ORIGINAL ARTICLE

Overview of the In-Vitro Diagnostic Medical Device Regulatory Process in Malaysia

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ABSTRACT

In-vitro diagnostic (IVD) medical devices are under the custody of the Medical Device Authority (MDA) and play an important role in diagnosing diseases, monitoring health conditions, and guiding treatment decisions. As Malaysia expands its role in becoming the global medical technology field, establishing a strong and efficient regulatory framework becomes essential. The current study highlights the regulatory process for licensing and registering IVD medical devices in Malaysia. Information on the licensing and registration processes was obtained from the MDA portal, with relevant data extracted from the MeDC@St platform. The registration data of IVD medical devices shows the same trend as following the 5-year validity of the certificate, and the data recorded about 223 IVD establishment licenses from 2016 to 2024. The development of a regulatory framework for the licensing and registration of IVD medical devices has played a crucial role in shaping the presence and development of such devices in Malaysia.
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INTRODUCTION

In-vitro Diagnostic (IVD) medical devices are essential in diagnosing diseases, monitoring health conditions, and guiding treatment decisions. These devices are designed to perform tests on samples derived from the human body, such as blood, urine, tissue, or other bodily fluids, to provide information about physiological or pathological conditions (3).

In Malaysia, the Medical Device Authority (MDA), a federal statutory agency under the Ministry of Health Malaysia (MOH), regulates medical devices in the country (13). MDA is responsible for enforcing the Medical Device Act 2012 (Act 737) to ensure public health and safety while at the same time facilitating the trade and development of the medical device industry (1).

The IVD segment dominated the market in 2023, driven by factors such as the increasing prevalence of infectious diseases and the growing number of tests among patients. Alongside this, there are increasing research and development activities among the key players operating in the market to develop and introduce novel test kits and products, addressing the growing demand for these solutions (4).

In 2023, the global medical devices market was valued at USD 518.46 billion and is projected to expand from USD 542.21 billion in 2024 to USD 886.80 billion by 2032, reflecting a compound annual growth rate (CAGR) of 6.3% during the forecast period. North America dominated the medical devices market with the largest market share of 38.16% in 2023. In conjunction with this, the U.S. medical device market is expected to experience significant growth by 2032, reaching an estimated value of USD 314.96 billion, driven by the resilient pipeline and increasing research and development investment by industry players (4).

According to the Malaysian Investment Development Authority (MIDA), more than five companies in Malaysia manufacture In-Vitro Diagnostic (IVD) Rapid Test Kits (RTKs), with the majority commencing production within the past two years to meet the heightened demand for COVID-19 rapid detection. Given the ongoing prevalence of COVID-19, domestic production of COVID-19 RTKs remains crucial, and the need for diagnostic testing continues to be imperative. The global IVD market was valued at USD 83.4 billion in 2020 and

is projected to expand at a compound annual growth rate (CAGR) of 4.5% from 2021 to 2027. This growth is primarily driven by the increased utilization of IVDs for COVID-19 diagnostics, alongside rising awareness of early disease detection and treatment in healthcare. (11).

Malaysia's New Industrial Master Plan (NIMP) 2030 is intended to establish the country as one of the global leaders in high-value industries, particularly in the sector of medical devices. Under NIMP 2030, Point of Care (POC) products, a part of IVD, are becoming the key focus areas for the medical device industry. The plan emphasizes innovation and regulatory excellence, strengthens international relations, enhances data security and accelerates government digitalization and integration to stimulate the growth of the medical technology industry (5). Supported by the strong regulatory framework led by the MDA, Malaysia ensures compliance with international standards, elevating its attractiveness as a medical device manufacturing destination. The implementation of NIMP 2030 is anticipated to drive industry transformation, placing Malaysia as a prominent player in the global medical technology field. As the country strengthens its role in this field, ensuring a robust and efficient regulatory framework becomes crucial. This study emphasizes the regulatory process for the licensing and registration of IVD medical devices, with a specific focus on Malaysia.

MATERIALS AND METHODS

Source and Gathering of information on the Regulatory Process of IVD Medical Device

The information related to the regulatory process of IVD medical devices is obtained from the official portal of the MDA (http://portal.mda.gov.my). In the portal, all the documents, such as guidance documents, circular letters and regulatory acts, are retrieved and referred to for an explanation of the respective processes.

Medical Device Centralised Online Application System (MeDC@St)

MDA has created a digital online application system known as MeDC@St (6), a platform through which the medical device industry representative needs to sign up and request the enrolment of license for medical devices and facilities as necessary, outlined in the Medical Device Regulations 2012. This system began on 1 July 2013 and consists of several modules, including establishment licensing and medical device registration.

Gathering Information Parameters

The information related to the records of licensee holder and IVD medical device registration is retrieved from the MeDC@St platform as depicted in Table I.

Table I: Parameter criteria for data collection from the MeDC@st platform.

Parameter	Data Collection
Year of records	2016-2024
Role of establishments	Manufacturer and Authorised Representative
Type of device	In-Vitro Diagnostic Device
Classification risk	Class A, B, C, and D

RESULTS AND DISCUSSION

IVD Medical Device Framework

Manufacturers of IVD medical devices shall be responsible for the device's lifecycle, which comprises the pre-market, placement on the market and post-market requirements. Under the pre-market, the manufacturer must ensure the device conforms to the essential principle of safety and performance (EPSP). Any relevant essential principle of the IVD medical device needs to be determined and ensure the requirements through the design and manufacturing controls (7). For others, the manufacturer needs to establish a quality management system (QMS) to manufacture their devices according to ISO 13485 and is also required to collect evidence of conformity (2).

During the placement of IVD medical devices on the Malaysian market, the manufacturer or authorized representative (AR) must comply with the requirements set out under Section 5 and Section 15 of the Medical Device Act 2012 (Act 737). This includes obtaining medical device registration and the relevant establishment license from the MDA. Organizations involved in the supply chain, including authorized representatives, distributors, and importers, are collectively called establishments under the Act (1). Each establishment must clearly define its role within the supply chain and, except for manufacturers, implement a Good Distribution Practice for Medical Devices (GDPMD) system. GDPMD serves as a QMS to ensure the safe handling, storage, and distribution of medical devices in compliance with regulatory requirements (2). For post-market requirements, establishments must comply with Sections 37 to 42 of the Act 737 (1). They are responsible for monitoring the safety and performance of IVD medical devices through post-market surveillance and vigilance activities. Additionally, establishments must fulfil other post-market obligations, including complaint handling, adverse event reporting, and product recall management, to ensure continued compliance and patient safety.

In-Vitro Devices Classification Risk

IVD medical devices are classified into Class A, B, C, and D based on their risk level, determined by the intended use and indications for use specified by the manufacturer (3). The intended user further influences the classification, whether the device is designed for use by healthcare professionals or laypersons. Additionally, the importance of the diagnostic information provided by the device plays a critical role in risk classification.

Devices that serve as the sole determinant for a diagnosis or provide complementary diagnostic information may fall into different risk classes. It includes devices used to monitor disease progression or patient condition. Furthermore, the impact of the test results on both the individual and public health is a key factor in determining the classification. Higher-risk classes are typically assigned to devices significantly influencing critical health decisions or public health safety.

Class A IVD medical devices possess a low individual risk and public health—examples of devices include analysers without reagents, specimen receptacles and glass slides. IVD medical devices such as pregnancy self-test kits, Vitamin B12, and Cretinine kits belong to the class B IVD medical devices that possess a moderate individual risk and/or low public health risk. Class C and D have high individual risks but differ in the public health risks, which are moderate and high, respectively. Examples of IVD medical devices include human leucocyte antigen (HLA) typing under class C, while the ABO system for the determination of blood type falls under Class D.

HLA typing is classified as Class C because errors primarily lead to significant adverse outcomes at the individual level, such as graft rejection or graft-versus-host disease, without posing an immediate or widespread risk to public health. A recent study has demonstrated that any degree of HLA mismatch can significantly impact transplant recipient outcomes (15). This finding indicates that inaccurate HLA typing results predominantly affect individual patients, as negative or incorrect HLA matching can directly compromise graft survival and post-transplant prognosis. This evidence supports the classification of HLA typing as a device with a high individual risk but limited application in public health. In contrast, ABO system is classified as Class D due to its pivotal role in ensuring transfusion safety; any misclassification may lead to acute, potentially fatal haemolytic transfusion reactions that can simultaneously affect multiple patients, thus constituting a severe public health threat. A report provides clear evidence that errors related to ABO system, including failures in patient identification and blood administration, have resulted in preventable deaths, significant morbidity, and a high frequency of near-miss events. These incidents not only endanger patient lives but also place considerable strain on healthcare systems (16).

IVD Medical Device Registration Process

Any IVD medical device that has already determined its classification risk, relevant rule and type of grouping could proceed with the medical device registration (8). Only Class A type of IVD medical devices are not required to do conformity assessment by the registered conformity assessment bodies (10). All technical documents related to IVD medical devices need to be submitted online using the MeDC@St platform. A certain fee is charged for each submission application, and the MDA officers will evaluate the submitted applications. The application will be approved after the required submission documents are completed, followed by the issuance of the medical device registration certificate valid for 5 years. Any changes to the information on the medical devices also need to be reported to the MDA through the online platform (14). The medical device registration certificate can be re-registered 1 year before the certificate expires. The overall framework of the IVD medical device registration process is illustrated in Figure IV. As of 2024, there are about 223 establishment licenses specifically for IVD medical devices that have been registered with MDA. These numbers are expected to increase due to regulatory factors, market demands and technological advancement of IVD medical devices around the world.

According to Figure 1, the number of registered IVD medical devices exhibited a significant increase from 2016 to 2018, coinciding with the enforcement of mandatory medical device registration in Malaysia along with regulatory changes and increased industry adoption of IVD technologies. This was followed by a sharp decline in 2019, with relatively low registration activity observed from 2019 to 2021. During this period, the overall number of IVD medical device registrations decreased due to market saturations with only a limited number of new registrations occurring for products newly introduced into the Malaysian market. Additionally, the five-year validity period of registration certificates also contributed to the reduced registration activity during this interval. This trend is further supported by the subsequent surge in registration applications observed in 2023, likely driven by the re-registration process undertaken by existing certificate holders whose device registrations were approaching expiration. The increases of registration activity during this year also contributed by the regulatory updates caused by post-COVID-19 pandemic where all COVID-19 related IVD medical devices who have received Conditional Approval (CA) by MDA have to be officially and fully registered in the MeDC@St platform (12).

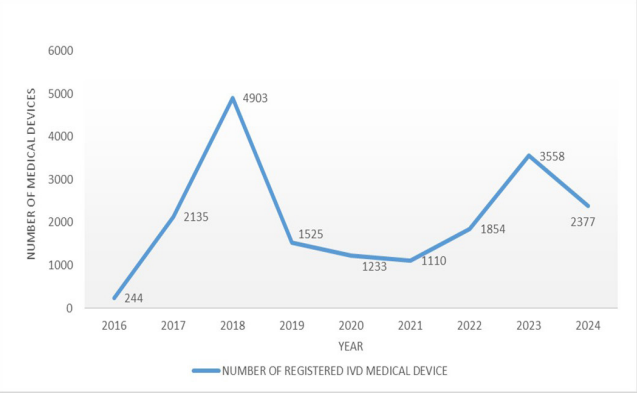

Fig. 1: Trend of Registered IVD Medical Device over Year (From 2016 to 2024).

Figure 2 and Figure 3 illustrate the relative proportion of IVD medical devices by classification, rather than the absolute registration numbers discussed previously. The distribution of IVD classes has remained relatively stable over the years, with Class A, B, and C constituting the majority of registrations. The highest proportion of registered IVD medical devices corresponds to Class A (low risk, green segment) and Class B (moderate risk, red segment), while Class C (high risk, blue segment) maintains a substantial share. In contrast, Class D (highest risk, yellow segment) consistently represents the smallest proportion across all years.

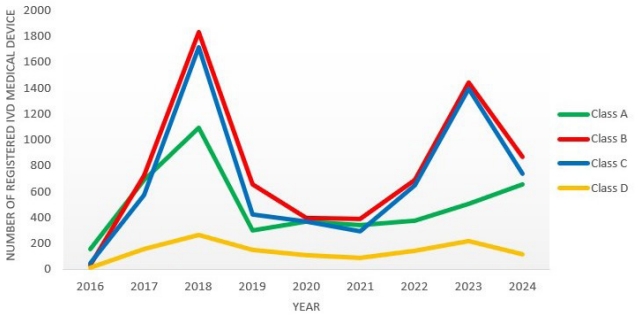

Fig. 2: Registered IVD Medical Devices according to Classification Risk over Year (From 2016 to 2024).

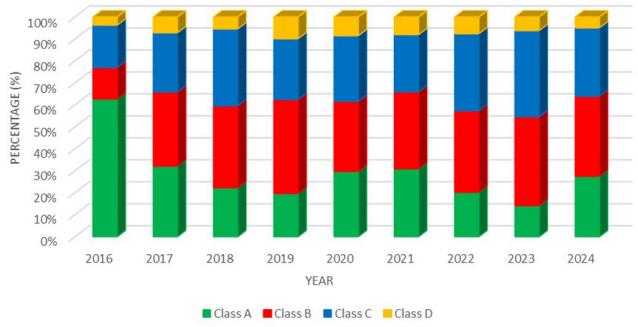

Fig. 3: Yearly Distribution of IVD Medical Devices According to Classification Risk.

The stability in these proportions suggests that Malaysia's regulatory framework effectively maintains a balanced distribution of IVD medical devices based on risk classification. The predominance of Class A and B devices aligns with the operational requirements of healthcare providers, as lower- and moderate-risk devices are more frequently utilized in routine diagnostics. Additionally, the observed increase in Class B and C devices may indicate progressive advancements in moderate- and high-risk diagnostic technologies, potentially driven by innovations in molecular diagnostics and automation. The re-registration surge observed in 2023, as depicted in Figure 1, may have influenced the relative distribution of registrations; however, the overall proportions have remained largely consistent.

Conformity Assessment and Parties Involved

Generally, IVD medical devices designed by the manufacturer shall ensure their safety and performance as intended and need to conform to the Essential Principle of Safety and Performance (EPSP) for Medical Devices. For instance, medical devices that fall under classification risk B, C or D must undergo a conformity assessment before submitting a registration application to the MDA for approval in Malaysia. Under this assessment, there are four elements to be reviewed by the auditor registered under the conformity assessment body (CAB): Quality Management System (QMS), Post Market Surveillance (PMS) system, technical documentation and a declaration of conformity (DOC) (7).

Manufacturers shall establish and maintain an effective QMS that meets international standards to ensure the safety and performance of the medical devices. The QMS scope depends on the organization's size, product type and regulatory needs. Besides, outsourced QMS

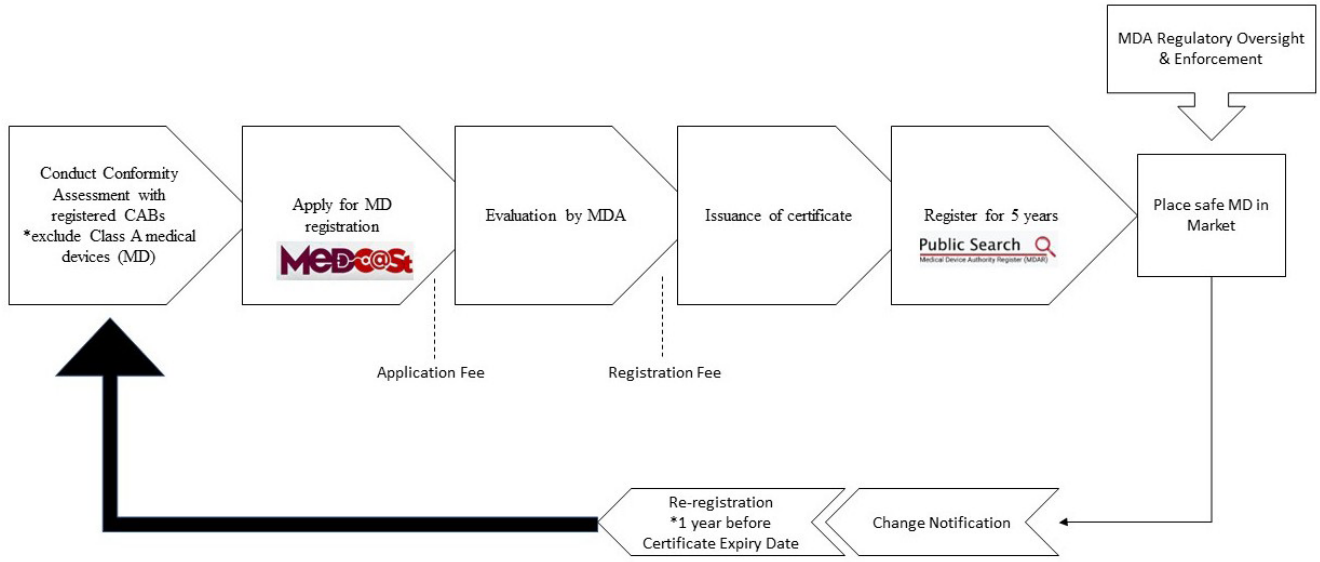

Fig. 4: Overall framework of IVD Medical Device Registration Process.

activities are also under the manufacturer's responsibility. The assessment will depend on the medical device classification risk, with stricter requirements for higher-risk classes. Class C and D IVD medical devices require complete QMS, including design and development, while not for Class B devices. Class A devices must have a QMS but are usually not subject to premarket on-site audits. MDA/CAB may review certifications and conduct audits if needed. Additionally, to maintain compliance with safety and performance standards throughout an IVD medical device's lifecycle, post-market activities such as complaint handling, vigilance reporting and corrective/preventive actions must be in place within the organizations.

Technical documentation refers to evidence of conformity of the IVD medical devices towards the Essential Principle. The evidence of conformity shall be presented according to the acceptable standards. For assessment, manufacturers must prepare a Common Submission Dossier Template (CSDT), which is written based on the device's classification risk and complexity (9). Higher-risk devices typically require more detailed evidence, with the depth and timing of the review by the regulatory authority or CAB depending on the device's classification risk and complexity. Lastly, IVD medical device manufacturers must provide a Declaration of Conformity (DOC) confirming compliance with safety and performance requirements. The DOC should include information such as the device's classification risk, manufacturer details, QMS validity and the signature of an authorized representative.

The current framework can make it challenging for CAB to maintain a consistent understanding of classification risk under the Medical Device Regulation 2012. Divergent interpretations among CAB may lead to misclassification and delays in the registration of IVD medical devices. To address this, the MDA will periodically issue classification risk updates (17) and conduct targeted awareness or training sessions for all CAB auditors. In addition, CAB must adopt a standardized reporting template to verify that manufacturers' submissions meet the MDA's minimum documentation requirements. To further streamline this process, the MDA has produced a uniform Conformity Assessment Report designed to guide CAB through each registration requirement for IVD medical devices (18).

Conformity Assessment and Parties Involved

In order to conduct a conformity assessment on IVD medical device application, there are lists of technical personnel's areas of expertise, as listed in Table II. CAB shall determine the organization's relevant scope expression and technical code before proceeding with the conformity assessment. For example, the Human Immunodeficiency Virus (HIV) Antigen Rapid Test Kit falls under the highest classification risk, D. Thus, the conformity assessment shall be done carefully, as the respective IVD medical device is intended to detect the presence of a transmissible agent which could cause a life-threatening disease with a high or suspected high risk of propagation. Relevant technical codes shall be used, such as IVD 0201- HIV Infection (HIV 1 and 2). The technical personnel shall ensure that the device manufacturer has fulfilled the essential elements for conformity assessment.

Table II: Medical Device Technical Areas In Vitro Diagnostic (IVD) Medical Devices

Code	Scope expression
IVD 0100: LIST A REAGENTS AND REAGENT PRODUCTS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR DETERMINING THE FOLLOWING BLOOD GROUPS	
IVD 0101	ABO system
IVD 0102	Rhesus (C, c, D, E, e)
IVD 0103	Anti-Kell
IVD 0200: LIST A REAGENTS AND REAGENT PRODUCTS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR THE DETECTION, CONFIRMATION AND QUANTIFICATION IN HUMAN SPECIMENS OF MARKERS OF	
IVD 0201	HIV infection (HIV 1 and 2)
IVD 0202	HTLV I and II
IVD 0203	Hepatitis B, C and D
IVD 0300: LIST B REAGENTS, REAGENT PRODUCTS AND DEVICES FOR SELF-DIAGNOSIS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR DETERMINING, DETECTION, QUANTIFICATION, DIAGNOSING, EVALUATING	
IVD 0301	Anti-Duffy and anti-Kidd
IVD 0302	Irregular anti-erythrocytic antibodies
IVD 0303	Congenital infections: rubella, toxoplasmosis
IVD 0304	Hereditary disease: phenylketonuria
IVD 0305	Human infections: cytomegalovirus, chlamydia
IVD 0306	HLA tissue groups: DR, A, B
IVD 0307	Tumoral marker: PSA
IVD 0308	Risk of trisomy 21 (incl. software)
IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
IVD 0400: DEVICES FOR SELF-TESTING	
IVD 0401	Clinical chemistry
IVD 0402	Haematology
IVD 0403	Immunology
IVD 0404	Molecular biology
IVD 0405	Pregnancy and ovulation
IVD 0406	Specimen receptacles
MDS 7200: SPECIFICS OF IN VITRO DIAGNOSTIC (IVD) MEDICAL DEVICES	
MDS 7206	IVDs in sterile condition
MDS 7207	IVDs utilising micromechanics
MDS 7208	IVDs utilising nanomaterials
MDS 7209	IVDs utilising biological active coating and/or material
MDS 7210	IVDs utilising material of human origin

Several technical documents, such as pre-clinical and clinical performances (9), are required for the technical personnel review. Under the pre-clinical performance, there are several tests the manufacturer should provide to CAB for review, such as analytical sensitivity tests

(Limit of Detection), analytical specificity (Interference), precision (Repeatability or Reproducibility), Cut-off Value and Trueness tests. Others, the stability of the reagents test also needs to be provided by the manufacturer. For clinical performance tests, the manufacturer also needs to determine results related to clinical sensitivity and specificity. The technical personnel must review all documents to determine whether all tests were conducted according to the experimental design planned.

CONCLUSION

Establishing the regulatory process for the licensing and registration of IVD medical devices has shown a significant trend in the existence of IVD medical devices in Malaysia. Besides, this process could support the growth and sustainability of the national industrial plan that has listed medical devices as one of the key focus areas, aiming to strengthen Malaysia's position as a global medtech hub.

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