



Guide on

# MEDICAL

**Devices Industry** in Malaysia



Your Ideal Business Location



**MIDA**

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

# 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 licenses and permits for the setting up of a business in the medical devices industry.

The Malaysian Industrial 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 19 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 about 330,252 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, machineries and appliances, chemicals, plastic products, iron, steel and metal products, and petroleum-based products. In 2008, the share of exports of manufactured goods to total exports was 70%. Imports comprise of 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 2008<sup>p</sup>

|                       |                                    |
|-----------------------|------------------------------------|
| Population            | 27.7 million                       |
| Labour force          | 12.0 million                       |
| Unemployment rate     | 3.7%                               |
| GDP                   | RM528.8 billion (USD158.6 billion) |
| GDP growth            | 4.6%                               |
| Per capita income     | RM25,796 (USD7,738)                |
| Inflation rate (CPI)  | 5.4%                               |
| Total export (f.o.b.) | RM663.5 billion (USD199.0 billion) |
| Total import (c.i.f.) | RM521.5 billion (USD156.4 billion) |

*p - preliminary*

Sources: 1. Bank Negara Malaysia Annual Report 2008  
2. Malaysia External Trade Statistics 2008, MATRADE

Exchange rate USD1 = RM3.33



## 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. Currently, about 7.02% of the country’s GDP will be spent on healthcare. This is expected to increase with the growing population and a longer life expectancy, as well as the Government’s increasing

expenditures on provision of better healthcare facilities and services.

Healthcare remains a priority of the Malaysian Government. For 2009, the Government increased budget allocation for healthcare by 20% to USD3.85 billion (RM13.7 billion). A total of USD618 million (RM2.2 billion) of the budget will be spent for healthcare development to enhance health facilities and provide medical equipment, increase supply of medicines, develop human resources, intensify research and enforcement activities, as well as to build more hospitals, clinics and quarters.

### Demographics

|  |      |
|--|------|
| Crude Birth Rate (per 1000 population)       | 17.5 |
| Crude Death Rate (per 1000 population)       | 4.5  |
| Infant Mortality Rate (per 1000 live births) | 6.3  |
| Life Expectancy - Male (age in years)        | 71.7 |
| Life Expectancy - Female (age in years)      | 76.5 |

\* Provisional data for 2007

### Health Facts - 2008

|   |          |
|---|----------|
| Number of registered doctors (Government & Private) | 25,102   |
| Population per doctor                               | 1,105    |
| Number of Hospitals                                 | 352*     |
| Number of Clinics                                   | 13,023** |
| Number of Beds                                      | 53,414   |
| Number of Dental chairs                             | 4,059**  |

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

\*\* Includes MOH dental clinics, MOH mobile dental clinics (including mobile & pre-school dental team), MOH health clinics, MOH community clinics, MOH maternal & child health clinics, MOH mobile health clinics, private medical clinics & private dental clinics.



## Medical Devices Industry

The medical devices industry is one of the new growth areas targeted for promotion and development by the Government. In Malaysia, the medical devices industry 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.



While the industry is still dominated by the production of rubber-based products comprising mainly medical gloves, catheters and condoms, there is a gradual shift towards the manufacture of non-rubber based higher value medical devices made from plastics, silicone and metal alloys. These includes, sutures, orthopaedic products, patient monitors, surgical instruments, medical tubes and bags, medical electrodes, endoscopes, dialysis solutions, procedural / urological kits, blood transfusion sets and diagnostic radiographic equipment. 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 low protein, powder-free medical gloves and safety gloves.

The industry is characterised by many small to medium-sized enterprises with some MNCs. The industry is capital and technology-intensive and employs over 20,400 people, most of whom are in the managerial, professional, supervisory and technical staff levels. Currently, there are more than 180 medical devices manufacturers in the country. The majority of the Malaysian-owned companies are involved in the production of surgical and examination gloves while the major foreign-owned companies are involved in the manufacture of medical gloves and other higher value products such as catheters, safety



| Major Foreign Companies Operating in Malaysia: |                   |
|--|-------------------|
| Europe   | Ambu              |
|  | B. Braun          |
|  | Isotron           |
|  | SSL International |
|  | SteriPack         |
|  | Redsense AB       |
|  | Kontron           |
| USA  | Ciba Vision       |
|  | Covidien          |
|  | CR Bard           |
|  | Teleflex          |
|  | Symmetry Medical  |
|  | Unomedical        |
| Asia   | Medipro           |
|  | Meditop           |
|  | Sagami            |
|  | Hoya Lens         |
| Australia                                      | Ansell            |
|  | Enersol           |

intravenous cannulae and needles, orthopaedic products, medical electrodes, dialyser and contact lenses.

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. The R&D activities undertaken include improvements to process control and product quality, product development such as latex compound formulations and process design of safety needles.

## Supporting Industries for Medical Devices

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

- 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

Investment Opportunities in the Medical Devices

Cardiovascular devices

Orthopaedic devices

In-vitro diagnostic devices

Electromedical equipment

Wound care products

Home care products



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 processes, conceptualising and building specialised automation equipment to meet 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. These companies serve the semiconductor, hard disk drive, and have the capabilities to also serve and meet the stringent requirements of the medical devices and pharmaceutical industries.

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 system
- Assembly system
- 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 sub-assemblies 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 expand their operations in Malaysia. Among them include Flextronics, Solectron, 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 Isotron (M) Sdn. Bhd. and Sterilgamma (M) Sdn. Bhd. as well as a Government-owned irradiation facility, MINTec-Sinagama, Malaysian Nuclear Agency (Nuclear Malaysia).

## Regional Operations



Malaysia is also a preferred location for regional operations such as operational headquarters, procurement and distribution centres and other shared services. Malaysia was ranked the third most attractive business location for Business Process Outsourcing (BPO) for three consecutive years by the AT Kearney's Global Services Location Index (formerly known as the Offshore Location Attractiveness Index). According to AT Kearney, Malaysia's successful performance was a result of the following:

- continued investment in world-class infrastructure;
- further incentives for corporations choosing to locate in Malaysia;
- greater flexibility on policy relating to expatriate employment; and
- efforts to deepen English language and technical skills.

MNCs in the healthcare sector that have established their regional operations in Malaysia include B. Braun, Ansell, IBA Health, Eppendorf, Siemens, AGFA, International Columbia US LLC and Adventa Health.

# Serving Asia and World Markets

The Malaysian market for medical devices is valued at USD626 million in 2009 and market projection for 2011 is expected to be USD717 million.

Malaysia is also the gateway to Asia - a region with the fastest growing economies and where 75% of the world's population resides.

Asia's healthcare market constitutes approximately 34% of the global healthcare market. A diverse range of medical equipment and products are imported to cater for Asia's growing healthcare needs. Medical device companies in Malaysia also have the advantage of the close proximity to the ASEAN market. With the full realisation of the ASEAN Free Trade Area (AFTA) in 2010, medical device manufacturers benefit from a single market with a total population of more than 580 million people, a combined GDP of USD1.2 trillion and total trade of USD1.62 trillion.

## Medical Equipment Market, 2009-2011 (USD Millions)

| Country          | 2009    | 2010    | 2011    |
|------------------|---------|---------|---------|
| Americas         | 107,979 | 113,605 | 119,564 |
| W. Europe        | 56,201  | 59,848  | 63,765  |
| Asia / Pacific   | 39,551  | 42,411  | 45,520  |
| *Malaysia        | 626     | 670     | 717     |
| E. Europe        | 9,635   | 10,723  | 11,955  |
| M. East / Africa | 5,844   | 6,181   | 6,545   |
| Total            | 219,210 | 232,768 | 247,350 |

Source: Espicom Business Intelligence March 2007

## Summary of the Medical Device Market in Malaysia 2009 (Projection)

|   |     |
|---|-----|
| Market Size (USD millions)              | 626 |
| Total health expenditure (USD millions) | 6.9 |
| as % of GDP                             | 3.8 |
| as % of world market                    | 0.1 |
| Growth rate (%)                         | 6.8 |
| Per capita expenditure (USD)            | 23  |

Source: Espicom Business Intelligence March 2007

## Asia's Projected Total Healthcare Expenditure, 2009 – 2011 (USD billions)

|              | 2009        | 2010        | 2011        |
|--------------|-------------|-------------|-------------|
| Indonesia    | 13.2        | 14.2        | 15.8        |
| Malaysia     | 6.9         | 7.5         | 8.2         |
| Philippines  | 4.2         | 4.4         | 4.7         |
| Singapore    | 6.0         | 6.4         | 6.9         |
| Thailand     | 8.7         | 9.5         | 10.4        |
| Vietnam      | 3.9         | 4.1         | 4.6         |
| <b>TOTAL</b> | <b>42.9</b> | <b>46.1</b> | <b>50.6</b> |

Source: Espicom Business Intelligence March 2007

## “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 Multimedia Super Corridor (MSC)
- Advanced MSC Malaysia Cybercities and Cybercentres

### A 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 RM1.19 trillion in 2008

### 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.



|   | RM     | USD    |
|---|--------|--------|
| <b>Reservation of a name</b>  | 30     | 8.45   |
| <b>For registration of a company, fees range according to nominal share capital, e.g:</b> |        |        |
| • Not exceeding RM100,000 (USD28,170)   | 1,000  | 282    |
| • RM 100,001-RM500,00 (USD28,170-USD140,845)  | 3,000  | 845    |
| • Exceeds RM500,000 (USD140,845) but does not exceed RM1 million (USD281,690)             | 5,000  | 1,408  |
| • RM1,000,001-RM5 million (USD281,690-USD 1.14mil)  | 8,000  | 2,254  |
| • Exceeds RM5 million (USD1.41 mil) but does not exceed RM10 million (USD2.82 mil)        | 10,000 | 2,817  |
| • RM10,000,001-RM25 million (USD2.82 mil-RM7.04mil)                                       | 20,000 | 5,634  |
| • RM25,000,001-RM50 million (USD7.04 mil-RM14.08 mil)                                     | 40,000 | 11,268 |
| • Exceeds RM50 million (USD14.08 mil) but does not exceed RM100 million (USD28.17 mil)    | 50,000 | 14,085 |
| • Exceeding RM100 million (USD28.17 mil)  | 70,000 | 19,718 |

USD1 = RM3.55 (As at July 2009)  
Source: Companies Act, 1965 (Act 125) & subsidiary legislations.

For the full range of fees, please visit SSM website at [www.ssm.com.my](http://www.ssm.com.my) and the Malaysian Institute of Chartered Secretaries and Administrators (MAICSA) website at [www.maicsa.org.my](http://www.maicsa.org.my).

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 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 non-resident 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  | 25%    |
| Resident companies with paid-up capital of RM2.5 million (USD704,760) and less at the beginning of the basis period for a year of assessment |        |
| • on the first RM500,000 (USD140,845) chargeable income  | 20%    |
| • on subsequent chargeable income  | 25%    |
| Personal Income Tax  |        |
| Resident individuals with chargeable income of RM16,667 (USD4,685) and above per annum (after deduction of personal reliefs)                 | 1%-27% |
| Non-resident individuals (not entitled to any personal reliefs)  | 27%    |
| Withholding Tax (Non-resident persons)   |        |
| • Special classes of income (use of moveable property, technical services, installation services on the supply of plant and machinery, etc.) | 10%    |
| • Interest   | 15%    |
| • Royalty  | 10%    |
| • Contract payment on:   |        |
| - account of contractor  | 10%    |
| - account of employee  | 3%     |
| • Other income such as commissions, guarantee fees, agency fees, brokerage fees, introducers fees etc.                                       | 10%    |

Source : Inland Revenue Board – [www.hasil.org.my](http://www.hasil.org.my)  
USD1 = RM3.55 (As at July 2009)

Sales Tax

Sales tax is imposed on certain imported and locally manufactured goods under the Sales Tax Act, 1972. The tax rate ranges from 5 - 10% for majority of the goods except for food preparations other than alcoholic and non-alcoholic compound preparations (other than those of heading No. 33.02) used for making beverages which falls under the tariff code 2106.90.490 with a tax rate of 20%.

5%-10%

Service Tax

Service tax is imposed on taxable services provided by taxable persons under the Service Act, 1975. Services include services provided by professionals (such as lawyers, engineers, architects, surveyors, consultants), advertising firms, private hospitals, insurance companies, communication companies, hotels and restaurants.

5%

Source : Royal Malaysian Customs – [www.customs.gov.my](http://www.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 Allowances | Annual Allowances |
|----------------------------------|--------------------|-------------------|
| Industrial buildings             | 10%                | 3%                |
| Computer and IT equipment        | 20%                | 40%               |
| Environmental control equipment  | 40%                | 20%               |
| Heavy machinery & motor vehicles | 20%                | 20%               |
| Plant and machinery              | 20%                | 14%               |
| Others                           | 20%                | 10%               |

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



## Availability of Industrial Estates and Specialised Parks

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) which are accorded facilities similar to those enjoyed by establishments in FIZs.

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 international cargo distribution and consolidation centre located at Pulau Indah in Port Klang, Selangor. 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 Harbor Waterfront Development, EduCity, Afiat Healthpark, International Destination Resort and Nusajaya Residences, all within a city that sets the benchmark for integrated developments across the globe. One of them is the Afiat Healthpark, which is a niche development tailored specifically towards developing healthcare facilities to meet the increasing demand for better healthcare services and wellness. Afiat Healthpark will provide world-class healthcare services by trusted professionals within a fully-integrated development area. Facilities within the Healthpark 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

The 5,116-acre Bandar Enstek was conceptualised to evoke crisp images of institution park, industrial hubs, commercial networks, residential living space and healthcare. It offers an extensive network of industrial, commercial, residential and institutional properties supported by first class facilities, amenities and infrastructure.



Enstek has developed a Medical City that will locate the entire medical and health industry value chain within a 528-acre development at Bandar Enstek, Nilai, Negeri Sembilan. The Medical City will be positioned as the centre for the development of biotechnology in bio-medical, bio-pharmaceutical and nutraceutical industries. It will also be a referral centre for medical, pharmaceutical and related biotechnology industries. Enstek will house a university hospital, medical health research centre, medical complex, commercial centre, convention centre, hotels and hostels for students. The Medical City is located next to techpark@enstek which is specifically developed to cater to the needs of biotechnology, advanced manufacturing technology and information communications technology industries and subsectors.

For further information on Enstek, please visit

[www.techpark.enstek.com](http://www.techpark.enstek.com)



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 Industrial 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 [www.medicaldevices.gov.my/](http://www.medicaldevices.gov.my/) [www.mdb.gov.my/](http://www.mdb.gov.my/)
- Atomic Energy Licensing Board (where applicable) [www.aelb.gov.my](http://www.aelb.gov.my)



Utilities

Electricity supply

Tenaga Nasional Berhad

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

Water supply

Local Water Authority

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

Telecommunications

Telekom Malaysia Bhd

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



Immigration

Expatriates

MIDA; or  
Immigration Department

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

Foreign Workers

Immigration Department

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

## 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 license 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.

A company whose equity participation has been approved will not be required to restructure its equity at any time as long as the company continues to comply with the original conditions of approval and retain the original features of the project.

## 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 foreigners, while “time posts” are posts approved for stipulated period. The current guidelines on the employment of expatriate personnel for manufacturing companies are as follows:

### Foreign paid-up capital of USD2 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\*\*

### Foreign paid-up capital of more than USD200,000 but less than USD2 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\*\*

### Foreign paid-up capital of less than USD200,000:

- 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 organisation / 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
- Layout Designs of Integrated Circuits

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)

The medical devices regulatory system is important to ensure the compliance of Malaysia medical devices with international standards of safety, quality and effectiveness. This is also to improve on Malaysia's market position and compete effectively in the global market. In this context, the Ministry of Health, Malaysia is formulating standards for medical devices that are harmonised with regional and international requirements so that Malaysian medical devices will not face unnecessary trade restrictions or technical barriers.

The medical devices regulatory system is implemented in stages. The first phase of the Malaysian medical devices registration scheme, which will be limited to the voluntary registration of establishments was launched on 12 January, 2006. Mandatory registration and full enforcement of the regulation is expected to be in place by 2010. A new department within the Ministry of Health's Engineering Division, the Medical Devices Bureau has been established to oversee the development of the medical devices regulatory system.

All applications for voluntary registration shall be made on-line via MeDVER which is a web-based registration system. It consists of 2 parts. Part 1 is an account creation system. Part 2 requests for information pertaining to medical devices establishments with respect to company profile, person responsible, medical devices particulars and pre and post-market details. All applications shall be made by using the following forms:

**Account Application Form**

(MeDVER-01)

**Establishment Registration Form**

(MeDVER-02)



For further information on registration, please visit the Medical Devices Bureau, Ministry of Health at

**[www.medicaldevices.gov.my](http://www.medicaldevices.gov.my) / [www.mdb.gov.my](http://www.mdb.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. Incentives for Operational Headquarters (OHQ)**
- vi. Incentives for International Procurement Centres (IPC)/Regional Distribution Centres (RDC)**
- vii. Incentives for Medical Devices Testing Laboratories**
- viii. Other Incentives**



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**i. Incentives for Manufacturing Companies**

- Pioneer Status with income tax exemption of 70% or 100% on statutory income for a period of 5 years; or
- Investment Tax Allowance of 60% or 100% on qualifying capital expenditure incurred for a period of 5 years, (to be offset against 70% or 100% of the statutory income); or
- Reinvestment Allowance of 60% on qualifying capital expenditure (to be offset against 70% or 100% of the statutory income) for 15 consecutive years

**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**

- 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. Incentives for Operational Headquarters (OHQ)**

- 100% income tax exemption for a period of 10 years for income derived from business, interest and royalties
- Dividends paid from the exempt income will be exempted from tax
- The income generated by an OHQ company in providing qualifying services to its related companies in Malaysia will not be taxed during its tax-exempt period, provided such income does not exceed 20% of its overall income derived by providing qualifying service
- Expatriates working in OHQ companies are taxed only on the portion of their chargeable income attributable to the number of days that they are in Malaysia.
- Import duty and sales tax exemption

**vi. Incentives for International Procurement Centres (IPC) / Regional Distribution Centres (RDC)**

- Full tax exemption of its statutory income for 10 years
- Dividends paid from the exempt income will be exempted from tax in the hands of its shareholders
- Expatriates working in IPC/RDC companies are taxed only on the portion of their chargeable income attributable to the number of days that they are in Malaysia.
- Import duty and sales tax exemption



**vii. Incentives for Medical Devices Testing Laboratories**

a) Companies investing in new laboratories of international standard for testing of medical equipment:

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

b) Companies upgrading existing testing laboratories for testing of medical equipment:

- Investment Tax Allowance of 60% on the qualifying capital expenditure for 5 years to be offset against 100% of the statutory income

**viii. Other Incentives**

a) Incentives for Export

- Double Deduction for the Promotion of Export
- Single Deduction for the Promotion of Export
- Double Deduction on Export Credit Insurance Premium



- Special Industrial Building Allowance for Warehouses
- Double Deduction on Freight Charges
- Incentive for the Implementation of RosettaNet
- Double Deduction for the Promotion of Malaysian Brand Names

#### b) General Incentives

- Exemption from Import Duty on Raw Materials/ Components
- Exemption from Import Duty and Sales Tax on Machinery/Equipment, Spare Parts and Consumables
- Exemption from Import Duty on Imported Medical Devices for Purpose of Kitting

For further information on incentives for investment, please visit MIDA at

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



## MALAYSIAN INDUSTRIAL DEVELOPMENT AUTHORITY

Block 4, Plaza Sentral, Jalan Stesen Sentral 5, Kuala Lumpur Sentral, 50470 Kuala Lumpur, Malaysia  
 Tel: (603) 2267 3633 Fax: (603) 2274 7970  
 E-mail: [investmalaysia@mida.gov.my](mailto:investmalaysia@mida.gov.my)  
 Website: [www.mida.gov.my](http://www.mida.gov.my)

## MIDA'S STATE OFFICES

### KEDAH & PERLIS

Director  
 Malaysian Industrial Development  
 Authority  
 Level 4, East Wing  
 No. 88, Menara Bina Darulaman  
 Berhad  
 Lebuhraya Darulaman  
 05100 Alor Setar, Kedah  
 Malaysia  
 Tel: (604) 731 3978  
 Fax: (604) 731 2439  
 E-mail: [kedah@mida.gov.my](mailto:kedah@mida.gov.my)

### PENANG

Director  
 Malaysian Industrial Development  
 Authority  
 4.03, 4th Floor, Menara Boustead  
 Penang  
 39, Jalan Sultan Ahmad Shah  
 10050, Pulau Pinang  
 Malaysia  
 Tel: (604) 228 0575  
 Fax: (604) 228 0327  
 E-mail: [penang@mida.gov.my](mailto:penang@mida.gov.my)

### PERAK

Director  
 Malaysian Industrial Development  
 Authority  
 4th Floor, Perak Techno Trade Centre  
 (PTTC)  
 Bandar Meru Raya  
 Off Jalan Jelapang  
 30720 Ipoh, Perak  
 Malaysia  
 Tel: (605) 526 9962/961  
 Fax: (605) 527 9960  
 E-mail: [perak@mida.gov.my](mailto:perak@mida.gov.my)

### MELAKA

Director  
 Malaysian Industrial Development  
 Authority  
 3rd Floor, Menara MITC  
 Kompleks MITC, Jalan Konvensyen  
 75450 Ayer Keroh, Melaka  
 Malaysia  
 Tel: (606) 232 2876/78  
 Fax: (606) 232 2875  
 E-mail: [melaka@mida.gov.my](mailto:melaka@mida.gov.my)

### NEGERI SEMBILAN

Director  
 Malaysian Industrial Development  
 Authority  
 Suite 13.01 & 13.02  
 13th Floor, Menara MAA  
 70200 Seremban,  
 Negeri Sembilan  
 Malaysia  
 Tel: (606) 762 7921/7884  
 Fax: (606) 762 7879  
 E-mail: [nsembilan@mida.gov.my](mailto:nsembilan@mida.gov.my)

### JOHOR

Director  
 Malaysian Industrial Development  
 Authority  
 Unit No. 15.03  
 Level 15, Wisma LKN  
 49, Jalan Wong Ah Fook  
 80000 Johor Bahru, Johor  
 Malaysia  
 Tel: (607) 224 2550/5500  
 Fax: (607) 224 2360  
 Email: [johor@mida.gov.my](mailto:johor@mida.gov.my)

### PAHANG

Director  
 Malaysian Industrial Development  
 Authority  
 Suite 3, 11th Floor  
 Kompleks Teruntum  
 P.O. Box 178  
 25720 Kuantan, Pahang  
 Malaysia  
 Tel: (609) 513 7334  
 Fax: (609) 513 7333  
 E-mail: [pahang@mida.gov.my](mailto:pahang@mida.gov.my)

### KELANTAN

Director  
 Malaysian Industrial Development  
 Authority  
 5th Floor, Bangunan PKINK  
 Jalan Tengku Maharani Puteri  
 15000 Kota Bharu, Kelantan  
 Malaysia  
 Tel: (609) 748 3151  
 Fax: (609) 744 7294  
 E-mail: [kelantan@mida.gov.my](mailto:kelantan@mida.gov.my)

### SELANGOR

Director  
 Malaysian Industrial Development  
 Authority  
 22nd Floor, Wisma MBSA  
 Persiaran Perbandaran  
 40000 Shah Alam  
 Selangor Darul Ehsan  
 Malaysia  
 Tel: (603) 5518 4260  
 Fax: (603) 5513 5392  
 E-mail: [selangor@mida.gov.my](mailto:selangor@mida.gov.my)

### TERENGGANU

Director  
 Malaysian Industrial Development  
 Authority  
 5th Floor  
 Menara Yayasan Islam Terengganu  
 Jalan Sultan Omar  
 20300 Kuala Terengganu, Terengganu  
 Malaysia  
 Tel: (609) 622 7200  
 Fax: (609) 623 2260  
 E-mail: [terengganu@mida.gov.my](mailto:terengganu@mida.gov.my)

### SABAH

Director  
 Malaysian Industrial Development  
 Authority  
 Lot D9.4 & D9.5, 9th Floor  
 Block D, Bangunan KWSP  
 Karamuning  
 88100 Kota Kinabalu  
 Sabah  
 Malaysia  
 Tel: (6088) 211 411  
 Fax: (6088) 211 412  
 E-mail: [sabah@mida.gov.my](mailto:sabah@mida.gov.my)

### SARAWAK

Director  
 Malaysian Industrial Development  
 Authority  
 Room 404, 4th Floor  
 Bangunan Bank Negara  
 No. 147, Jalan Satok  
 P.O. Box 716  
 93714 Kuching, Sarawak  
 Malaysia  
 Tel: (6082) 254 251/237 484  
 Fax: (6082) 252 375  
 E-mail: [sarawak@mida.gov.my](mailto:sarawak@mida.gov.my)

## MIDA'S OVERSEAS OFFICES

### ASIA - PACIFIC

#### AUSTRALIA

Consul-Investment/Director  
 Consulate of Malaysia/MIDA Sydney  
 Malaysian Industrial Development  
 Authority  
 Level 6  
 16 Spring Street  
 Sydney, NSW 2000  
 Australia  
 Tel: (612) 9251 1933  
 Fax: (612) 9251 4333  
 E-mail: [midasyd@bigpond.net.au](mailto:midasyd@bigpond.net.au)

#### JAPAN

**Tokyo**  
 Director  
 Malaysian Industrial Development  
 Authority  
 32F, Shiroyama Trust Tower  
 4-3-1, Toranomon, Minato-ku  
 Tokyo 105-6032  
 Japan  
 Tel: (813) 5777 8808  
 Fax: (813) 5777 8809  
 E-mail: [midatokyo@midajapan.or.jp](mailto:midatokyo@midajapan.or.jp)  
 Website: [www.midajapan.or.jp](http://www.midajapan.or.jp)



## MIDA'S OVERSEAS OFFICES

### Osaka

Director  
Malaysian Industrial Development  
Authority  
Mainichi Intecio 18F  
3-4-5 Umeda, Kita-ku  
Osaka 530-0001  
Japan  
Tel: (816) 6451 6661  
Fax: (816) 6451 6626  
E-mail: midaosaka@mida.or.jp

### KOREA, REPUBLIC OF

Counsellor (Investment)  
Embassy of Malaysia  
(Investment Section)  
Malaysian Industrial Development  
Authority  
17th Floor, SC First Bank Building  
100, Gongpyung-dong  
Jongro-gu  
Seoul 110-702  
Republic of Korea  
Tel: (822) 733 6130/6131  
Fax: (822) 733 6132  
E-mail: midasel@chollian.net

### PEOPLE'S REPUBLIC OF CHINA

#### Shanghai

Consul (Investment)  
Consulate General of Malaysia  
Malaysian Industrial Development  
Authority  
Units 807-809, Level 8  
Shanghai Kerry Centre  
No. 1515, Nanjing Road (West)  
Shanghai, 200040  
People's Republic of China  
Tel: (8621) 6289 4547/  
5298 6335  
Fax: (8621) 6279 4009  
E-mail: midash@online.sh.cn

#### Guangzhou

Director  
Malaysian Industrial Development  
Authority  
Unit 1804B-05  
CITIC Plaza Office Tower  
233 Tianhe Bei Road  
Guangzhou  
510610 China  
Tel: (8620) 8752 0739  
Fax: (8620) 8752 0753  
E-mail: midagz@mida.org.cn

### TAIWAN

Director (Investment)  
Malaysian Friendship & Trade Centre  
Malaysian Industrial Development  
Authority  
12F Suite A, Hung Kuo Building  
No. 167, Tun Hua North Road  
Taipei 105  
Taiwan  
Tel: (8862) 2713 5020/  
2718 6094  
Fax: (8862) 2514 7581  
E-mail: midatpe@ms18.hinet.net

### INDIA

Director/Consul Investment  
Malaysian Industrial Development  
Authority  
Consulate General of Malaysia  
(Investment Section)  
81 & 87, 8th Floor, 3rd North Avenue  
Marker Maxity  
Bandra Kurla Complex, Bandra (E)  
Mumbai 400051  
India  
Tel: (9122) 2659 1155/1156  
Fax: (9122) 2659 1154  
E-mail: mida.mumbai@mida.ind.in

### UNITED ARAB EMIRATES

Director/Consul Investment  
Malaysian Industrial Development  
Authority  
Consulate General of Malaysia  
(Investment Section)  
Unit 2204-2206, 22nd Floor Tower A  
Business Central Tower  
Dubai Media City  
(P.O. Box 4598)  
Dubai  
United Arab Emirates  
Tel: (9714) 4343 696/697  
Fax: (9714) 4343 698  
E-mail: mida\_dxb@eim.ae

## EUROPE

### FRANCE

Director  
Malaysian Industrial Development  
Authority  
42, Avenue Kleber  
75116 Paris  
France  
Tel: (331) 4727 3689/6696  
Fax: (331) 4755 6375  
E-mail: mida.paris@wanadoo.fr

### GERMANY

Director/Consul Investment  
Malaysian Industrial Development  
Authority  
Consulate General of Malaysia  
(Investment Section)  
17th Floor, Frankfurt Kastor  
Platz der Einheit 1  
60327 Frankfurt am Main  
Germany  
Tel: (49069) 7680 7080  
Fax: (49221) 7680 708-20  
E-mail: mida.frankfurt@t-online.de

### ITALY

Consul-Investment  
Consulate of Malaysia  
(Investment Section)  
Malaysian Industrial Development  
Authority  
5th Floor,  
Piazza Missori 3  
20123 Milan  
Italy  
Tel: (3902) 3046 5221  
Fax: (3902) 3046 5242  
E-mail: midamln@tin.it

### SWEDEN

Economic Counsellor  
Malaysian Industrial Development  
Authority  
c/o Embassy of Malaysia  
Karlavägen 37  
P.O. Box 26053  
SE-10041 Stockholm  
Sweden  
Tel: (468) 791 7942/440 8400  
Fax: (468) 791 8761  
E-mail: mida@malemb.se

### UNITED KINGDOM

Director  
Malaysian Industrial Development  
Authority  
17 Curzon Street  
London W1J 5HR  
United Kingdom  
Tel: (4420) 7493 0616  
Fax: (4420) 7493 8804  
E-mail: midalon@btconnect.com

## NORTH AMERICA

### LOS ANGELES

Consul-Investment  
Consulate General of Malaysia  
(Investment Section)  
Malaysian Industrial Development  
Authority  
550, South Hope Street, Suite 400  
Los Angeles, California 90071  
United States of America  
Tel: (213) 955 9183/9877  
Fax: (213) 955 9878  
E-mail: lacamida@aol.com

### SAN JOSE

Director  
Malaysian Industrial Development  
Authority  
226, Airport Parkway, Suite 480  
San Jose, California 95110  
United States of America  
Tel: (408) 392 0617/8  
Fax: (408) 392 0619  
E-mail: midasanjose@aol.com

### CHICAGO

Director  
Malaysian Industrial Development  
Authority  
John Hancock Center, Suite 1515  
875, North Michigan Avenue  
Chicago, Illinois 60611  
United States of America  
Tel: (312) 787 4532  
Fax: (312) 787 4769  
E-mail: mida@midachicago.org

### NEW YORK

Consul-Investment  
Consulate General of Malaysia  
(Investment Section)  
313 East, 43rd Street, New York  
New York 10017  
United States of America  
Tel: (212) 687 2491  
Fax: (212) 490 8450  
E-mail: mida@midany.org

### BOSTON

Director  
Malaysian Industrial Development  
Authority  
One International Place, Floor 8  
Boston, MA 02110  
United States of America  
Tel: (617) 338 1128/338 1129  
Fax: (617) 338 6667  
E-mail: midaboston@aol.com

## MALAYSIA EXTERNAL TRADE DEVELOPMENT CORPORATION (MATRADE)

Menara MATRADE, Jalan Khidmat Usaha, Off Jalan Duta, 50480 Kuala Lumpur, Malaysia  
Tel: (603) 6207 7077 Fax: (603) 6203 7037 Toll Free: 1800-88-7280  
E-mail: [info@matrade.gov.my](mailto:info@matrade.gov.my) Website: [www.matrade.gov.my](http://www.matrade.gov.my)

### MATRADE'S STATE OFFICES

#### JOHOR

Director  
MATRADE Southern Regional Office  
Malaysia External Trade Development Corporation (MATRADE)  
Suite 6B, Tingkat 6  
Menara Ansar, 65 Jln Trus  
80000 Johor Bahru  
Johor  
Tel: (607) 222 9400  
Faks: (607) 222 9500  
E-mail: [johor@matrade.gov.my](mailto:johor@matrade.gov.my)

#### PENANG

Malaysia External Trade Development Corporation (MATRADE)  
1st Floor, FMM Building  
2767, Mukim 1, Lebuh Tenggara 2  
Bandar Seberang Jaya  
13700 Seberang Perai Tengah  
Pulau Pinang, Malaysia  
Tel: (604) 398 2020  
Fax: (604) 398 2288  
E-mail: [penang@matrade.gov.my](mailto:penang@matrade.gov.my)

#### TERENGGANU

Director  
MATRADE Eastern Regional Office  
Malaysia External Trade Development Corporation (MATRADE)  
Tingkat 5, Menara Yayasan Islam  
Terengganu  
Jalan Sultan Omar  
20300 Kuala Terengganu  
Terengganu  
Tel: (609) 624 4778  
Faks: (609) 624 0778  
Email: [terengganu@matrade.gov.my](mailto:terengganu@matrade.gov.my)

#### SABAH

Malaysia External Trade Development Corporation (MATRADE)  
Lot C5.2A, Tingkat 5, Block C  
Bangunan KWSP  
Jalan Karamunsing  
88100 Kota Kinabalu  
Sabah, Malaysia  
Tel: (6088) 240 881/ 242 881  
Fax: (6088) 243 881  
E-mail: [sabah@matrade.gov.my](mailto:sabah@matrade.gov.my)

#### SARAWAK

Malaysia External Trade Development Corporation (MATRADE)  
Tingkat 10, Menara Grand  
Lot 42, Section 46, Ban Hock Road  
93100 Kuching  
Sarawak  
Tel: (6082) 246 780 /248 780  
Fax: (6082) 256 780  
E-mail: [sarawak@matrade.gov.my](mailto:sarawak@matrade.gov.my)

### MATRADE'S OVERSEAS OFFICES

#### AUSTRALIA

Trade Commissioner  
Consulate of Malaysia (Commercial Section)  
Level 4, Malaysia Airlines Building  
16 Spring Street  
NSW 2000, Australia  
Tel: (612) 9252 2270  
Fax: (612) 9252 2285  
E-mail: [sidney@matrade.gov.my](mailto:sidney@matrade.gov.my)

#### ASIA

##### CENTRAL ASIA

#### UZBEKISTAN

Marketing Officer  
Trade Office  
Embassy of Malaysia  
28, Maryam Yakubova Street  
Yakkasaray District  
100 031 Tashkent  
Republic of Uzbekistan  
Tel: (99871) 256 67 07  
Fax: (99871) 256 69 09  
E-mail: [tashkent@matrade.gov.my](mailto:tashkent@matrade.gov.my)

##### EAST ASIA

#### CHINA

##### BEIJING

Trade Commissioner  
Embassy of Malaysia (Trade Section)  
Unit E, 11th Floor, Tower B  
Gateway Plaza  
No. 18, Xiaguangli, North Road  
Dongsanhuan  
Chaoyang District, Beijing 100027  
People's Republic of China  
Tel: (8610) 8451 5109/5113/5110  
Fax: (8610) 8451 5112  
E-mail: [beijing@matrade.gov.my](mailto:beijing@matrade.gov.my)

#### CHENGDU

Director  
Malaysia External Trade Development Corporation  
Level 18, The Office Tower  
Shangri-La Centre  
9 Binjiang Road East  
Chengdu 610021, Sichuan Province  
People's Republic of China  
Tel: (8628) 6687 7517  
Fax: (8628) 6687 7524  
E-mail: [chengdu@matrade.gov.my](mailto:chengdu@matrade.gov.my)

#### GUANGZHOU

Trade Commissioner  
Consulate General of Malaysia (Trade Section)  
Unit 5305, Citic Plaza Office Tower  
233, Tianhe Bei Road  
Guangzhou, 510610 Guangdong  
People's Republic of China  
Tel: (8620) 3877 3865/3975  
Fax: (8620) 3877 3985  
E-mail: [guangzhou@matrade.gov.my](mailto:guangzhou@matrade.gov.my)

#### HONG KONG

Trade Commissioner/Consul  
Consulate General of Malaysia (Trade Section)  
19th Floor, Malaysia Building  
50, Gloucester Road, Wanchai  
Hong Kong Special Administrative  
Region of the People's Republic of China  
Tel: (852) 2527 8109  
Fax: (852) 2804 2866  
E-mail: [hongkong@matrade.gov.my](mailto:hongkong@matrade.gov.my)

#### SHANGHAI

Trade Commissioner  
Consulate General of Malaysia (Trade Section)  
Unit 807-809, Level 8  
Shanghai Kerry Centre  
1515, Nanjing Road (West)  
Shanghai, 200040  
People's Republic of China  
Tel: (8621) 6289 4420/4467  
Fax: (8621) 6289 4381  
E-mail: [shanghai@matrade.gov.my](mailto:shanghai@matrade.gov.my)

#### TAIWAN

Director  
Malaysian Friendship & Trade Centre  
(Trade Section)  
10F-D, Hung Kuo Building  
No. 167 Dun Hua North Road  
Taipei 105, Taiwan  
Tel: (8862) 2545 2260  
Fax: (8862) 2718 1877  
E-mail: [taipei@matrade.gov.my](mailto:taipei@matrade.gov.my)

## MATRADE'S OVERSEAS OFFICES

### JAPAN

#### TOKYO

Director  
Malaysia External Trade Development Corporation  
6th Floor, Ginza Showadori Building,  
8-14-14, Ginza, Chuo-ku  
Tokyo 104-0061, Japan  
Tel: (813) 3544 0712/0713  
Fax: (813) 3544 0714  
E-mail: [tokyo@matrade.gov.my](mailto:tokyo@matrade.gov.my)

#### OSAKA

Marketing Officer  
Malaysia External Trade Development Corporation (MATRADE)  
Mainichi Intecio 18F  
3-4-5, Umeda  
Kita-ku, Osaka 530-0001  
Japan  
Tel: (816) 6451 6520  
Fax: (816) 6451 6521  
E-mail: [osaka@matrade.gov.my](mailto:osaka@matrade.gov.my)

### KOREA, REPUBLIC OF

Trade Commissioner  
Embassy of Malaysia (Trade & Investment Section)  
17th Floor, SC First Bank Building  
100, Gongpyeong-dong  
Jongno-gu  
Seoul 110-702  
Republic of Korea  
Tel: (00822) 739 6813/6814/6812  
Fax: (00822) 739 6815  
E-mail: [seoul@matrade.gov.my](mailto:seoul@matrade.gov.my)

## SOUTH ASIA

### INDIA

Trade Commissioner  
Consulate General of Malaysia (Trade Section)  
Capitale 2A, 2nd Floor  
554 & 555, Anna Salai  
Teynampet, Chennai 600 018  
India  
Tel: (9144) 2431 3722/3723  
Fax: (9144) 2431 3725  
E-mail: [chennai@matrade.gov.my](mailto:chennai@matrade.gov.my)

## SOUTH EAST ASIA

### CAMBODIA

Marketing Officer  
Malaysia External Trade Development Corporation  
No. 10, Street 242, Vithei Okhna Peich  
Sangkat Chaktomuk, Khan Daun Penh  
Phnom Penh, Cambodia  
Tel: (855) 2372 4003  
Fax: (855) 2372 4003  
E-mail: [phnompenh@matrade.gov.my](mailto:phnompenh@matrade.gov.my)

### INDONESIA

Trade Commissioner  
Embassy of Malaysia (Trade Section)  
12th Floor, Plaza Mutiara  
Jln. Lingkar Kuningan  
Kav. E. 1.2, No. 1 & 2  
Kawasan Mega Kuningan  
Jakarta 12950  
Indonesia  
Tel: (6221) 576 4297/4322  
Fax: (6221) 576 4321  
E-mail: [jakarta@matrade.gov.my](mailto:jakarta@matrade.gov.my)

### PHILIPPINES

Trade Commissioner  
Embassy of Malaysia  
Trade Office  
10/F, The World Trade Centre  
330 Sen. Gil Puyat Avenue  
Makati City 1200  
Metro Manila, Philippines  
Tel: (632) 864 0761  
Fax: (632) 891 1695  
E-mail: [manila@matrade.gov.my](mailto:manila@matrade.gov.my)

### SINGAPORE

Director  
Malaysia External Trade Development Corporation  
#33-01/03 Shaw Towers  
100, Beach Road  
Singapore 189702  
Tel: (65) 6392 2238  
Fax: (65) 6392 2239  
E-mail: [singapore@matrade.gov.my](mailto:singapore@matrade.gov.my)

### THAILAND

Trade Commissioner  
Embassy of Malaysia (Trade Office)  
35, South Sathorn Road  
Tungmahamed, Sathorn  
Bangkok, 10120  
Thailand  
Tel: (662) 679 2190-9 ext: 2209  
Fax: (662) 679 2200/2131  
E-mail: [bangkok@matrade.gov.my](mailto:bangkok@matrade.gov.my)

### VIETNAM

#### HO CHI MINH CITY

Trade Commissioner  
Consulate General of Malaysia (Trade Section)  
1208, 12th Floor, Me Linh Point Tower  
2, Ngo Duc Ke Street, District 1  
Ho Chi Minh City, Vietnam  
Tel: (848) 3829 9023/8256  
Fax: (848) 3823 1882  
E-mail: [hcmc@matrade.gov.my](mailto:hcmc@matrade.gov.my)

### HANOI

Marketing Officer  
Embassy of Malaysia  
Trade Office  
45-46 Dien Bien Phu Street  
Ba Dinh District Hanoi  
Vietnam  
Tel: (844) 3734 7521  
Fax: (844) 3734 7520  
E-mail: [hanoi@matrade.gov.my](mailto:hanoi@matrade.gov.my)

## WEST ASIA

### SAUDI ARABIA

Trade Commissioner  
Consulate General of Malaysia  
(Commercial Section)  
14th Floor, Saudi Business Centre  
Madina Road  
P.O. Box 20802  
Jeddah 21465  
Saudi Arabia  
Tel: (9662) 653 2143/98  
Fax: (9662) 653 0274  
E-mail: [jeddah@matrade.gov.my](mailto:jeddah@matrade.gov.my)

### UNITED ARAB EMIRATES

Trade Commissioner  
Consulate General of Malaysia  
Malaysia Trade Centre  
Lot 1-3 Ground Floor &  
6-10 Mezzanine Floors  
Al-Safeena Building, Near Lamcy  
Plaza  
Zaabeel Road  
P.O. Box 4598, Dubai  
United Arab Emirates  
Tel: (9714) 335 5528/38  
Fax: (9714) 335 2220  
E-mail: [dubai@matrade.gov.my](mailto:dubai@matrade.gov.my)

## EUROPE

### FRANCE

Trade Commissioner  
Service Commercial De Malaisie  
De L' Ambassade De Malaisie  
90, Avenue Des Champs Elysees  
75008 Paris, France  
Tel: (331) 4076 0000/0034  
Fax: (331) 4076 0001  
E-mail: [paris@matrade.gov.my](mailto:paris@matrade.gov.my)

### GERMANY

Trade Commissioner/Consul  
Consulate of Malaysia (Trade Section)  
Kastor-Hochhaus (Commerzbank)  
17th Floor, Platz der Einheit 1  
60327 Frankfurt am Main  
Germany  
Tel: (49069) 870 037-230  
Fax: (49069) 870 037-245  
E-mail: [frankfurt@matrade.gov.my](mailto:frankfurt@matrade.gov.my)

## MATRADE'S OVERSEAS OFFICES

### HUNGARY

Trade Commissioner  
Embassy of Malaysia (Trade Section)  
Ground Floor, Museum Atrium  
Dozsa Gyorgy ut 84/b  
1068 Budapest, Hungary  
Tel: (361) 461 0290  
Fax: (361) 461 0291  
E-mail: budapest@matrade.gov.my

### ITALY

Trade Commissioner/Consule  
Consulate of Malaysia  
Malaysia External Trade Development  
Corporation (MATRADE)  
Piazza Missori 3  
4th Floor, 20123  
Milan, Italy  
Tel: (3902) 669 81839  
Fax: (3902) 670 2872  
E-mail: milan@matrade.gov.my

### THE NETHERLANDS

Trade Commissioner  
Embassy of Malaysia (Commercial  
Section)  
Rustenburgweg 2  
2517 KE The Hague  
The Netherlands  
Tel: (3110) 462 7759  
Fax: (3110) 462 7349  
E-mail: rotterdam@matrade.gov.my

### RUSSIA

Trade Commissioner  
Embassy of Malaysia (Trade Section)  
Mosfilmovskaya Ulitsa 50  
Moscow 117192  
Russian Federation  
Tel: (7499) 147 1514/ 1523  
Fax: (7499) 143 6043  
E-mail: moscow@matrade.gov.my

### UKRAINE

Marketing Officer  
Trade Office (MATRADE)  
Embassy of Malaysia  
No. 25 Bulivska Street  
Perchersk, Kiev 01014  
Ukraine  
Tel: (38044) 286 7128  
Fax: (38044) 286 8942  
E-mail: kiev@matrade.gov.my

### UNITED KINGDOM

Trade Commissioner  
Malaysian Trade Commission  
(Commercial Section)  
3rd & 4th Floor, 17 Curzon Street  
London W1J 5HR  
United Kingdom  
Tel: (4420) 7499 5255/4644  
Fax: (4420) 7499 4597  
E-mail: london@matrade.gov.my

## NORTH AMERICA

### CANADA

Trade Commissioner  
Consulate General of Malaysia (Trade  
Office)  
First Canadian Place  
100 King Street West  
Suite 5130 (P.O. Box 389)  
Toronto, Ontario M5X 1E2  
Canada  
Tel: (1416) 504 6111  
Fax: (1416) 504 8315  
E-mail: toronto@matrade.gov.my

### LOS ANGELES

Trade Commissioner  
Consulate General of Malaysia  
(Commercial Section)  
550 South Hope Street, Suite 400  
Los Angeles, CA 90071  
United States of America  
Tel: (1213) 892 9034  
Fax: (1213) 955 9142  
E-mail: losangeles@  
matrade.gov.my

### MIAMI

Director  
Malaysia Trade Centre  
703 Waterford Way, Suite 150  
Miami, Florida 33126  
United States of America  
Tel: (1305) 267 8779  
Fax: (1305) 267 8784  
E-mail: miami@matrade.gov.my

### NEW YORK

Trade Commissioner  
Consulate General of Malaysia  
Commercial Section  
3rd Floor, 313 East, 43rd Street  
New York, NY 10017  
United States of America  
Tel: (1212) 682 0232/  
Fax: (1212) 983 1987  
E-mail: newyork@matrade.gov.my

## SOUTH AMERICA

### BRAZIL

Trade Commissioner  
Embassy of Malaysia (Commercial  
Section)  
771, Alameda Santos, Suite 72  
7th Floor, 01419-001, Sao Paulo  
Brazil  
Tel: (5511) 3285 2966  
Fax: (5511) 3289 1595  
E-mail: saopaulo@matrade.gov.my

### CHILE

Trade Commissioner  
Oficina Commercial De Malasia  
Embajada De Malasia  
Avda. Tajamar 183  
Oficina 302 – Las Condes  
Santiago, Chile  
Tel: (562) 234 2647  
Fax: (562) 234 2652  
E-mail: santiago@matrade.gov.my

### MEXICO

Trade Commissioner  
Embassy of Malaysia, Mexico City  
Paseo de Las Palmas # 425  
Torre Optima 3, Office 1101 & 1102  
Col. Lomas de Chapultepec  
Del. Miguel Hidalgo C.P 11000  
Mexico D.F.  
Tel: (5255) 5201 4540  
Fax: (5255) 5202 7338  
E-mail: mexico@  
matrade.gov.my

## AFRICA

### EGYPT

Trade Commissioner  
Embassy of Malaysia (Commercial  
Section)  
17th Floor, North Tower  
Nile City Building  
Cornish El-Nil Street  
Cairo, Egypt  
Tel: (202) 461 9063/9064  
Fax: (202) 461 9065  
E-mail: cairo@matrade.gov.my

### KENYA

Trade Commissioner  
Malaysian Trade Commission  
3rd Floor, Victoria Towers  
Kilimanjaro Avenue – Upper Hill  
P.O. Box 48916  
00100 GPO Nairobi  
Kenya  
Tel: (25420) 273 0070/0071  
Fax: (25420) 273 0069  
E-mail: nairobi@matrade.gov.my

### SOUTH AFRICA

Trade Commissioner  
Malaysia Trade Centre  
Ground Floor, Building 5  
Commerce Square Office Park  
39 Rivonia Road, Sandhurst  
Sandton, Johannesburg, RSA  
Tel: (2711) 268 2380/2381  
Fax: (2711) 268 2382  
E-mail: johannesburg@  
matrade.gov.my

## RELEVANT ORGANISATIONS

### Ministry of Health Malaysia

Level 11, Block E7 Complex E,  
Precinct 1  
Federal Government  
Administration Centre  
62590 Putrajaya, Malaysia  
Tel: (603) 8883 2877  
Fax: (603) 8883 2571  
Website: [www.moh.gov.my](http://www.moh.gov.my)  
E-mail: [kkm@moh.gov.my](mailto:kkm@moh.gov.my)

### Medical Device Bureau

Ministry of Health Malaysia  
Block E6, Level 5, Complex E,  
Precinct 1  
Federal Government  
Administration Centre  
62590 Putrajaya, Malaysia  
Tel: (603) 8883 2282  
Fax: (603) 8883 6184/2283  
Website: [www.mdb.gov.my](http://www.mdb.gov.my)  
Email: [mdb@mdb.gov.my](mailto:mdb@mdb.gov.my)

### Ministry of International Trade & Industry (MITI)

Block 10  
Government Offices Complex  
Jalan Duta 50622  
Kuala Lumpur  
Malaysia  
Tel: (603) 6203 3022  
Fax: (603) 6201 2337  
E-mail: [webmiti@miti.gov.my](mailto:webmiti@miti.gov.my)  
Website: [www.miti.gov.my](http://www.miti.gov.my)

### Royal Customs Malaysia

Level 7 North  
Ministry of Finance Complex,  
Precinct 2  
No. 3 Persiaran Perdana  
Federal Government  
Administrative Centre  
62592 Putrajaya  
Malaysia  
Tel: (603) 8882 2300/2500  
Fax: (603) 8889 5884  
Website: [www.customs.gov.my](http://www.customs.gov.my)  
E-Mail: [kastam@customs.gov.my](mailto:kastam@customs.gov.my)

### Atomic Energy Licensing Board (AELB)

Ministry of Science  
Technology and Innovation  
Batu 24, Jalan Dengkil  
43800 Selangor  
Malaysia  
Tel: (603) 8922 5888  
Fax: (603) 8922 3685  
Website: [www.aelb.gov.my](http://www.aelb.gov.my)

### Companies Commission of Malaysia (SSM)

2nd, 10-19th Floor, Putra Place  
100, Jalan Putra  
50622 Kuala Lumpur  
Malaysia  
Tel: (603) 4047 6000  
Fax: (603) 4047 6317  
Website: [www.ssm.com.my](http://www.ssm.com.my)  
E-mail: [enquiry@ssm.com.my](mailto:enquiry@ssm.com.my)

### Department of Water Supply Ministry of Energy, Green Technology & Water

Level 1, Block E4/5, Complex E  
Federal Government  
Administrative Centre  
62668 Putrajaya  
Malaysia  
Tel: (603) 8883 6000  
Fax: (603) 8889 3712  
Email: [jba@ktak.gov.my](mailto:jba@ktak.gov.my)  
Website: [www.jba.gov.my](http://www.jba.gov.my)

### Department of Environment Ministry of Natural Resources and Environment

Level 1-4, Podium 2&3, Wisma  
Sumber Asli  
No. 25, Persiaran Perdana,  
Precinct 4  
Federal Government  
Administrative Centre  
62574 Putrajaya  
Malaysia  
Tel: (603) 8871 2000 /  
8871 2200  
Fax: (603) 8889 1973 / 75  
Website: [www.doe.gov.my](http://www.doe.gov.my)  
E-mail: [webmaster@doe.gov.my](mailto:webmaster@doe.gov.my)

### Department of Occupational Safety and Health

Level 2, 3 and 4, Block D3,  
Complex D  
Federal Government  
Administrative Centre  
62530 Putrajaya  
Malaysia  
Tel: (603) 8886 5000  
Fax: (603) 8889 2443  
Website: <http://dosh.mohr.gov.my>  
E-mail: [jkkp@mohr.gov.my](mailto:jkkp@mohr.gov.my)

### Fire and Rescue Department

Lebuh Wawasan  
Precinct 7  
62250 Putrajaya  
Malaysia  
Tel: (603) 8888 0036  
Fax: (603) 8888 0025  
Email: [korporat@bomba.gov.my](mailto:korporat@bomba.gov.my)  
Website: [www.bomba.gov.my](http://www.bomba.gov.my)

### Immigration Department

Level 1 - 7 (Podium)  
Block 2G4, Precinct 2  
Federal Government  
Administrative Centre  
62550 Putrajaya  
Malaysia  
Tel: (603) 8880 1000  
Fax: (603) 8880 1200  
Website: [www.imi.gov.my](http://www.imi.gov.my)  
E-mail: [pro@imi.gov.my](mailto:pro@imi.gov.my)

### Telekom Malaysia Berhad

Level 51, North Wing, Menara  
TM  
Off Jalan Pantai Baru  
50672 Kuala Lumpur  
Malaysia  
Tel: (603) 2240 1221  
Tel: (603) 2283 2415  
Website: [www.tm.com.my](http://www.tm.com.my)  
E-mail: [feedback@tm.com.my](mailto:feedback@tm.com.my)

### Inland Revenue Board

13th Floor, Block 9  
Government Office Complex  
Jalan Duta, P.O. Box 11833  
50758 Kuala Lumpur  
Malaysia  
Tel: (603) 6201 7101  
Fax: (603) 6203 9592  
Website: [www.hasil.gov.my](http://www.hasil.gov.my)  
E-mail: [callcentre@hasil.gov.my](mailto:callcentre@hasil.gov.my)



RELEVANT ORGANISATIONS

**Intellectual Property Corporation Of Malaysia**  
 Level 32, Menara Dayabumi  
 Jalan Sultan Hishamuddin  
 50623 Kuala Lumpur  
 Malaysia  
 Tel: (603) 2263 2100  
 Fax: (603) 2274 1332  
 Website: [www.myipo.gov.my](http://www.myipo.gov.my)  
 E-mail: [general@myipo.gov.my](mailto:general@myipo.gov.my)

**SIRIM Berhad (Standards and Industrial Research Institute of Malaysia)**  
 No. 1, Persiaran Dato' Menteri  
 Seksyen 2, P.O. Box 7035  
 40911 Shah Alam  
 Selangor Darul Ehsan  
 General Line : 603 55446000  
 Fax : 603 55108095

Customer Service Centre  
 Hotline : 603 55103535  
 Tel: 603 55446693 /  
 55446692 / 55446631  
 Fax: 603 55446694  
 website : [www.sirim.my](http://www.sirim.my)  
 e-mail: [web@sirim.my](mailto:web@sirim.my)

**Enstek**  
 No. 1, Lebu Enstek  
 71760 Bandar Enstek, Negeri Sembilan  
 Malaysia  
 Tel: (606) 7916 888  
 Fax: (606) 7917 788  
 Website: [www.th-properties.com](http://www.th-properties.com)  
 E-mail: [enquiries@th-properties.com](mailto:enquiries@th-properties.com)

**Kulim Hi-Tech Malaysia**  
 Kulim Technology Park  
 Corporation Sdn Bhd  
 Suite 3.01 - 3.02  
 3rd Floor KHTP Business Centre  
 Kulim Hi-Tech Park, 09000  
 Kulim  
 Kedah Darul Aman  
 Malaysia  
 Tel: (604) 403 2420  
 Fax: (604) 403 1973  
 Website: [www.khtp.com.my](http://www.khtp.com.my)  
 E-mail: [promotion@khtp.com.my](mailto:promotion@khtp.com.my) /  
[marketing@khtp.com.my](mailto:marketing@khtp.com.my)

**Nusajaya**  
 Nusajaya Centre  
 No. 8, Persiaran Ledang Heights  
 81550 Nusajaya, Johor  
 Malaysia  
 Tel: (607) 277 3700  
 Fax: (607) 277 3701  
 Website: [www.nusajayacity.com](http://www.nusajayacity.com)  
 E-mail: [info@uemland.uemnet.com](mailto:info@uemland.uemnet.com)

**Port Klang Free Zone**  
 Port Klang Free Zone Sdn Bhd  
 PO Box 261, Jalan Pelabuhan  
 42009 Port Klang  
 Selangor Darul Ehsan  
 Malaysia  
 Tel: (603) 3101 5568  
 Fax: (603) 3101 4489  
 Website: [www.pkfz.com](http://www.pkfz.com)  
 E-mail: [info@pkfz.com](mailto:info@pkfz.com)

**Tenaga Nasional Berhad**  
 129, Jalan Bangsar  
 59200 Kuala Lumpur  
 Malaysia  
 Tel: (603) 2296 5566  
 Fax: (603) 2283 3638/2288 1419  
 Website: [www.tnb.com.my](http://www.tnb.com.my)  
 E-mail: [webadmin@tnb.com.my](mailto:webadmin@tnb.com.my)

**Technology Park Malaysia**  
 Technology Park Malaysia Corporation  
 Sdn Bhd  
 Level 5, Enterprise 4  
 Technology Park Malaysia  
 57000 Bukit Jalil, Kuala Lumpur  
 Malaysia  
 Tel: (603) 8998 2020  
 Fax: (603) 8998 2110  
 Website: [www.tpm.com.my](http://www.tpm.com.my)  
 E-mail: [webmaster@tpm.com.my](mailto:webmaster@tpm.com.my)

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**Malaysian Industrial Development Authority**

Block 4, Plaza Sentral, Jalan Stesen Sentral 5

50470 Kuala Lumpur, Malaysia

Tel: (603) 2267 3633

Fax: (603) 2274 7970

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

E-mail: [investmalaysia@mida.gov.my](mailto:investmalaysia@mida.gov.my)

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