territories according to the standard for medical devices defined by local law. The regulatory authorities selected by each member state will need to possess appropriate experience, including administrative and technical expertise, and be capable of taking consistent and efficient action. If any member state selects a regulatory body that lacks such qualities, or is tainted by cronyism, nepotism or corruption, this will negatively affect the standard of medical devices produced in that territory and may render them non compliant with the requirements of the AMDD.
Chapter 5
Conclusion and Recommendations

5.1 Conclusion

Thailand is one of the ASEAN countries that, as soon as it signs the AMDD, will have to amend its national laws to conform to the AMDD rules and regulations. It is apparent that there are quite a few changes needed. In the meantime, there have been discussions and preparations among ASEAN members on various topics, including medical devices. They have set up a seminar to draft an agreement requiring medical devices in the region to meet uniform, higher standards. Consequently, it is time for Thailand to alter and upgrade its laws to conform to the ASEAN and international standards.

The most important issue requiring amendment is to re-define the definition of medical devices in Thai law to conform to the AMDD. Some medical devices in Thailand may cause harm to the public. These unqualified medical devices may negatively affect the export of such products within ASEAN, or in the global market, and may decrease the revenue of medical device exporters. Amending the MDA 2008 will upgrade the medical device standard and render them compatible with those of the AMDD. In addition, the definitions of medical devices, the categories of medical devices and their risks, and the post-market alerting system all need to be revised. There should also be some additional procedure to control pre-market development and placement in the market. Moreover, it is important to have safety rules, essential principles, and conformity assessment that are compatible with the requirements of the AMDD.

Thailand has already started some amendments to MDA 2008, based on the text of the AMDD. Drafts have been prepared regarding re-categorizing medical devices by grouping them into two types; IVD medical devices and non-IVD medical devices. These two types are further categorized according to their risks by classifying them into Class A through Class D, ranging from low risk to high risk. Moreover, some additional provisions have been proposed, such as the definition of medical devices would include devices intended for human use only, consistent with the definition in the AMDD.
5.2 Recommendations

In addition to those changes, Thailand should alter some other provisions of MDA 2008 in line with the AMDD to improve the quality of medical devices manufactured in Thailand and make them more efficient and safe. First the, Minister of Public Health should announce the establishment of new standards for medical device manufactured in Thailand. Good manufacturing practices, distribution practices and clinical practices should be established as regular requirements for the manufacturers of medical devices. International standards such as ISO 13485 and 14971 should be also established as required standards for medical devices. Moreover, the Ministry of Public Health should create a plan and series of seminars to help manufacturers of medical device in Thailand to improve their manufacturing processes to comply with the AMDD.

Second, the AMDD will soon force Thailand's medical device laws to change, imposing a dramatic impact upon entrepreneurs, who must develop new business processes that conform to significantly higher standards. Moreover, government officials responsible for enforcing the law and registering medical devices will also face significant changes to their roles and responsibilities. Consequently, the Ministry of Public Health must prepare for the impending modification of medical device standards in Thailand by training its officials to keep them abreast of critical developments. The Ministry must plan a program of training seminars for its officers to impart the necessary knowledge of the requirements of the AMDD. Presently, Ministry officials do not have adequate knowledge, skills or expertise to interpret the provisions of the new law or monitor compliance with the higher medical device standards it imposes.

Third, the AMDD gives the regulatory authority in each ASEAN member state the authority to perform conformity assessments of medical devices by themselves, or to appoint private third parties to conduct this procedure. These assessments require more skill and expertise than the ordinary government officer possesses. Private third parties have more specialized knowledge and experience to assess the quality of medical devices than government officials do. However, if the Ministry of Public Health nonetheless concludes that the assessment process should be performed by government officers, the Ministry either must prepare a plan for improving and
developing the skills and experience of its own personnel to administer the assessment procedure, or else recruit specialists to become public servants to conduct the assessments.

Fourth, public servants in Thailand have significant problems regarding the proper scope of their roles. Some public servants try to transfer their duties, or delegate their own responsibilities, to officials in other sectors. The Minister of Public Health must solve this serious problem by issuing and assigning clear responsibilities to public officials. The regulatory authority is the mainspring for regulating and monitoring medical devices in Thailand. Medical devices in Thailand will either achieve the standards required under AMDD, or fail to achieve them, depending on the performance of the regulatory authority. The Minister should therefore announce guidelines regarding the scope of the duties of the regulatory authority which give clear directions on matters such as the regulatory system, authority to draft or adopt laws and regulations, interpretation of government policies regarding medical devices under various circumstances, monitoring of the importing and exporting of medical devices, the scope of consultations with the owners of medical device companies, and enforcement of laws and regulations against offenders. In each case, the Ministry should clearly describe the particular role or duty of the regulatory authority. Moreover, the regulatory authority and other responsible public servants should possess more knowledge of medical devices than members of the general public, so the Ministry should develop a plan for recruiting qualified officials. After recruiting and hiring have taken place, there should be a procedure to review and evaluate the officers’ performance.

Fifth, not only should the role of the public servants who serve on the regulatory authority be clear, but also the role and duties of the medical device manufacturers. The Minister of Public Health must provide such information regarding the responsibilities of the manufacturers under the AMDD to the public. This information will serve as a guideline for medical device manufacturers to interpret their new role and duties with respect to their business. Furthermore, the Minister may decide to arrange seminars for medical device makers to provide them with the information they should know, such as the steps for registering their businesses and products or appointing authorized representatives. This would help
entrepreneurs understand their new responsibilities under the AMDD.

Sixth, as the AMDD enters into force, the application form for registering medical devices in Thailand will be modified. At present, the application for registration in Thailand is very different from the CSDT that is specified in the AMDD. The Minister of Public Health must prepare a new application template conforming to the CSDT and provide such template to business owners for review and comment before it is officially adopted. This new application form will be significantly different from the old one, and may be difficult to understand. The sooner the Minister can prepare and provide a draft of this document, the more opportunity it will present for stakeholders to study, understand and provide feedback on it before it is officially adopted.

Seventh, the length of the registration period is one of the persistent problems of the government sector. The Minister of Public Health must revise the registration process to accommodate medical device makers. This presents a good opportunity to streamline the old registration process, which requires a long period and is very complicated. The transaction period must be reduced to a shorter term. A long transaction period delays entrepreneurs’ opportunity to begin doing business. Some government sectors are now using the benefits of the internet and IT services to accommodate applicants; for example, the Department of Business Development is developing their own registration process and allowing applicants to submit their application form via the internet. If the Minister of Public Health can adopt such IT services for their own registration process, it will help business owners register their products more quickly and easily, and will reduce the period of time required for registration. Furthermore, the fee for registration should be reconsidered. The Minister should set a fee that is appropriate for the medical device industry. If the fee is too high, it will be a burden for new entrepreneurs.

Eighth, the AMDD not only establishes a registration process for medical devices, but also process for the monitoring of medical devices by the regulatory authority after the devices have been placed in the market. The Minister of Public Health must carefully plan and implement a procedure for monitoring medical devices to prevent any harm to the public from faulty or poorly-designed medical devices, whether registered or not. Some medical device manufacturers try to avoid the
registration process because their products did not meet the required standard. Moreover, some medical devices meet the standard, but once the device is in the market, its maker tries to alter the manufacturing process to reduce costs and increase profits. For these reasons, the Minister should develop a procedure for the regulatory authority to monitor the market and arrest offenders immediately, before such device harm the public, and set serious penalties to deter manufacturers from trying to cut corners, evade the standards or violate the laws and regulations. If the Minister adapts the CE Mark post-market system for monitoring medical devices, this should be a sufficient measure to regulate medical devices marketed in Thailand.

Finally, the AMDD regulations require that certain medical devices undergo a clinical test process. This process is very complicated, and the Minister of Public Health must prepare a detailed plan for implementing it. The Minister should provide information regarding the clinical test process to the producer of medical device companies, or designate an organization to gather information and identify a third party who has the requisite knowledge and experience to conduct such clinical tests for the business owners.

In conclusion, it can be asserted that the AMDD should be beneficial to Thailand. It can promote medical devices' business, and enhance the devices' standards. This will make the Thailand entrepreneurs more competitive, and this may be able to compete with other entrepreneurs in the world.
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Appendix

ASEAN Agreement on Medical Device Directive
ASEAN AGREEMENT ON MEDICAL DEVICE DIRECTIVE

The Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Republic of the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand and the Socialist Republic of Viet Nam, Member States of the Association of Southeast Asian Nations (hereinafter collectively referred to as "Member States" or singularly as "Member State"),

MINDFUL that in the year 1992, the ASEAN Heads of Government declared that an ASEAN Free Trade Area (AFTA) shall be established in the region and that in 1995, they agreed to accelerate its implementation to the year 2003;

NOTING the ASEAN Trade in Goods Agreement which entered into force on 17 May 2010 providing for cooperation to supplement and complement the liberalisation of trade including, among others, the harmonisation of standards, conformity assessment procedures and technical regulations as a means of reducing technical barriers to trade;

MINDFUL that the Declaration of ASEAN Concord II (Bali Concord II) adopted by the ASEAN Heads of Government during the 9th ASEAN Summit in Bali, Indonesia on 7 October 2003, commits ASEAN to deepen and broaden its internal economic integration and linkages, with the participation of the private sector, so as to realise an ASEAN Economic Community;

MINDFUL that the establishment of the ASEAN Economic Community has been accelerated from 2020 to 2015 which will create ASEAN as a single market and production base;

REITERATING their commitments to the Agreement on Technical Barriers to Trade of the World Trade Organisation, which encourages Contracting Parties to enter into
negotiations for the conclusion of agreements for the mutual recognition of results of each other’s conformity assessment and mandates, among other matters, the elimination of unnecessary obstacles to trade including those relating to technical regulations;

RECALLING the ASEAN Framework Agreement for the Integration of Priority Sectors and the ASEAN Sectoral Integration Protocol for Healthcare signed on 29 November 2004 in Vientiane, Laos PDR; and

HAVING regard to the principles of harmonization of medical device regulations, the harmonized common technical documents and the progress made in its implementation

HAVE AGREED as follows:

ARTICLE 1
GENERAL PROVISIONS

(1) Each Member States shall undertake all necessary measures to ensure that only medical devices which conform to the provisions of this ASEAN Agreement on Medical Device Directive (hereinafter referred to as “Agreement”) and its Annexes may be placed on the markets of Member States.

(2) Subject to the provisions of this Agreement each Member State shall require that the person responsible for placing the medical device in a Member State or the authorized representative shall register the medical device with the Regulatory Authority of that Member State.

(3) Subject to the provisions of this Agreement, each Member State shall require that the person responsible for placing the medical device in that Member State or the authorized representative shall be licensed by the Regulatory Authority of that Member State before placing the medical device in that Member State.
ARTICLE 2
DEFINITIONS AND SCOPE

(1) This Agreement shall apply to medical devices and their accessories. For the purposes of this Agreement, accessories shall be treated as medical devices in their own right. Both medical devices and accessories shall hereinafter be termed devices. For the purpose of this Agreement, unless the context otherwise requires, the terms:

(a) “medical device” shall mean any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article:

(i) intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:-

(A) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(B) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

(C) investigation, replacement, modification, or support of the anatomy or of a physiological process,

(D) supporting or sustaining life,

(E) control of conception,

(F) disinfection of medical devices,

(G) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means,

(b) “Accessory” means an article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose.

(c) “Adverse event” means either a malfunction or a deterioration in the
characteristics or performance of a supplied medical device or use error, which either has caused or could have caused or contributed to death, or injury to health of patients or other persons.

(d) "Authorized representative" means any person in a Member State who, explicitly designated by the product owner, acts and may be addressed by authorities and bodies in a Member State instead of the product owner with regard to the latter’s obligations under this Agreement, and relevant laws and regulations of the Member State.

(e) "Authorized distributor", in relation to the placing on the market of a medical device, means any person who has been authorized by the product owner or authorized representative to distribute the medical device in that Member State.

(f) "Custom-made medical device" means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. For the purposes of this definition, a duly qualified medical practitioner is defined as a person who is duly qualified by the relevant laws and regulations of the Member State where the custom-made medical device is used.

For purposes of clarity, mass produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made medical devices.

(g) "Device intended for clinical investigation" means any device intended for use by a duly qualified medical practitioner when conducting investigations as referred to in Annex 8, in an adequate human clinical environment. For the purposes of conducting of clinical investigation, a duly qualified medical practitioner is defined as a person who is duly qualified by the relevant laws and regulations of the Member State where the clinical investigation is carried out, and by virtue of his professional qualifications, is authorized to carry out such investigation.

(h) "Field Safety Corrective Action" means any action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. This may include:

(i) the return of a medical device to the product owner or its
representative;

(ii) device modification which may include;

(a) retrofit in accordance with the product owner's modification or design change;

(b) permanent or temporary changes to the labeling or instruction or use;

(c) software upgrades including those carried out by remote access;

(d) modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the devices.

(iii) device exchange;

(iv) device destruction;

(vi) advice given by product owner regarding the use of the device.

(i) “Intended purpose” means the use for which the medical device is intended according to the specifications of its product owner as stated on any or all of the following:

(i) the label of the medical device;

(ii) the instructions for use of the medical device;

(iii) the promotional materials in relation to the medical device.

(j) “in vitro diagnostic (IVD) medical device” means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information:

(i) concerning a physiological or pathological state or a congenital abnormality;

(ii) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or

(iii) to monitor therapeutic measures; and includes a specimen receptacle.

(k) “manufacture”, in relation to a medical device, means to make, fabricate,
produce or process the medical device and includes —

(i) any process carried out in the course of so making, fabricating, producing or processing the medical device; and/or

(ii) the packaging and labeling of the medical device before it is supplied.

(l) “Person” means a natural person or a legal entity including a corporation, a partnership or association duly established and existed under applicable laws and regulations of Member States.

(m) “Physical manufacturer”, in relation to a medical device, means any person who performs the activity of manufacture.

(n) “Placing on the market” means the making available in return for payment or free of charge of a medical device other than a device intended for clinical investigation, with a view to distribution and/or use on the market of a Member State.

(o) “Product owner”, in relation to a medical device, means any person who

(i) supplies the medical device under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

(ii) is responsible for designing, manufacturing, assembling, processing, labeling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

(p) “Putting into service” means the stage at which a medical device has been made available to the final user as being ready for use on the market of a Member State for its intended purpose.

(q) “Refurbished Medical Device” means a medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and which may have had the following work carried out on it:

(i) stripping into component parts or sub-assemblies;

(ii) checking their suitability for reuse;

(iii) replacement of components/sub-assemblies not suitable for reuse;

(iv) assembly of the reclaimed and/or replacement components/sub-
assemblies;

(v) testing of the assembled device against either original or revised release criteria; or

(vi) identifying an assembled medical device as a refurbished medical device.

(r) “Register” means to obtain marketing approval for a medical device from the Regulatory Authority of a Member State in order to place the medical device on the market of that Member State.

(s) ”Regulatory Authority” means the regulatory authority or entity of that Member State which exercises a legal right to control the import, manufacture, export, distribution, transfer, use and the sale of medical devices within that Member State’s jurisdiction and which may take regulatory action to ensure that the products marketed within its jurisdiction comply with regulatory requirements.

(t) “Sponsor” means an individual or organisation taking responsibility and liability for the initiation or implementation of a clinical investigation.

(2) This Agreement shall not apply to the following:-

(a) human blood, plasma or blood cells of human origin or to medical devices which incorporate at the time of placing on the markets of Member States such human blood, plasma or blood cells of human origin, except if

(i) it is incorporated in an IVD medical device, or

(ii) it is incorporated in a medical device as a human blood derivative with an action ancillary to that of the medical device.

(b) transplants or tissues or cells of human origin nor to products incorporating or derived from tissues or cells of human origin, except if it is incorporated in an IVD medical device; or

(c) transplants or tissues or cells of animal origin, unless

(i) it is incorporated in an IVD medical device, or

(ii) it is a medical device manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissues or cells. “Non-viable” means in relation to a biological entity, an entity that is incapable of growth, development and reproduction.

ARTICLE 3
ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICE

Medical devices shall meet the essential principles set out in Annex 1 (Essential Principles of Safety and Performance of Medical Devices), as may be applicable, taking account of the intended purpose of the medical device concerned.

ARTICLE 4
CLASSIFICATION OF MEDICAL DEVICES

(1) Medical devices shall be classified into the following four classes, in accordance with risk classification rules set out in Annex 2 (Risk Classification Rules for Medical Devices other than IVD Devices) and Annex 3 (Risk Classification Rules for IVD Devices):

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Low risk</td>
</tr>
<tr>
<td>B</td>
<td>Low-moderate risk</td>
</tr>
<tr>
<td>C</td>
<td>Moderate-high risk</td>
</tr>
<tr>
<td>D</td>
<td>High risk</td>
</tr>
</tbody>
</table>

(2) In the event that a medical device may be assigned into 2 or more classes of medical devices, the Regulatory Authority of the Member State shall assign the medical device into such of those classes as represents the highest health risk posed to an end-user of the medical device.

(3) In the event that a medical device is designed to be used in combination with another medical device, each of the medical devices shall be classified separately.

(4) In the event the medical device has 2 or more intended purposes, the medical device shall, subject to Article 4(3), be assigned into a class of medical devices having regard to the most critical intended purpose of the medical device.

(5) In the event of a dispute between a Member State and any person in the
classification of a medical device, the Regulatory Authority of the Member State shall decide on the proper classification of the medical device concerned.

(6) Member State who reclassifies or differs in its application of the classification rules set out in Annex 2 and Annex 3 shall notify, with the reasons thereof, to the ASEAN Medical Device Committee (AMDC) of such measures taken.

ARTICLE 5

CONFORMITY ASSESSMENT OF MEDICAL DEVICES

(1) A medical device placed on the market of a Member State shall be assessed by the Regulatory Authority of the Member State, or any appointed bodies recognised by the Member State, as the case may be, for conformity and compliance with at least the requirements laid down in this Agreement unless the medical device has been exempted from the requirement for registration under paragraph 2 of Article 6.

(2) Member States shall put in place an appropriate system for the conformity assessment of medical devices under paragraph 1 of this Article.

ARTICLE 6

REGISTRATION AND PLACEMENT ON THE MARKET

(1) A medical device which is required to be assessed by a Member State and has been assessed by the Regulatory Authority of that Member State to be in conformity and in compliance with the requirements laid down in this Agreement may be placed on the market of that Member State.

(2) A medical device to be placed on the market of a Member State shall be registered with the Regulatory Authority of that Member State. The Regulatory Authority of the Member State may exempt certain medical devices from the requirement for registration where appropriate.

(3) Member States shall put in place an appropriate system for the registration of medical devices with the Regulatory Authority of that Member State.
(4) Custom-made medical devices shall not be subjected to product registration requirements.

(5) Notwithstanding paragraph 1 and 2 of this Article, the Regulatory Authorities of a Member State may, pursuant on duly justified request or by their own initiative authorize the use within the territory of that Member State, of medical devices which have not undergone registration with the Regulatory Authority and where such use is in the interest or protection of public health.

ARTICLE 7
LICENSEING OF PERSONS RESPONSIBLE FOR PLACING MEDICAL DEVICES ON THE MARKETS OF MEMBER STATES

Each Member State shall require a person who is responsible for placing medical devices on the market to be licensed by the Regulatory Authority of that Member State before the medical devices are placed on the market of that Member State. Member States shall put in place an appropriate system for the licensing of persons responsible for placing medical devices on their markets.

ARTICLE 8
TECHNICAL DOCUMENTS FOR MEDICAL DEVICES

Member States shall undertake appropriate measures to adopt and implement the following common technical documents which are annexed to this Agreement:
(a) Annex 4 - ASEAN Common Submission Dossier Template (CSDT)
(b) Annex 5 - Post Marketing Alerts System (PMAS) Requirements ; and
(c) Annex 6 - Harmonized set of elements for a Product Owner’s or Physical Manufacturer’s Declaration of Conformity (DoC)

ARTICLE 9
REFERENCE TO STANDARDS AND RELEVANT DOCUMENTS

(1) Medical devices which conform to the relevant standards recognized by the AMDC or other standards accepted by the Regulatory Authority of a Member State for
the medical device to be placed in the market of that Member State shall be deemed to comply with the essential principles referred to in Article 3.

(2) The AMDC may revise by consensus, the list of recognised technical standards referred to in paragraph 1 of this Article.

ARTICLE 10
LABELLING

(1) A medical device shall be labeled 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 labeling requirements for a medical device in accordance with Annex 7 (Labeling 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.

ARTICLE 11
MEDICAL DEVICE CLAIMS

(1) Medical device claims shall be subjected to regulatory control of Member States.

(2) As a general rule, claimed benefits of a medical device shall be justified by substantial evidence and/or by the medical device composition/formulation/component or preparation itself in accordance with the requirements as set out in Annex 1. (Essential Principles for Safety and Performance of Medical Devices).

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 labeling 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 sub paragraph (a), leading to product recall of medical devices of the same type by the product owner, authorized representative, authorized distributor or person responsible for placing medical device into the market.

(2) After carrying out an assessment, if possible together with the product owner, a Member State shall inform the other Member States of the incidents referred to in paragraph 1 for which relevant measures have been taken or are contemplated.

(3) Each Member State shall require that any person who is responsible for the manufacture or placing the medical devices on the market of that Member State to:-

(a) keep all relevant records pertaining to the tractability of the medical device, for such period and format as the Regulatory Authority in the Member State may stipulate;

(b) produce such records for inspection when required by the Regulatory Authority in the Member State;

(c) inform the Regulatory Authority, within he stated prescribed time and format of the Regulatory Authority in the Member State, where he becomes aware of any adverse event that has arisen or can arise from the use of the medical device placed on the market in the Member State; and

(d) inform the Regulatory Authority, within the stated prescribed time and format of the Regulatory Authority in the Member State, when he performs or intends to perform a field safety corrective action (FSCA) on a medical device placed on the market in the Member State.
ARTICLE 13

CLINICAL INVESTIGATION

Member States shall put in place an appropriate system for the conduct of clinical investigation of medical devices, taking into account the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and any subsequent amendments or revisions to this Declaration by the World Medical Association. It is acknowledged that all measures relating to the protection of human subjects are required to be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results, which may include the following requirements:

(1) In the case of medical devices intended for clinical investigation, the Regulatory Authority of the Member State may require the product owner, or his authorize representative, or the sponsor of the clinical investigation in a Member State, as the case may be, to follow the procedure referred to in Annex 8 (Clinical Investigation) and register with the Regulatory Authority of that Member State in which the investigations are to be conducted.

(2) The Regulatory Authority of the Member State may require that the clinical investigations be conducted in accordance with the provisions of Annex 8 (Clinical Investigation).

(3) The Regulatory Authority of that Member State may require the product owner or his authorized representative, or the sponsor of the clinical investigation in a Member State, as the case may be, to submit or make available on request, as deem appropriate by, the report referred to in Annex 8.

(4) Where a clinical investigation is refused or halted by a Member State, that Member State may communicate its decision and the grounds thereof to all Member States and the AMDC. Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State may
inform all Member States and the AMDC concerned about its actions and the grounds for the actions taken.

(5) The Regulatory Authority of a Member State may require that the product owner or his authorized representative, or the sponsor of the clinical investigation in a Member State, as the case may be, to notify of the end of the clinical investigation, with justification(s) in case of temporary suspension or of early termination. In the case of early termination of the clinical investigation on safety grounds, this notification may be communicated to the Regulatory Authority of all Member States where the clinical investigation is carried out.

ARTICLE 14
INSTITUTIONAL ARRANGEMENTS

(1) The AMDC shall be established with the overall responsibility of coordinating, reviewing and monitoring the implementation of this ASEAN Agreement and shall comprise representatives from the Regulatory Authority of each Member State.

(2) The ASEAN Consultative Committee for Standards and Quality (ACCSQ) and the ASEAN Secretariat shall provide support in coordinating and monitoring the implementation of this ASEAN Medical Device Directive and assist the AMDC in all matters relating thereto.

(3) The AMDC may establish an ASEAN Medical Device Technical Committee (AMDTC) to assist the AMDC in reviewing the technical and safety issues.

ARTICLE 15
SAFEGUARD CLAUSES

(1) Member States acknowledge that a medical device placed on the market of Member States shall not compromise the health or safety of patients, users or, where applicable, other persons, when applied under normal or reasonably foreseeable
conditions of use, taking account, in particular, of the medical device’s presentation, packaging, its labeling, instructions for its use and where appropriate, disposal, warning statements as well as any other indication or information provided by the product owner or his authorized representative or by any other person responsible for placing the medical device on the market.

(2) Where a Regulatory Authority ascertains that a medical device placed on the market of a Member State, when correctly installed, maintained and used for its intended purpose, may compromise the health or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such medical device from the market or prohibit or restrict their being placed on the market or put into service. That Member State shall immediately inform the other Member States of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Agreement is due to:

(a) failure to meet the essential principles set out in Annex 1 (Essential Principles for Safety and Performance of Medical Devices);

(b) incorrect application of the standards referred to in Article 9, in so far as it is claimed that the standards have been applied; or

(c) shortcomings in the standards themselves.

ARTICLE 16
CONFIDENTIALITY

Without prejudice to the existing national provisions, Member States shall require that all the parties involved in the application of this Agreement are bound to observe confidentiality with regard to all confidential information obtained in carrying out their tasks. This confidentiality obligation does not however affect or prevent:

(a) the disclosure of any information by any Member State to another Member State pursuant to any provision in this Agreement;

(b) the disclosure of any confidential information with the permission of the person from whom the information was obtained;
(c) the disclosure of information for the purposes of the administration or enforcement of the requirements of this Agreement including the disclosure of any information to any adviser engaged by the Regulatory Authority of a Member State to advise on any aspect of the medical device to which the information relates and the dissemination of warnings or information for the public interest;

(d) the disclosure of information for the purposes of assisting in any investigation or prosecution of any offense under the national law of a Member State; and

(e) any requirement by any court or the provisions of any national law of a Member State to provide information.

ARTICLE 17
SPECIAL CASES

(1) A Member State may refuse to register or prohibit the marketing of a medical device in its market or subject it to special conditions or different controls, as it deems appropriate, although the medical device complies with the requirements of the Agreement, for reasons specific to religious or cultural sensitivity.

(2) A Member State may refuse or prohibit a refurbished medical device to be placed on its market or put into service, as it deems appropriate, even if such medical device complies with the requirements of the Agreement.

(3) Nothing in this Agreement shall be construed to limit the authority of a Member State to determine, through its legislative, regulatory and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment and for consumers.

(4) Nothing in this Agreement shall be construed to limit the authority of a Member State to take all appropriate and immediate measures whenever it ascertains that a medical device may:

(a) compromise the public health or safety in its territory;

(b) not meet the legislative, regulatory, or administrative provisions within the
scope of this Agreement; or

(c) otherwise fails to comply with a requirement within the scope of this Agreement.

(5) A Member State who places a restriction or ban on specific medical devices shall notify the other Member States with the reasons thereof, together with a copy to the AMDC of such measures taken.

ARTICLE 18
IMPLEMENTATION

(1) Member States shall undertake appropriate measures to implement this Agreement.

(2) Member States shall undertake appropriate measures to ensure that the technical infrastructures necessary are in place to implement this Agreement.

(3) Member States shall ensure that the texts of such provisions of national laws, which they adopt in the field governed by this Agreement are communicated to the other Member States with a copy to the ASEAN Secretariat, who shall promptly notify the AMDC.

(4) Member States shall ensure that post marketing surveillance is in place and shall have full authority to enforce the law on medical devices found to be not complying with this Agreement.

ARTICLE 19
REVISIONS, MODIFICATIONS AND AMENDMENTS

(1) The provisions of all or any part of this Agreement may be revised, modified or amended, by written agreement of all Member States.

(2) Notwithstanding paragraph 1 of this Article, the Annexes of this Agreement may be revised, modified or amended subject to the endorsement of AMDC.

(3) Any revision, modification or amendment shall not prejudice the rights and
obligations arising from or based on this Agreement prior and up to the date of such revision, modification or amendment.

ARTICLE 20
DISPUTE SETTLEMENT

The ASEAN Protocol on Enhanced Dispute Settlement Mechanism signed on 29 November 2004 in Vientiane, Lao PDR and amendments thereto, shall apply to the settlement of disputes concerning the interpretation or implementation of this Agreement.

ARTICLE 21
RESERVATIONS

Member States shall make no reservation with respect to any of the provisions of this Agreement.

ARTICLE 22
ENTRY INTO FORCE

(1) This Agreement shall be subject to ratification and/or acceptance by Member States in accordance with their internal domestic requirement.

(2) This Agreement shall enter into force on 1 January 2015 and shall be in force only among the Member States that have ratified and/or accepted it.

(3) The Secretary-General of ASEAN shall promptly notify all Member States of the notifications or deposit of each instrument of ratification and/or acceptance referred to in paragraph 1 of this Article.

ARTICLE 23
ANNEXES

The Annexes to this Agreement constitute an integral part of this Agreement.
ARTICLE 24
DEPOSITARY

This Agreement shall be deposited with the Secretary-General of ASEAN, who shall promptly furnish each Member State a certified copy thereof.

IN WITNESS WHEREOF the undersigned, being duly authorized by their respective