

MALAYSIA'S MEDICAL DEVICES INDUSTRY: IMMENSE GROWTH POTENTIAL



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MALAYSIA'S MEDICAL DEVICES INDUSTRY: IMMENSE GROWTH POTENTIAL

The medical devices industry in Malaysia is poised for growth and development, well supported by a conducive environment for manufacturing and investment, and a healthcare system that is mature and globally recognised. Notably, Malaysia's healthcare system has been lauded by the World Health Organisation (WHO) as a sustainable model which is accessible and affordable by all, served by both the public and private sectors. The Government continues to prioritise national health and wellbeing as it has been laid out as one of the three main themes of the Twelfth Malaysia Plan (12MP) 2021-2025 and will undertake a medium-to long-term reform of its healthcare sector while gradually aiming to increase healthcare spending every year towards maintaining a world-class healthcare system.

Establishing a manufacturing base in Malaysia offers the perfect opportunity to tap into the burgeoning Asia Pacific healthcare market. It is predicted that over 60 per cent of the world's population will be living in Asia by 2030 with one in four people aged of 60 or older. As more emphasis is placed on healthcare and wellness, driven by the needs of an ageing population and unexpected situations like the COVID-19 pandemic, demand for medical devices and consumables is consistently on the rise.

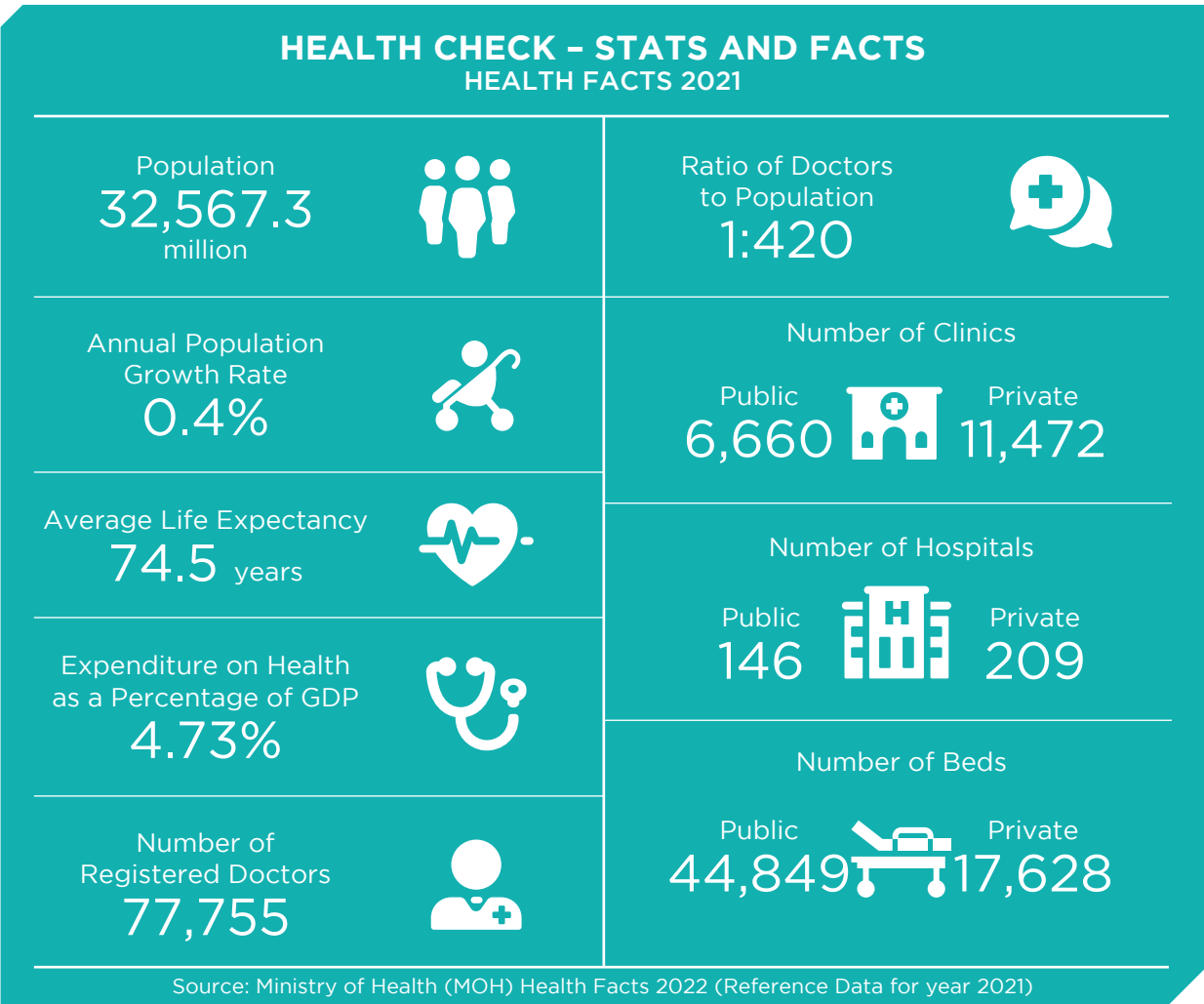
Consumables such as syringes, test kits, rubber gloves, and personal protective equipment (PPE), increased tremendously during the pandemic years. Many elective surgeries which had been postponed during the height of the pandemic are now being rescheduled, re-stimulating demand. The shift to home care using more portable medical devices is also another factor that will increase the demand for medical equipment.



A SNAPSHOT OF MALAYSIA

Sitting in the heart of the ASEAN region, Malaysia has 13 states and three Federal Territories – its capital city of Kuala Lumpur, the administrative heart of Putrajaya and its offshore financial centre of Labuan. A growing centre of excellence for a wide range of business and investment opportunities, the country’s infrastructure is well developed with a comprehensive network of roads, airways, and ports as shipping gateways to the global market.

Starting out as an economy reliant on natural resources such as rubber, tin and palm oil, Malaysia is today a major exporter of manufactured goods. These include electrical and electronic items, machinery and appliances, chemicals and chemical products as well as iron, steel and metal products. Major exports also include petroleum products, liquefied natural gas and palm oil. Meanwhile imports comprise mainly intermediate goods such as primary and processed industrial supplies, thermionic valves and tubes, parts and accessories of capital goods, primary and processed fuel lubricants, and parts and accessories for transport equipment.



A THRIVING ECOSYSTEM AND LANDSCAPE



Malaysia's medical device industry produces a wide range of products and equipment ranging from medical gloves, implantable devices, orthopaedic devices and dialysers. It also includes diagnostic imaging equipment and minimally invasive surgery equipment as well as other devices used for surgical, dental, optical and general health purposes. Malaysia is the largest market for medical devices in the ASEAN region with an estimated total market size of USD1.8 billion. Over 90 per cent of the medical devices manufactured in Malaysia are exported to its top 10 export destinations namely the United States of America (the USA), Germany, Singapore, Japan, Belgium, People's Republic of China (PRC), the Netherlands, Brazil, the United Kingdom (UK) and Australia.

The industry is moving up the value chain as higher value-added and complex products are being manufactured in Malaysia. These include pacemakers, defibrillators, surgical

instruments, medical electrodes, endoscopes, dialysis solutions, radiographic and ultrasound diagnostic systems, in-vitro diagnostic devices and health monitoring devices. Furthermore, the sector extends to the production of hospital support systems, including medical gases, anaesthesia sets, fixed operation theatre and examination tables, as well as disposable wearable surgical gear. Medical glove manufacturers have diversified into higher quality and specialty gloves, such as accelerator-free and chemotherapy special function gloves and antimicrobial gloves. As a rubber-producing nation, Malaysia remains the world's leading manufacturer and exporter of catheters and surgical and examination gloves, supplying 80 per cent of the world market for catheters and 60 per cent for rubber gloves, inclusive of those for medical use.

In order to compete globally in an increasingly competitive industry, Malaysian medical device manufacturers are expanding

their base into higher value products and moving into product and process research and development (R&D) as well as design and prototyping. The adoption of higher technology processes and the use of new materials, better coating for improved performance and increased automation is moving the manufacturing of medical devices towards Industry 4.0.

Malaysia is evolving as a major production hub for medical devices in the region as well as globally, with more than 200 medical devices manufacturing companies thriving in a well-connected industry ecosystem. Thirty of these companies are multinationals that have made Malaysia their manufacturing base. Among these MNCs are reputable names such as Abbott, and B-Braun. The industry employs over 70,000 skilled workers who represent the human capital of the industry.

MAJOR FOREIGN COMPANIES OPERATING IN MALAYSIA:



EUROPE

- Ambu
- B. Braun
- SteriPack
- Smith & Nephew

AUSTRALIA

- Ansell
- Cochlear
- Resmed

ASIA

- Medipro
- Meditop
- Sagami
- Hoya Lens

USA

- Ciba Vision
- Boston Scientific
- Becton, Dickinson and Company (BD)
- Tecomet
- Haemonetics
- Abbott
- Lake Region
- Mediquip
- Teleflex
- Johnson & Johnson
- Dexcom
- Insulet
- Masimo

MAJOR DOMESTIC COMPANIES OPERATING IN MALAYSIA:

- Top Glove
- Hartalega
- Supermax Corporation
- Muzamal Industry
- LKL Advance Metaltech
- Cross Protection
- OSA Technology
- Granulab
- Straits Orthopaedics
- ABio Orthopaedics
- Ideal Healthcare
- Allen Healthcare
- Epsilon
- Kossan









The COVID-19 pandemic has created an upswell in the demand for hospital support equipment such as anaesthesia sets, fixed operation theatre and examination tables as well as disposable items like surgical gowns, drapes and packs, surgical and medical caps, and masks that are manufactured locally. Some of the more complex medical devices manufactured locally add value to the nation as they require higher-end knowledge and skills, which shifts Malaysia up the medical device value chain.

HIGH VALUE ADDED AND COMPLEX MEDICAL DEVICES PRODUCED IN MALAYSIA			
 Pacemakers	 Defibrillators	 Orthopaedic Products	
 Patient Monitors	 Surgical Instruments	 Medical Electrodes	
 Endoscopes	 Dialysis Solutions	 Diagnostic Radiographic Equipment	
 Ultrasound Diagnostic System	 Drug Delivery Devices	 In-Vitro Diagnostic Devices	 Health Monitoring Devices

In a move towards increasing value, local medical glove manufacturers have also diversified into specialty gloves such as accelerator free special function gloves, chemotherapy special function gloves and antimicrobial gloves.

In addition to this, MIDA encourages local companies to intensify R&D activities in developing state-of-the-

art technologies to produce high-end medical devices products which has higher complexity and added value in treating critical illnesses in the areas of cardiology and renal dysfunction, as well as related advanced surgical equipment. The following categories of medical devices have been earmarked by MIDA as having good growth potential.

INVESTMENT OPPORTUNITIES IN THE MEDICAL DEVICES	
 Consumables	 Surgical instruments, implants and clinical devices
 Health Equipment	 Point-of-Care
 Non and minimally invasive products	 Medical devices from the convergence of technologies

A GROWING NETWORK OF A COMPLEMENTARY ECOSYSTEM

One of the key success factors for the growth of the medical device industry in Malaysia is the presence of a complete and complementary high-tech manufacturing ecosystem which includes sterilisation services, medical packaging, ESS i.e. precision engineering, tool and die, plastic injection moulding, contract moulding and assembly, machinery fabrication, electronics manufacturing services, universities, research and training institutes as well as testing and accreditation bodies.

The growing network of suppliers conforming to world-class standards that support the country's medical devices industry is as follows:

MACHINERY AND EQUIPMENT (M&E) INDUSTRIES

Machining specialists and design houses for industrial automation processes, conceptualising and building specialised automation equipment. Also, heavily engaged in R&D to develop new automation processes.

PRODUCTS / OUTPUTS FOR THE MEDICAL DEVICE INDUSTRY

- › Packaging machinery
- › Labelling equipment
- › Heat sealing machines
- › Printing/barcoding equipment
- › Testing machinery
- › Automation systems
- › Assembly systems
- › Cleanroom engineering
- › Laboratory equipment
- › Medical refrigeration equipment
- › Specialised M&E for medical industry

EXAMPLE OF COMPANIES

Kobay, Genetec, LKT, Pentamaster, Upeca

PLASTIC PARTS & COMPONENTS

Provide injection moulded parts and components for medical device producers

PRODUCTS / OUTPUTS FOR THE MEDICAL DEVICE INDUSTRY

- › Plastic injection moulded parts & components and sub-assemblies thereof for the medical devices industry
- › Cleanroom, medical & ESD flexible packaging product

EXAMPLE OF COMPANIES

Tip Corporation Sdn. Bhd.,
Cal Comp (Malaysia) Sdn. Bhd.

ELECTRONICS MANUFACTURING SERVICES (EMS)

EMS companies provide vital support to the semiconductor, consumer electronics, computer and peripherals, medical devices, communications and data storage industries. They also manufacture products and parts for Original Equipment Manufacturers (OEMs) and Original Design Manufacturers (ODMs). They also provide total manufacturing solutions by undertaking product design, manufacturing and distribution services for customers.

PRODUCTS / OUTPUTS FOR THE MEDICAL DEVICE INDUSTRY

- Design, development and manufacture; and re-manufacturing of PCB assemblies and complete products (box-built) and system integration for microprocessor applications, industrial, telecommunication including healthcare and medical devices
- High end computing & information storage system, medical, test & scientific equipment/instrumentation

EXAMPLE OF COMPANIES

Flextronics, Sanmina-SCI, Celestica, Jabil Circuit and Plexus

ENGINEERING SUPPORTING INDUSTRY

Capabilities in a diverse range of products/activities namely, moulds and dies, metal casting, machining, metal stamping, surface engineering and metal fabrication. Other capabilities include producing components and subassemblies, and total solutions to meet the stringent requirements by the medical devices industry.

PRODUCTS / OUTPUTS FOR THE MEDICAL DEVICE INDUSTRY

- Precision machining
- Investment casting parts
- Die casting parts
- Metal injection moulding
- Powder metallurgy parts
- Moulding and extrusions
- Surface engineering
- Instrumentation control and Quality Control (QC)
- Tubing
- Sterile medical packaging
- Medical compounds

STERILISATION SERVICES

Sterilisation services that are available locally include gamma, electron beam and ethylene oxide.

PRODUCTS / OUTPUTS FOR THE MEDICAL DEVICE INDUSTRY

- Gamma
- Ethylene Oxide
- Electron Beam

EXAMPLE OF COMPANIES

Steris, SINAGAMA (Government-owned irradiation facility), Nuclear Malaysia (Malaysian Nuclear Agency), KHTP, Worldwide Medivest

EFFICIENT LOGISTICS AND WELL-DEVELOPED INFRASTRUCTURE

Malaysia continues to drive the development and upgrading of infrastructure to support the nation's overall growth and the manufacturing industry. Integrated logistics have ensured that Malaysia's medical device products reach markets in Asia and beyond, enabled by the extensive infrastructure that includes world-class airports, seaports and a sophisticated telecommunications network.



Malaysia has over 600 industrial estates that cater to the needs of companies across a broad range of industries. To date, there are 22 Free Industrial Zones (FIZs) that have been developed throughout the country. FIZs are export processing zones which have been developed to cater to the needs of export-oriented industries such as the medical

devices industry.

Companies in the FIZs enjoy duty-free imports of raw materials, components, parts, machinery and equipment directly required in the manufacturing process. In areas where FIZs are not available, companies can set up Licensed Manufacturing Warehouses (LMWs).



Many medical device manufacturers are clustered in specialised high-tech industrial parks which cater to the technology and research-intensive nature of these activities, and are equipped with state-of-the-art buildings and fully integrated high technology features. The top five are as below:

KULIM HI-TECH PARK (KHTP)

- First high-tech park in Malaysia, established in 1966
- Located in the state of Kedah, northwest Malaysia
- 4,400 acres have been developed, with an additional 7,000 acres currently in progress
- Connectivity to world-class infrastructure
- Incorporates various mixed development zones

For further information, visit www.khtp.com.my

PENANG SCIENCE PARK

- Located 23km from the Penang Port, 5km from the North-South Highway, and 10km from Butterworth
- Infrastructure and amenities designed for high-tech, biotech and halal industries and SMI park

For further information, visit www.pdc.gov.my

PORT KLANG FREE ZONE (PKFZ)

- Located adjacent to Westport and close to Kuala Lumpur, 45 minutes from KLIA
- 1000 acres Free Commercial and Industrial Zone
- International cargo distribution and consolidation centre
- Entrepot trade and manufacturing for export
- Links to 120 countries and 500 ports around the world

For further information, visit www.pkfz.com

ENSTEK

- Techpark@enstek is located 10 minutes from KLIA and 38 minutes from downtown Kuala Lumpur via the ERL
- World-class tech hub designed for eco-conscious industries, such as biotechnology, green technology and information technology.
- Ready infrastructure and amenities

For further information, visit techpark.enstek.com

SPECIALISED PARKS DEVELOPED BY THE MALAYSIA GOVERNMENT AGENCIES

Kulim Hi-Tech Park

Penang Science Park

Technology Park Malaysia

Port Klang Free Zone

Enstek

Nusajaya

NUSAJAYA

- Located in the South Economic Corridor in the Iskandar Development Region, Johor
- 24,000 acres of integrated urban development
- Comprises 7 developments including Kota Iskandar, the southern Industrial and Logistics Clusters (SiLC), Puteri Harbour Waterfront Development, EduCity, Residences Afiat Healthpark and Medini, International Destination Resort and Nusajaya Residences
- Centres of excellence and medical R&D

For further information, visit www.nusajayacity.com

Picture: Map of Peninsular and East Malaysia showing locations of specialised high-tech parks

GETTING STARTED REGULATING THE INDUSTRY

THE MEDICAL DEVICE AUTHORITY (MDA)

The Medical Device Act 2012 (737), based on recommendations from the World Health Organisation (WHO), was enacted to regulate the medical device industry and outlines the requirements of the registration of medical devices and the Conformity Assessment Body (CAB). With the enforcement of the Medical Device Act 2012, all medical devices manufactured, imported or sold in Malaysia are required to be registered with the Medical Device Authority (MDA), a body under the Malaysian Ministry of Health, responsible for regulating the medical devices industry.

The Medical Devices Regulations 2012 is aimed at protecting patients and other customers from substandard and unregistered medical devices.

The MDA implemented the Medical Device Regulations 2019 from 1 July 2020, formulated to drive standards and compliance for adverse event (AE) reporting within the current registration system and also encourage stronger post-market vigilance. These regulations came into effect to align with the ASEAN Medical Device Directive (AMDD) which lays out a common set of rules for MedTech regulation in the region. Although it is not a law in ASEAN countries, all member countries will be required to pass laws with similar provisions. This will increase market access and support regional growth in Asia.

ASSESSMENT AND REGISTRATION MATTERS

In Malaysia, medical devices are classified similarly to the classification scheme used in the European Union, which relates to the level of associated risks, depending on the intended purpose of the device and the effectiveness of the risk management techniques during design, manufacture and use.

Based on a set of rules, medical devices are classified into four risk classes. In general, low-risk devices are those that are applied externally to the body; and if applied correctly, involve minimum risk to the patients. Higher risk devices are those that penetrate the human body, involve a high-energy source, or are used to sustain life. Medical devices are categorised into classes A, B, C and D depending on the risk level and intended use.



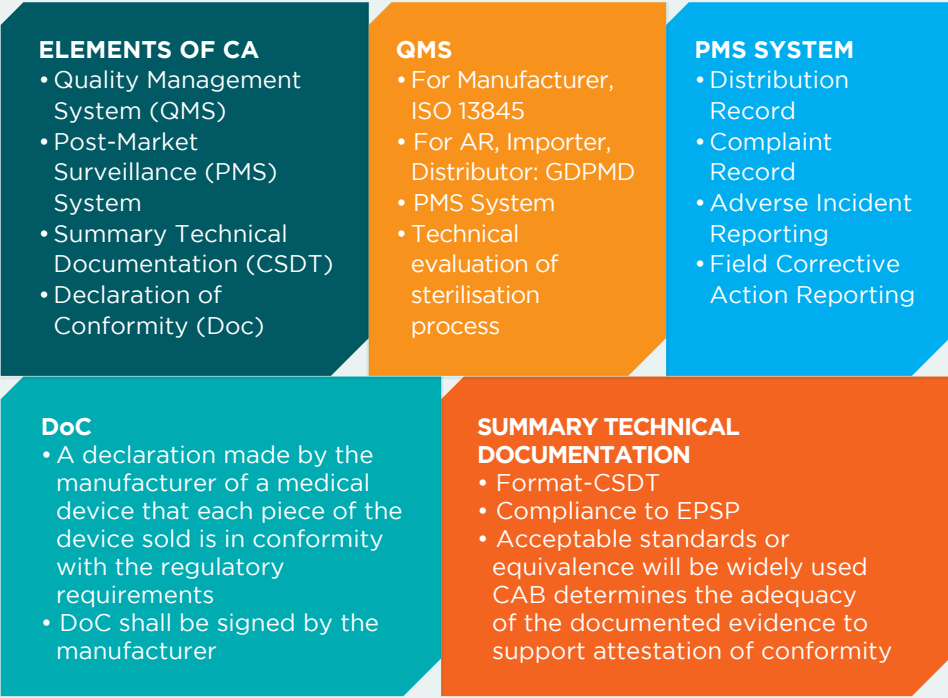
GENERAL CLASSIFICATION SYSTEM FOR MEDICAL DEVICES		
CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Simple surgical instruments, tongue depressor, thermometer, examination light, simple wound dressing, oxygen mask, stethoscopes
B	Low-Moderate Risk	Hypodermic needles, suction equipment
C	Moderate-High Risk	Lung ventilator, orthopaedic implants, defibrillator
D	High Risk	Pacemakers and their leads, implantable defibrillators, heart valves, vascular prostheses, stents

All applications for Establishment Licensing and Medical Device Registration shall be made online via MeDC@st 2.0 which is a web-based registration system.

CONFORMITY ASSESSMENT

Part of the medical device registration process is the Conformity Assessment (CA), which is a systematic examination of evidence generated and procedures undertaken by the manufacturer under the requirements established by the Regulatory Authority to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance for Medical Devices.

Elements of Conformity Assessment for the purpose of medical device registration shall comprise the following elements:



CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICES APPROVED BY RECOGNISED COUNTRIES

Section 7 of Act 737 requires that a medical device is subject to conformity assessment by a registered CAB prior to its registration. However, many medical devices have already have been assessed and approved in countries recognised by MDA, and these will be given certain exemptions.

For more information on registration and the licensing of medical devices, please visit the MDA’s portal at <https://portal.mda.gov.my/faq/registration-licensing-enforcement.html>

ACCREDITATION - ISO 13485

Medical device manufacturers need to obtain the ISO 13485 Quality Management System (QMS) for Medical Devices.

ISO 13485 is an international standard that serves as a model for medical device manufacturers to meet regulatory requirements. It includes specific requirements for medical devices and excludes some requirements in ISO 9001 that are not applicable. This standard applies for organisations that design, develop and produce medical devices. Certification to the standard requires that an organization's quality management system pass a third-party Medical Device Single Audit Program, or "MDSAP" Audit. This can be accomplished through organisations such as SIRIM, an industrial research and technology agency in Malaysia, wholly-owned by the Malaysian Government under the Ministry of Investment, Trade and Industry (MITI). TUV SUD and BSI Services Malaysia Sdn. Bhd. are also companies that provide accreditation services.



INTELLECTUAL PROPERTY PROTECTION

Malaysia has strong IP protection mechanism and is committed to safeguarding IP on inventions. To align its IP with international standards and provides adequate protection for both local and foreign investors, Malaysia is a signatory to the following treaties:

- World Intellectual Property Organisation (WIPO) 1967;
- Paris Convention for the Protection of Industrial Property 1883;
- Berne Convention for the Protection of Literary and Artistic Works (1886);
- Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement;
- Patent Cooperation Treaty (PCT) 1970

TYPES OF IP:



Patents



Trademarks



Industrial Designs



Copyrights



Geographical Indications

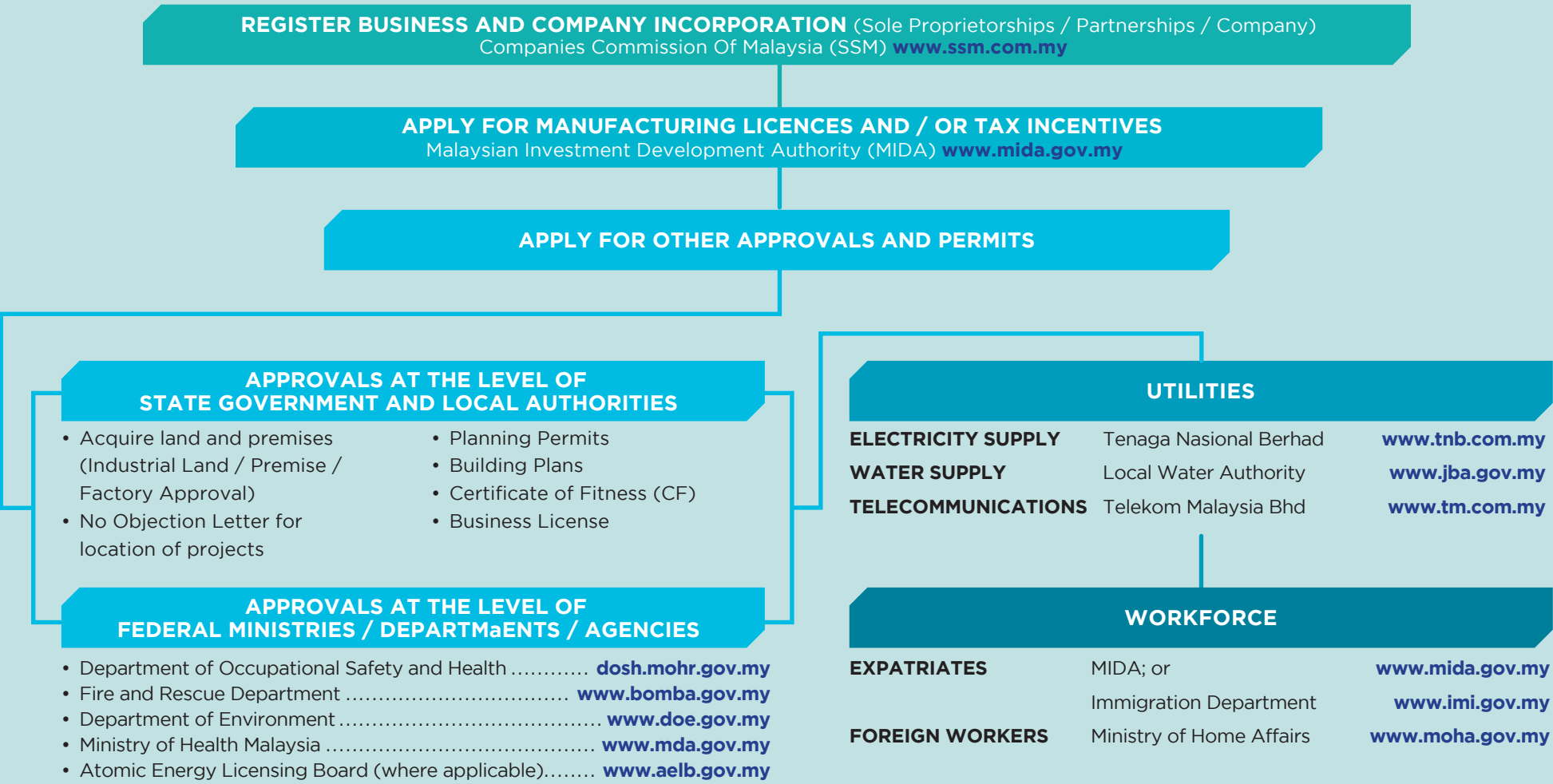


ID Layout Designs

For further information on IP protection in Malaysia, please visit the Intellectual Property Corporation of Malaysia at www.myipo.gov.my

GUIDE TO SETTING UP YOUR BUSINESS

Establishing a business is a transparent and straightforward process, as outlined below.



APPROVAL OF
MANUFACTURING
PROJECTS

Under the Industrial Co-ordination Act 1975 (ICA) manufacturing companies are required to apply for a manufacturing licence, approved by the Ministry Investment, Trade & Industry (MITI). This refers to manufacturing companies with shareholders funds of RM2.5 million and above, or engaging 75 or more full-time paid employees.

Foreign investors can now hold 100 per cent of the equity in all investments in new projects, as well as investments in expansion/ diversification projects by existing companies.


Malaysia’s commitment in creating a safe investment environment has convinced more than 4,000 international companies from over 50 countries to make Malaysia their offshore base.

APPROVAL OF EXPATRIATE POSTS

Manufacturing companies are allowed to recruit expatriate personnel to man key posts and term posts, addressing shortages in trained Malaysians workforce and ensuring the protection of their investment within the country. Key posts refer to posts that are permanently filled by expatriates, while term posts are posts approved for a stipulated period up to 5 years.

The current guidelines on Expatriate Post for manufacturing companies are as follows:

a.




Minimum paid-up capital requirement for applications based on equity ownership:

Malaysian:
RM250,000.00

Joint Ventures:
RM350,000.00

Foreign:
RM500,000.00

c.




Minimum academic qualifications and working experience in related field requirements (only applicable for term posts):

- Degree Holders with 3 years of experience
- Diploma Holders with 5 years of experience
- High School Certification Holders with 10 years of experience


Companies are also required to train local understudies to take up the post after 6 months from the date the post is filled.

b.



Minimum basic salary of **RM5,000.00** per month per expatriate or as proposed (whichever is higher).

d.



The additional guidelines on the employment of expatriate personnel in Key Posts for manufacturing companies require that the company’s foreign paid-up capital be at least RM1 million, which must be owned by the company as stated in their SSM e-Info Company Profile.

Pre-Requisite requirements before submission of expatriate post application to MIDA are as follows:



Registration of company account at ESD Online System via <https://esd.imi.gov.my/>



Advertise the expatriate position at <https://www.myfuturejobs.gov.my/> and obtain approval. However, exemption on advertisement is granted subject to the following criteria:

- Important positions (C-Suite and Key Posts) AND expatriate/s with monthly income of RM15,000 and above
- Representative Office / Regional Office (RE/RO)
- Investors / Shareholders/Owners
- Corporate Transfers / Placements / Trade Agreements



TAX INCENTIVES

The manufacturing of medical devices and related products is categorised as “promoted activities” or “promoted products”. Please refer to the List of Promoted Activities and Products in MIDA website at www.mida.gov.my.

Some of the major tax incentives available for the medical devices industry are as follows:-

- I. INCENTIVES FOR MANUFACTURING COMPANIES
- II. INCENTIVES FOR HIGH TECHNOLOGY COMPANIES
- III. INCENTIVES FOR STRATEGIC PROJECTS
- IV. INCENTIVES FOR RESEARCH AND DEVELOPMENT (R&D)
- V. REINVESTMENT ALLOWANCE
- VI. AUTOMATION CAPITAL ALLOWANCE EXPENDITURE (ACA)

INCENTIVES FOR MANUFACTURING COMPANIES



- Pioneer Status with income tax exemption of 70% of statutory income for a period of 5 years; or
- Investment Tax Allowance of 60% on qualifying capital expenditure incurred for a period of 5 years, to be offset against 70% of the statutory income.

INCENTIVES FOR HIGH TECHNOLOGY COMPANIES



- Pioneer Status with full income tax exemption on statutory income for 5 years; or
- Investment Tax Allowance of 60% on the qualifying capital expenditure for 5 years to be offset against 100% of the statutory income.

INCENTIVES FOR STRATEGIC PROJECTS



Incentives for Strategic Projects are dependent on: -

- a) **LEVEL OF INVESTMENT**
- b) **HIGH TECHNOLOGY / TECHNOLOGY TRANSFER**
- c) **LINKAGES WITH LOCAL ECOSYSTEM / VENDOR DEVELOPMENT PROGRAMME**
- d) **HIGH INCOME EMPLOYMENT / TECHNICAL SKILLS**
- e) **LEVEL OF R&D UNDERTAKEN LOCALLY**
 - Pioneer Status with full income tax exemption on statutory income for 10 years; or
 - Investment Tax Allowance of 100% of the qualifying capital expenditure for 5 years to be offset against 100% of the statutory income.

INCENTIVES FOR RESEARCH AND DEVELOPMENT (R&D)

a) **CONTRACT R&D COMPANY**

- Pioneer Status with 100% income tax exemption on statutory income for 5 years; or
- Investment Tax Allowance of 100% on the qualifying capital expenditure for 10 years to be offset against 70% of the statutory income.

b) **R&D COMPANY**

- Investment Tax Allowance of 100% on the qualifying capital expenditure for 10 years to be offset against 70% of the statutory income.

c) **IN-HOUSE RESEARCH**

- Investment Tax Allowance of 50% on the qualifying capital expenditure for 10 years to be offset against 70% of the statutory income.

ADDITIONAL REINVESTMENT ALLOWANCE

The Additional Reinvestment Allowance incentive was announced under the Pelan Jana Semula Ekonomi Negara (PENJANA) and subsequently, in Budget 2022. To further encourage the reinvestment activities of existing companies, the Additional Reinvestment Allowance will be given to the manufacturing projects and selected agricultural activities whose RA and Special RA incentives periods have expired and continue reinvesting in year of assessment (YA) 2020 to year of assessment (YA) 2024.

The incentive is given at the rate of 60% on the qualifying capital expenditure incurred for reinvestment activities made within 3+2 years of assessment (YA 2020 – YA 2024).



AUTOMATION CAPITAL ALLOWANCE EXPENDITURE (ACA)

Manufacturers are also eligible to apply for Automation Capital Allowance Expenditure (ACA). The capital allowance to increase automation in labour intensive industries was announced in the 2015 Budget on 10 October 2014. This incentive is expected to be the key factor to encourage automation in the manufacturing sector. Investments incurred between the assessment years of 2015 to 2023 are eligible to for ACA consideration.

CATEGORIES FOR AUTOMATION CAPITAL ALLOWANCE

CATEGORY 1:

For high labour-intensive industries (rubber products, plastics, wood, furniture and textiles), an automation capital allowance of 200% will be provided on the first RM4 million expenditure incurred* within 8 years of assessment from 2015 to 2023; and

CATEGORY 2:

For other industries, automation capital allowance of 200% will be provided on the first RM2 million expenditure incurred* within 8 years of assessment from 2015 to 2023.

**Note: "Incurred" refers to plant and machinery purchased and used for the purpose of the business in the approved Year of Assessment.*



WHY GLOBAL BUSINESS LEADERS CHOOSE MALAYSIA AS THEIR NEW HOME FOR RELOCATION

Malaysia is committed to making the medical device industry a key contributor to the manufacturing sector, in line with the nation's aspiration towards becoming a high-income economy driven by innovation, creativity and high-value activities. The Government is actively promoting Malaysia as a regional manufacturing hub in the Asia-Pacific region. The industry has grown over the past 20 years, evolving from rubber-based products and consumables to premium and high-tech medical devices products starting in the 2010s. As a result, the sector is critically important in meeting the nation's demand for better healthcare as well as serving the global market.

There is a ready manufacturing support ecosystem for medical devices ranging from machinery and equipment (M&E) industries, engineering supporting industries, electronic manufacturing services, and sterilisation services to research and development and human capital development.

Overall, Malaysia stands out in ASEAN as the best location in attracting prospective medical device companies, considering the robustness of the regulatory framework, sophisticated logistics and distribution networks.



WHY MALAYSIA

SUPPORTIVE GOVERNMENT POLICIES

- Pro-business policies
- Responsive government
- Liberal investment policies
- Attractive tax and investment incentives
- Liberal exchange control regime
- Intellectual property protection

EDUCATED HUMAN CAPITAL

- Talented, educated and productive workforce
- Multilingual workforce, with English widely spoken
- Comprehensive vocational system and industrial training, including advanced skills training
- Harmonious industrial relations with minimal trade disputes

DEVELOPED INFRASTRUCTURE

- Network of well-maintained highways and railways
- Well-equipped seaports and airports
- High quality telecommunications network and services
- Fully developed industrial parks, including free industrial zones, technology parks and the MSC Malaysia
- Advanced MSC Malaysia Cybercities and Cybercentres

VIBRANT BUSINESS ENVIRONMENT

- Market oriented economy
- Well-developed financial and banking sector
- Wide use of English, especially in business and corporate sector
- Legal and accounting practices based on the British system
- Large local business community with a long history in international business links
- Large foreign business community in all business sectors
- Extensive trade links and regional trade agreements

QUALITY OF LIFE

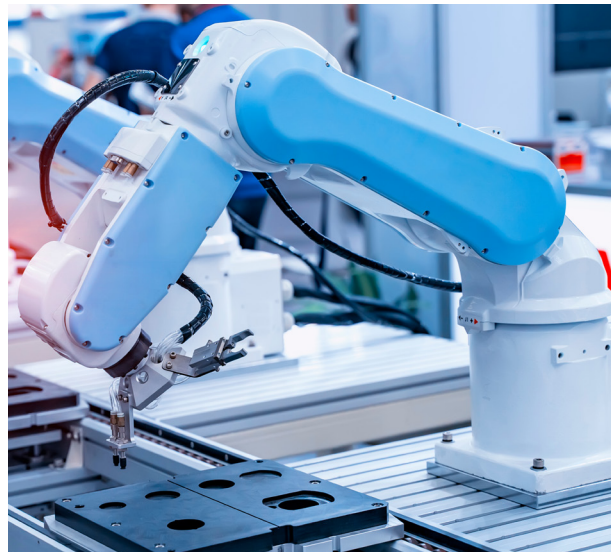
- Friendly and hospitable Malaysians
- Safe and comfortable living environment
- Excellent housing, modern amenities, good healthcare and medical facilities
- Excellent educational institutions
- World class recreational and sports facilities
- Excellent retail environment

SUCCESS STORIES

B. BRAUN

Established in 1972, B. Braun is a pioneer foreign investor in the northern state, which has evolved into the nexus for the medical device industry in Malaysia. Occupying a 193,285 square metre (47.8 acres) site in Penang's Free Industrial Zone, B. Braun Medical Industries is one of the largest production sites of the Group, with over 7,600 employees. The site houses three production plants dedicated to manufacturing intravenous access solutions, pharmaceutical products and surgical instruments for the global markets. Additionally, it serves as the Group's global Centre of Excellence for Intravenous Access equipped with full R&D capabilities as well as the regional headquarters B. Braun's Asia Pacific.

In 2006, B. Braun Medical Industries Sdn. Bhd. (BMI), Penang plant was recognised as the Global Centre of Excellence (CoE) for Intravenous Access products including R&D and production technology. Products manufactured in B. Braun Medical Industries Penang are exported to the US, Japan, Germany, and several other major markets around the world.



B. Braun expanded its Global Test Centre for Medical Devices in Penang in June 2020, proving Malaysia's capabilities in scientific measurement. The Global Test Centre based in Penang has managed to triple its scientific measurements for medical devices related to intravenous access and drug delivery systems to more than 600,000 per year. In addition, the medical devices for infusion systems, central venous puncture and pain control, which are being manufactured in Germany, have also been added to the portfolio being tested in Penang. This success has been attributed to the proven competencies, strong product knowledge and efficiency displayed by the local team of Malaysian engineers.

SUCCESS STORIES

SMITH & NEPHEW

Smith & Nephew plc, also known as Smith + Nephew, is a British multinational medical equipment manufacturing company headquartered in Watford, England. Its establishment in 1856 started with a small pharmacy in Whitefriargate, UK and it has transformed into a global supplier of advanced medical equipment with approximately 16,000 employees worldwide.

At present, the company serve its customers through three global business unit namely orthopaedics, sports medicine + ENT and advanced wound management. Its main portfolio is a medical technology business focused on repair, regeneration of soft and hard tissue. In 2020, Smith + Nephew accounted for 11% of the global market share for hip and/or knee implant.

In 2019, the ompany expanded its global operations to Penang, Malaysia with investment valued at RM1.488 billion for a full stretch of 15 years. The orthopaedics implant manufacturing plant, located in Batu Kawan, marked Smith + Nephew's first manufacturing venture in Southeast Asia. The facility operates with a total manpower of 793, with 98% being local Malaysian skilled in various technical disciplines within the scientific and engineering fields. Notably, 99.5% of the products manufactured at this facility are exported globally. Smith+Nephew's presence in Malaysia contributes not only to its own global footprint but also to the growth of local companies and the overall medical devices industry's ecosystem. This, in turn, will strengthen our reputation as an ideal med-tech manufacturing hub in ASEAN.



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