



Guide on

# MEDICAL

**Devices Industry** in Malaysia



Your Ideal Business Location

# Preface

This guidebook for the medical devices industry in Malaysia serves as an important source of information for investors intending to invest in this industry. It also spells out the procedures and requirements for the various applications for licences and permits for the setting up of a business in the medical devices industry.

The Malaysian Investment Development Authority (MIDA) is the government's principal agency under the Ministry of International Trade and Industry (MITI) and is in charge of the promotion and coordination of industrial development in Malaysia. MIDA assists companies which intend to invest in the manufacturing and services sectors in the country. MIDA has a global network of 20 overseas offices covering North America, Europe and the Asia Pacific to assist investors.

Within Malaysia, MIDA has 12 branch offices in the various states to facilitate investors in the implementation and operation of their projects. For more information on investment opportunities in Malaysia and contact details of MIDA, please visit MIDA's website at [www.mida.gov.my](http://www.mida.gov.my).



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## Background of Malaysia

Malaysia covers an area of 330,396 square kilometres, consisting of 13 states, namely Johor, Kedah, Kelantan, Melaka, Negeri Sembilan, Pahang, Perak, Perlis, Penang, Sabah, Sarawak, Selangor and Terengganu. Apart from the 13 states, there are three Federal Territories, which are Kuala Lumpur, Putrajaya and Labuan. Kuala Lumpur is the capital of Malaysia. Malaysia lies entirely in the equatorial zone and the average daily temperature throughout Malaysia varies from 21°C to 32°C.

Malaysia is a multi-ethnic country. The principal ethnic groups are Malays, followed by Chinese and Indians. Other significant groups are the indigenous people of Sarawak and Sabah, including the Dayaks, Kadazans, Bajaus, Melanaus and Muruts.

Major exports of Malaysia are manufactured goods such as electrical and electronics products, machinery and appliances, chemicals and chemical products, iron, steel and metal products, and petroleum-based products and processed food. In the year 2019, the share of exports of manufactured goods to total exports is 84.6%. 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.



## Key Economic Indicators

	2018	2019
Population	32.4 million	33.6 million
Labour force	15.3 million	15.5 million
Unemployment rate	3.3%	3.3%
GDP	RM1,362.8 billion	RM1,421.5 billion
GDP growth	4.8%	4.3%
Per capita income	RM42,937 (USD10,321)	RM44,686 (USD10,741)
Inflation rate (CPI)	1.5% - 2.5%	2.1% (2020 est.)
Total export (f.o.b.)	RM1,003.5 billion	RM986.4 billion
Total import (c.i.f.)	RM879.8 billion	RM849 billion

Exchange Rate : USD 1 = RM4.09 (December 2019)

Sources:

1. Department of Statistics Malaysia (DOSM)

2. MATRADE Press Release: Malaysia's Trade Performance for 2019 and December 2019



## Prioritising Healthcare

Malaysia's primary care model has been acknowledged by the World Health Organization as a viable system to achieve "Health for All". The demand for quality healthcare continues to rise in Malaysia with increasing affluence and rising consumer awareness. Spurred by

demographic shifts such as extended longevity and a rise in lifestyle diseases such as cardiovascular ailments and diabetes, the healthcare industry has become a powerful engine of economic growth.

Healthcare remains a priority of the Malaysian Government. The medical devices is one of the priority sectors under the Healthcare National Key Economic Area (NKEA). The Government targeted RM35.3 billion of growth in the Healthcare NKEA. With the Healthcare NKEA, higher value jobs can be created, infrastructure can be upgraded and both specialist skill-sets and technology can be harnessed to improve the quality of care for patients. The medical devices industry has also been earmarked as one of the highly potential growth sectors under the Eleventh Malaysia Plan (11MP).

### Demographics – 2017

Crude Birth Rate (per 1000 population)	16.1*
Crude Death Rate (per 1000 population)	5.2
Infant Mortality Rate (per 1000 live births)	7.3
Life Expectancy - Male (age in years)	72.7
Life Expectancy - Female (age in years)	77.4

\* Provisional/Preliminary data (as of December 2017)

### Health Facts – 2017

Number of registered doctors (Government & Private)	57,831
Population per doctor	1 : 554
Number of Hospitals	354
Number of Clinics	16,409
Number of Beds	66,814
Number of Dental Chairs	6,029***

\* Includes Government hospitals, MOH special medical institutions, non-MOH Government hospitals & private hospitals.

\*\* Includes MOH dental clinics, MOH mobile dental clinics (including mobile and pre-school team); MOH Health Clinics, MOH Community Clinics, MOH maternal & child heart clinics, MOH mobile health clinics, private medical clinics & private dental clinics.

\*\*\* Includes MOH dental clinics and MOH mobile dental clinics.

Source: Ministry of Health, Malaysia, (as at December 2017)

## Medical Devices Industry

In the Eleventh Malaysia Plan CRM (11), the medical devices sector has been identified as one of the levy industries with high potential growth.

The medical devices industry in Malaysia encompasses a broad range of products and equipment from examination gloves, implantable devices, orthopaedic devices and dialysers to imaging equipment and other devices which can be used for medical, surgical dental, optical and general health purposes. Malaysia remains the world's leading producer 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, including medical gloves.



The industry is moving up the value chain as more high value added and complex products are being manufactured in Malaysia. These include pacemakers, defibrillators, orthopaedic products, patient monitors, surgical instruments, medical electrodes, endoscopes, dialysis solutions, diagnostic radiographic equipment, ultrasound diagnostic systems, intraocular lens and in-vitro diagnostic devices. Apart from these products, hospital support systems such as medical gas, anaesthesia sets and fixed operation theatre and examination tables and equipment as well as disposable surgical gowns, drapes and packs, surgical and medical caps, and masks are also being manufactured. Medical glove manufacturers have also diversified into higher quality and specialty gloves, such as special function gloves i.e. accelerator free special function gloves, chemotherapy special function gloves and antimicrobial gloves.

The country is evolving as a hub of medical devices manufacturing in the Asia Pacific region with more than 200 medical devices manufacturing companies thriving in a well-connected industry ecosystem. The industry is capital and technology-intensive and employs over 70,000 people, most of whom are in the managerial, professional, supervisory and technical staff levels.



As the global environment for the medical devices industry becomes more competitive with new and innovative products being rapidly developed, manufacturers are expanding and widening their base into higher value products and increasingly moving into product and process R&D as well as design and prototyping. Higher technology processes are utilised such as the utilisation of new materials, better coating for improved performance, increased automation and more efficient processing technologies moving towards Industry 4.0.

**Major Foreign Companies Operating in Malaysia:**

Europe	Ambu
	B. Braun
	SteriPack
Asia	Medipro
	Meditop
	Sagami
	Hoya Lens
Australia	Ansell, Cochlear
	Resmed
USA	Ciba Vision
	Boston Scientific
	CR Bard
	Tecomet
	Haemonetics
	St. Jude Medical (Abbott)
	Lake Region
	Mediquip
	Teleflex
	Johnson & Johnson

**Major Domestic Companies Operating in Malaysia:**

Top Glove Sdn Bhd
Hartalega Sdn Bhd
Supermax Corporation Berhad
Muzamal Industry Sdn Bhd
LKL Advance Metaltech Sdn Bhd
Vigilenz Medical Devices Sdn Bhd
OSA Technology
Granulab (M) Sdn Bhd
Straits Orthopaedics (Mfg) Sdn Bhd
ABio Orthopaedics Sdn Bhd
Ideal Healthcare Sdn Bhd
Allen Healthcare Products (M) Sdn Bhd
Epsilon Medical Devices Sdn Bhd
Kossan Latex Industries (M) Sdn

## Supporting Infrastructure for Medical Devices

The existence of strong medical devices supporting infrastructure such as sterilisation services, sterile medical packaging, precision engineering, tool and die making, contract moulding and assembly, machinery fabrication, electronics manufacturing services, universities, research and training institutes as well as testing and accreditation bodies has also positioned Malaysia as an outsourcing destination and a medical device manufacturing hub within ASEAN.

Malaysia is the largest market for medical devices in ASEAN region with an estimated total market size of USD1.4 billion (BMI, Espicom).

A growing network of suppliers conforming to world-class standards supports the country's medical devices industry. The supporting infrastructure capable of meeting the needs of the medical devices industry include:

- Machinery and equipment (M&E) industries
- Engineering supporting industries
- Electronic Manufacturing Services
- Sterilisation services

The M&E industry in Malaysia is driven by technological advances, process specialisation and customer requirements for shorter throughput times, faster delivery and lower costs. Malaysian machine specialists such as Kobay, Genetec, LKT, Pentamaster and Upeca are primarily design houses for industrial automation

#### Investment Opportunities in the Medical Devices

Cardiovascular devices

Orthopaedic devices

In-vitro diagnostic devices

Electromedical equipment

Wound care products

Home-healthcare and self-care products

processes, conceptualising and building specialised automation equipment to meet 6 Status of Industries their clients' various needs. They are also heavily involved in R&D to develop new automation processes in tandem with stringent requirements specified by their clients.

They are able to produce custom-designed machinery and fabricate according to users' specific requirements. The M&E and modules for the medical devices industry that can be produced are as follows:

- Packaging machinery
- Labeling equipment
- Heat sealing machines
- Printing/bar coding equipment
- Testing machinery
- Automation systems
- Assembly systems
- Clean room engineering
- Laboratory equipment
- Medical refrigeration equipment
- Specialised M&E for medical industry



Malaysia's engineering supporting industry has achieved international recognition in terms of capability and quality in a diverse range of products/activities namely, moulds and dies, metal casting, machining, metal stamping, surface engineering and metal fabrication. This industry has the capability to produce components and subassemblies, and also provide total solutions to meet the stringent requirements needed by the medical devices industry. The products/services available are:

- Precision machining
- Investment casting parts
- Die casting parts
- Metal injection moulding



- Powder metallurgy parts
- Moulding and extrusions
- Surface engineering
- Instrumentation control and QC
- Tubing
- Sterile medical packaging
- Medical compounds

The rapid development of the E&E industry has encouraged the establishment of electronics manufacturing services (EMS) companies in Malaysia. These companies provide vital support to the semiconductor, consumer electronics, computer and peripherals, medical devices, communications and data storage industries. Leading EMS companies, many of whom rank among the top 50 companies worldwide, have established and expanded their operations in Malaysia. Among them include Flextronics, Sanmina-SCI, Celestica, Jabil Circuit and Plexus. These companies manufacture products and parts for Original Equipment Manufacturers (OEMs) and Original Design Manufacturers (ODMs). They provide total manufacturing solutions by undertaking product design, manufacturing and distribution services for customers.

Sterilisation services such as gamma, electron beam and ethylene oxide are also available locally. The local companies providing these services are Steris as well as a Government-owned irradiation facility, SINAGAMA, Malaysian Nuclear Agency (Nuclear Malaysia).

## “Why Malaysia”

### Supportive Government Policies

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

### An Educated Workforce

- Talented, young, educated and productive workforce
- Multilingual workforce speaking two or three languages, including English
- Comprehensive system of vocational 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, including the Labuan International Financial Exchange
- Wide use of English, especially in business
- Legal and accounting practice 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 - country's total trade was valued at RM1.8 trillion in 2019

### Quality of Life

- Friendly and hospitable Malaysians
- Safe and comfortable living environment
- Excellent housing, modern amenities, good healthcare and medical facilities
- Excellent educational institutions including international schools for expatriate children
- World-class recreational and sports facilities
- Excellent shopping with goods from all over the world

## Starting a Business

In general, the overall cost of doing business in Malaysia is competitive. In Malaysia, the process is facilitated by experienced and reputable agencies that exist both within and outside the Federal and local governments.

To start a business in Malaysia, the main fees which need to be paid are fees to the Companies Commission of Malaysia (SSM) and fees for company secretarial services.

### Main fees to be paid to the Companies Commission of Malaysia (SSM): (Refer to the Companies Regulations 2017)

Matter	Fee (RM)	Fee (USD)
Application for reservation of name of company under section 27 of the Act	50.00 for every thirty days or part thereof with a maximum of 180 days	11.71 for every thirty days or part thereof with a maximum of 180 days

#### Application for incorporation under section 14 of the Act:

(a) Company limited by share	1,000	234
(b) Company limited by guarantee	3,000	703
(c) Unlimited Company	1,000	234

#### Application for registration of foreign company under Section 562 of the Act:

(a) with share capital		
i. not more than RM 1,000,000.00	5,000	1,171
ii. exceeding RM 1,000,000.00 but not exceeding RM 10,000,000.00	20,000	4,684
iii. exceeding RM 10,000,000.00 but not exceeding RM 50,000,000.00	40,000	9,368
iv. exceeding RM 50,000,000.00 but not exceeding RM 100,000,000.00	60,000	14,052
v. exceeding RM 100,000,000.00	70,000	16,393
(b) without share capital	70,000	16,393

For the full range of fees, please visit [www.ssm.com.my](http://www.ssm.com.my)

Source: Companies Act 2016 (Act 777)

Other costs of doing business in Malaysia that investors need to know are rental rates for prime office space, cost of industrial land, cost of ready-built factory and average construction costs of factory building. The costs will depend on the business location selected by the investors.

For more details on these costs, please visit MIDA's website at [www.mida.gov.my](http://www.mida.gov.my)



## Taxation

Generally, all income of companies and individuals accrued in or derived from Malaysia, or derived from sources outside Malaysia and received in Malaysia is subject to income tax. However, income remitted to Malaysia by resident companies (other than companies carrying on the business of banking, insurance, air and sea transportation), non-resident companies and nonresident individuals are exempted from tax. Effective from the year of assessment 2004, income remitted to Malaysia by a resident individual is exempted from tax.

### Company Tax

Resident and non-resident companies	24%
Resident companies with paid-up capital of RM2.5 million and less at the beginning of the basis period for a year of assessment	
• on the first RM500,000 chargeable income	17%
• on subsequent chargeable income	24%

### Personal Income Tax

• Resident individuals with chargeable income (after deduction of personal reliefs) of more than RM5,000 and not more than RM1,000,000	1%-26%
• Resident individuals with chargeable income (after deduction of personal reliefs) of more than RM1,000,000	28%
• Non-resident individuals (not entitled to any personal relief's)	26%

### Withholding Tax (Non-resident persons)

• Special classes of income which is derived from Malaysia:	10%
» Amounts paid for services rendered in connection with the use of property or rights or installation services or operation on the supply of plant, machinery or other apparatus)	
» Amounts paid for technical advice, assistance or services rendered in connection with technical management or administration of scientific, industrial or commercial projects	
» Rent or payment for the use of any moveable property.	
• Interest derived from Malaysia	15%
• Royalty derived from Malaysia	10%
• Remuneration or income from service performed or rendered in Malaysia by public entertainer	15%
• Contract payment:	
» Payable by the non-resident contractor	10%
» Payable by employees of the non-resident contractor	3%
• Gains or profits falling under paragraph 4(f) Income Tax Act 1967	10%

## Sales and Service Tax

Effective from 1 September 2018, the Sales Tax Act 2018 and the Service Tax Act 2018 together with its respective subsidiary legislations are introduced to replace the Goods and Services Tax (GST) Act 2014.

### Sales Tax

Under the Sales Tax Act 2018, sales tax is charged and levied on imported and locally manufactured goods either at the time of importation or at the time the goods are sold or otherwise disposed of by the registered manufacturer.

Sales tax administered in Malaysia is a single stage tax imposed on the finished goods manufactured in Malaysia and goods imported into Malaysia.

Sales tax is imposed on taxable goods manufactured in Malaysia by any registered manufacturer at the time the goods are sold, disposed of other than by sales or used other than as a material in the manufacture of goods.

Sales tax on imported goods is charged when the goods are declared, duty paid and released from customs control.

Manufacturers who manufacture taxable goods with sales value which exceeds RM500,000 within the period of 12 months, are required to be registered pursuant to Section 12 Sales Tax Act 2018.

Manufacturers who manufacture taxable goods with sales value of RM500,000 and below, have the option to be registered on a voluntary basis under Section 14 of the Sales Tax Act 2018 to enable them to enjoy the facilities given under the Act.

Manufacturers who carry out its business as a subcontractor and the total labour charge of the subcontract works exceeds RM500,000 within 12 months, are required to be registered pursuant to Section 12 of the Sales Tax Act 2018.

### Rates of Sales Tax

Sales tax is generally at 10%, certain non-essential foodstuffs, alcoholic beverages, tobacco/cigarettes and building materials are taxed at 5% while certain petroleum products and motor oil are taxed at individual specific rates.

### Service Tax

Service tax in Malaysia is a form of indirect single stage tax imposed on specified services termed as “taxable services”. The Service tax cannot be levied on any service which is not included in the list of taxable services prescribed by the Minister under the First Schedule of Service Tax Regulations 2018.

The Service Tax Act 2018 (STA 2018) applies throughout Malaysia excluding designated areas, free zones, licensed warehouses, licensed manufacturing warehouses and Joint Development Area (JDA).

**Taxable Service**

Taxable services are any services which are listed in the various categories in the First Schedule of Service Tax Regulations 2018. Any taxable person providing taxable services and exceeding the respective thresholds is required to be registered. The categories are accommodation, food and beverage operator, night-clubs, dance halls, health and wellness centres, private club, golf club and golf driving range, betting and gaming services, professional services and other service providers such as insurance, telecommunication, parking operator, advertising and etc.

**Charge to Tax**

Service tax is charged on any provision of taxable services provided in Malaysia by a registered person in carrying on his business.

The service tax is due and payable when payment is received for any taxable service provided to a customer by the registered person. The service tax is not chargeable for imported and exported services under the STA 2018.

**Rate of Service Tax**

The rate of service tax is fixed under the Service Tax (Rate of Tax) Order 2018 and comes into force on 1 September 2018. The rate of service tax is 6% of the price or premium for insurance policy, value of betting and gaming, etc. of the taxable service as determined under section 9 of STA 2018.

**Rate of Service Tax for Credit and Charge Cards**

The rate of service tax on the provision of credit card or charge card services is RM25 per year on the principal and supplementary card. The service tax is chargeable on the date of the issuance of the card and every 12 months thereafter or part thereof after the issuance of the card or on the date of the renewal of the card and every 12 months thereafter or part thereof after the renewal of the card.

*For more information, please visit*  
<https://mysst.customs.gov.my>

## Rates of Capital Allowances

Capital allowances are given on qualifying capital expenditure. Initial allowances are given only once, while annual allowances are given every year by the straightline method. Some of the items accorded allowances are shown below. For plant and machinery, companies are advised to verify with the Inland Revenue Board on the specific items which qualify.

	Initial Allowance	Annual Allowance
Industrial buildings	10%	3%
Plant and machinery	20%	14%
Heavy machinery and motor vehicles	20%	20%
Computer and IT equipment	20%	40%
Environmental control equipment	40%	20%
Others	20%	10%

Source: Inland Revenue Board - [www.hasil.org.my](http://www.hasil.org.my)

## Efficient Logistics and Well-Developed Infrastructure

The prime advantage to manufacturers in Malaysia has been and continues to be the nation's persistent drive to develop and upgrade its infrastructure. Integrated logistics have ensured that Malaysia's medical device products reach markets in Asia and worldwide on time, enabled by the extensive infrastructure that includes world-class airports, seaports and sophisticated telecommunications network.



Industries in Malaysia are mainly located in over 200 industrial estates or parks and 13 Free Industrial Zones (FIZs) developed throughout the country. FIZs are export processing zones which have been developed to cater to the needs of export-oriented industries such as medical devices industry. Companies in FIZs are allowed 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).

Malaysia has also developed specialized parks to cater to the needs of specific industries which are technology-intensive and research-intensive. These parks comprise state-of-the-art buildings with specific functions and fully-integrated high technology park.

Specialised parks developed by the Malaysia government agencies are as follows:



### Port Klang Free Zone (PKFZ)

PKFZ is an integrated 1,000-acre Free Commercial and Industrial Zone providing facilities for international cargo distribution and consolidation centre. PKFZ is a mixed development project comprising manufacturing activities complemented by amenities designed to facilitate the growth of regional distribution centres or international procurement centres. It has been designed to promote entreport trade and manufacturing activities involved in the production of goods primarily for export. Factories and logistics companies can be located in the same zone to enable easier co-ordination and smoother supply chain management. PKFZ has trade links to 120 countries and 500 ports around the world, and is situated adjacent to Westport and close to the Malaysian capital, Kuala Lumpur and its International Airport KLIA (45 minutes from PKFZ). PKFZ is also near to Northport, thereby providing establishments with direct access for convenient export or import of goods. Furthermore, PKFZ offers excellent road and rail network linkages to the mainland and hinterland via highways, expressways and railways.

For further information on PKFZ, please visit

[www.pkfz.com](http://www.pkfz.com)



### Nusajaya

Nusajaya is a 24,000-acre integrated urban development area in Johor. It is a key Flagship Zone within the South Economic Corridor which is known as Iskandar Development Region (IDR). Nusajaya is linked by a comprehensive network of main roads and the North-South Expressway to major international airports, cargo hubs and seaports. Nusajaya comprises seven signature developments – Kota Iskandar (Johor state new administrative centre), the southern Industrial

and Logistics Clusters (SiLC), Puteri Harbour Waterfront Development, EduCity, Afiat Healthpark and Medini, International Destination Resort and Nusajaya Residences, all within a city that sets the benchmark for integrated developments across the globe. Two of them, namely, the Afiat Healthpark and Medini are niche developments tailored specifically towards developing healthcare facilities to meet the increasing demand for better healthcare services and wellness. Afiat Healthpark and Medini will provide worldclass healthcare services by trusted professionals within a fully-integrated development area. Facilities within the Afiat Healthpark and Medini include hospitals, polyclinics, specialists suites, centres of excellence and research and development facilities, complemented by wellness centres that create a truly holistic healthcare environment.

For further information on Nusajaya, please visit [www.nusajacity.com](http://www.nusajacity.com)

### Enstek

Located within the township of Bandar Enstek, [techpark@enstek](mailto:techpark@enstek) is just 10 minute away from Kuala Lumpur International Airport (KLIA) and only 38 minutes from downtown Kuala Lumpur via the Express Rail Link (ERL).

Bandar Enstek consists of 4 main components; residential area, technology land park, commercial hub and institutional zones. Techpark@enstek is envisaged to become a world-class technology hub catering for the need of high technology and eco-conscious industries such as biotechnology, green technology and information technology (ICT) industries. It is also endowed with ready infrastructure and amenities to support such sectors.



### Penang Science Park

Penang Science Park is designed with good infrastructure and amenities to cater for strategic industries such as high technology, biotechnology, halal industries and SMI park.

Facilities / Centres	Distance / Driving Time
Penang International Airport	42 km (40 minutes)
Penang Port (Butterworth)	23 km (20 minutes)
North-South Highway	5 km (5 minutes)
Urban Centres	19 km (20 minutes)
Butterworth, Seberang Jaya	10 km (15 minutes)
Batu Kawan (new township)	5 km (5 minutes)
University Technology Mara	10 km (10 minutes)
University Science Malaysia	20 km (25 minutes)
Japan Malaysian Tech, Institute	within the park

For further information on Penang Science Park, please visit [www.pdc.gov.my](http://www.pdc.gov.my)

### Kulim Hi-Tech Park (KHTP)

The Kulim Hi-Tech Park (KHTP), officially opened in 1996, is the first Hi-Tech Park in Malaysia. The KHTP is situated in the district of Kulim, in the state of Kedah, in the north-west of Peninsular Malaysia. With more than 4,400 acres developed, KHTP is continuing to develop another 7,000 acres and more to cater to growing industry demands and offers connectivity to an integrated world-class infrastructure.

Right from the onset, the development of KHTP incorporates elements or zones, namely:

- industrial;
- amenity;
- housing;
- urban; and
- institutional.

For further information on Kulim Hi - Tech Park, visit [www.khtp.com.my](http://www.khtp.com.my)

**Register business and company incorporation  
(Sole proprietorships / Partnerships / Company)**

Companies Commission of Malaysia (SSM)

[www.ssm.com.my](http://www.ssm.com.my)



**Apply for Manufacturing Licenses and/or Tax Incentives**

Malaysian Investment Development Authority (MIDA)

[www.mida.gov.my](http://www.mida.gov.my)



**Apply for Other Approvals and Permits**

**Approvals at the Level of State Government and Local Authorities**

- Acquire land and premises (Industrial land / Premise / Factory Approval)
- No Objection Letter for location of projects
- Planning Permits
- Building Plans
- Certificate of Fitness (CF)
- Business License.

**Approvals at the Level of Federal Ministries / Departments / Agencies**

- Department of Occupational Safety and Health <http://dosh.mohr.gov.my>
- Fire and Rescue Department [www.bomba.gov.my](http://www.bomba.gov.my)
- Department of Environment [www.doe.gov.my](http://www.doe.gov.my)
- Ministry of Health Malaysia [www.mda.gov.my](http://www.mda.gov.my)
- Atomic Energy Licensing Board (where applicable) [www.aelb.gov.my](http://www.aelb.gov.my)



**Utilities**

Electricity supply	Tenaga Nasional Berhad	<a href="http://www.tnb.com.my">www.tnb.com.my</a>
Water supply	Local Water Authority	<a href="http://www.jba.gov.my">www.jba.gov.my</a>
Telecommunications	Telekom Malaysia Bhd	<a href="http://www.tm.com.my">www.tm.com.my</a>



**Utilities**

Expatriates	MIDA; or Immigration Department	<a href="http://www.mida.gov.my">www.mida.gov.my</a> <a href="http://www.imi.gov.my">www.imi.gov.my</a>
Foreign Workers	Ministry of Home Affairs	<a href="http://www.moha.gov.my">www.moha.gov.my</a>

## Approval of Manufacturing Projects



The Industrial Co-ordination Act 1975 (ICA) requires manufacturing companies with shareholders' funds of RM2.5 million and above or engaging 75 or more full-time paid employees to apply for a manufacturing licence for approval by the Ministry of International Trade and Industry (MITI).

Foreign investors can now hold 100% 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 bring in expatriate personnel i.e “key posts” and “time posts” where there is a shortage of trained Malaysians as well as to safeguard their investments in the country. Key posts refer to posts that are permanently filled by expatriates, while “time posts” are posts approved for stipulated period. The current guidelines on the employment of expatriate personnel for manufacturing companies are as follows:

- i. **Foreign paid-up capital of USD\$2 million and above:**
  - A maximum of 10 expatriate posts, including five key posts.
  - Can be employed for up to a maximum of 10 years for executive posts\*, and 5 years for non-executive posts\*\*
  
- ii. **Foreign paid-up capital of more than USD\$200,000 but less than USD\$2 million:**
  - A maximum of five expatriate posts, including at least one key post.
  - Can be employed for up to a maximum 10 years for executive posts\*, and 5 years for non-executive posts\*\*
  
- iii. **Foreign paid-up capital of less than USD\$200,000:**
  - Key posts can be considered where the foreign paid-up capital is at least RM500,000.
  - Time posts can be considered for up to 10 years for executive posts\* and 5 years for non-executive posts\*\*

The number of key posts and time posts allowed depends on the merits of each case

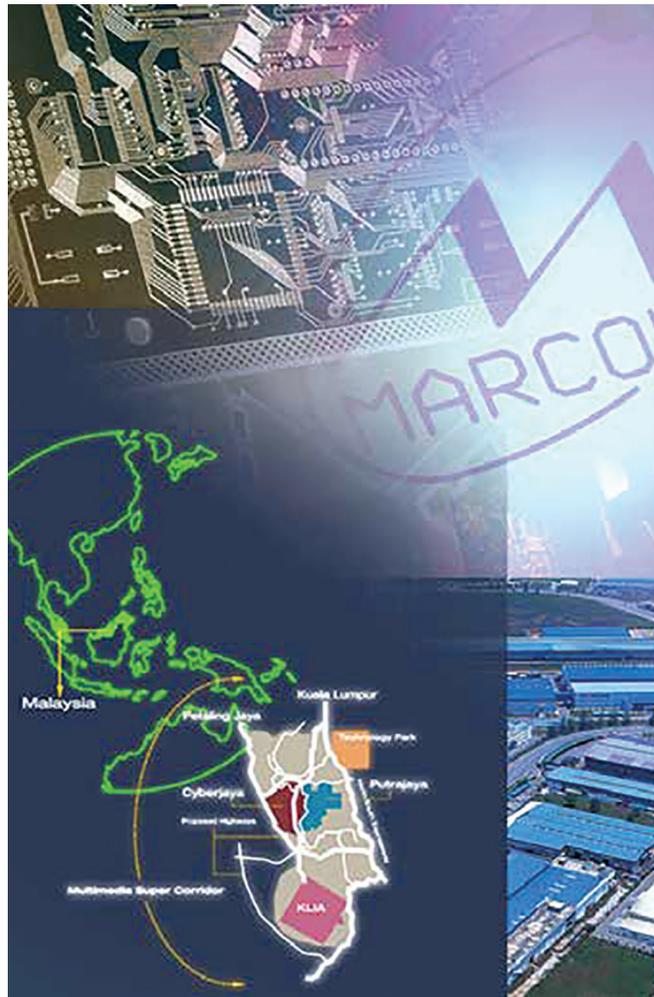
\* *posts that require professional qualifications and practical experience*

\*\* *posts that require technical skills and experience.*



Malaysia has strong IP protection in place and is committed to safeguarding IP on inventions. To ensure IP protection in Malaysia is in line with international standards and provides protection for both local and foreign investors, Malaysia is a party 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



#### IP in Malaysia comprises:

- 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](http://www.myipo.gov.my)

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 Ministry of Health Malaysia responsible in regulating the medical devices industry.

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

All medical devices carry certain level of the associated risks which depend on the intended purposes 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-risks devices are those that are applied external to the body; and if applied correctly, involve minimum risk to the patients. The higher risk devices are those that penetrate the human body, and involve a high-energy source, or used to sustain life. Medical devices are categorised into 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 which is a web-based registration system.

For further information on registration, please visit the Medical Devices Authority (MDA), Ministry of Health Malaysia at [www.mda.gov.my](http://www.mda.gov.my)

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](http://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 & Development (R&D)
- v. Reinvestment Allowance
- vi. Automation Capital Allowance Expenditure (ACA)
- vii. Incentives for the Principal Hub
- viii. Other Incentives



**i. Incentives for Manufacturing Companies**

- Pioneer Status with income tax exemption of 70% on 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)

**ii. 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

**iii. 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% on the qualifying capital expenditure for 5 years to be offset against 100% of the statutory income

#### iv. Incentives for Research & 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

#### v. Reinvestment Allowance

The Additional Reinvestment Allowance incentive was announced under the Pelan Jana Semula Ekonomi Negara (PENJANA). 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 period have expired and continue reinvesting in year of assessment (YA) 2020 to year of assessment (YA) 2022.

The incentive is given at the rate of 60% on the qualifying capital expenditure incurred for reinvestment activities made within 3 years of assessment (YA 2020 – YA 2022).

#### vi. 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 2015 Budget on 10 October 2014. This incentive is expected to be the key factor to encourage automation in the manufacturing sector. Investment incurred between year of assessment from 2015 to 2023 are eligible to be considered for ACA.

- **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.

### vii. Incentives for the Principal Hub

A Principal Hub refers to a locally incorporated company that uses Malaysia as a base for conducting its regional or global businesses and operations to manage, control, and support its key functions including management of risks, decision making, strategic business activities, trading, finance, management and human resource.

The Principal Hub initiative is a driver for innovation as it encourages the transfer of high-value technology to the country, including R&D and high-end technical support. It also creates job opportunities for Malaysians in a knowledge rich environment.

Malaysia has seen a steady increase in companies setting up their regional headquarters in the country whereby a total of 35 PH projects have been approved. Not only do they bring in business for the long term, which stands at RM35.1 billion but also spill-over effects of spending on ancillary services amounting to RM5.5 billion and the creation of 2,686 high value jobs for Malaysians over the next 10 years.

It is evident that the PH incentive has been successful in encouraging many MNCs to make Malaysia their regional operations hub. The attractiveness of the PH incentive was further enhanced under Budget 2019 which is PH 2.0, whereby companies with existing operations in Malaysia can now enjoy 10% corporate tax rate on their statutory income, compared to the earlier treatment of tax exemption on only value-added income. The enhancement of the PH Incentive reflects the commitment of the Malaysian Government to support the continued business growth of MNCs and local companies which have long made Malaysia their base for regional expansion.

The PH2.0 guidelines is already available in MIDA's website at [www.mida.gov.my](http://www.mida.gov.my)

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### viii. Other Incentives

- Exemption from Import Duty on Raw Materials/Components
- Exemption from Import Duty and Sales Tax on Machinery/Equipment, Spare Parts and Consumables

For further information on incentives for investment, please visit

**[www.mida.gov.my](http://www.mida.gov.my)**

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