

MEDICAL DEVICES INDUSTRY

- In Malaysia, the medical devices industry spans a wide range of industries from rubber and latex, textiles, plastics, machinery and engineering support and electronics.
- Under the Eleventh Malaysia Plan (RMK-11), the Government has identified medical devices as one of the high potential growth sectors. The industry has also been identified as one of the growth areas under the Healthcare NKEA under which eight (8) EPPs were announced and targeted to contribute RM17.1 billion in revenue and RM11.4 billion in GNI, as well as generate 86,000 jobs by 2020.
- There are approximately more than 200 medical devices manufacturers, mainly the small and medium enterprises (SMEs) manufacturing medical gloves. However, the industry also includes higher value-added and technologically advanced products such as cardiac pacemakers, stents, orthopaedic implantable devices, electro-medical, therapeutic and monitoring devices. Major local producers include:
 - Abio Orthopaedics Sdn. Bhd.;
 - Straits Orthopaedics (Mfg) Sdn. Bhd.;
 - Vigilenz Medical Devices Sdn. Bhd.;
 - Granulab (M) Sdn. Bhd.;
 - Hospitech Manufacturing Services Sdn. Bhd.;
 - OSA Technology Sdn. Bhd.;
 - Top Glove Sdn. Bhd.; and
 - Kossan Latex Industries (M) Sdn. Bhd.
- There are currently more than 30 MNCs producing high value-added medical devices, making Malaysia their offshore location for manufacturing operations, such as Agilent, B. Braun, St. Jude Medical, C.R. Bard, Symmetry Medical, Teleflex, Resmed, Ciba Vision, Kelpac Medical, Ambu, Toshiba Medical Systems and Haemonetics.
- List of major local and foreign companies is as below:
 - Local Companies:

Company	Products	Location
ABio Orthopaedics Sdn Bhd	Orthopaedic products	Penang
Straits Orthopaedics (Mfg) Sdn. Bhd.	Orthopaedic products	Penang
Vigilenz Medical Devices Sdn. Bhd.	Sutures & disposable articles for surgeries	Penang.
Granulab (M) Sdn. Bhd.	Bone graft substitutes	Selangor
Hospitech Manufacturing Services Sdn. Bhd.	PVC Catheters, bandages and gauze	Selangor
OSA Technology Sdn. Bhd.	Orthopaedic trauma implants and instrumentation system	Selangor

Company	Products	Location
Top Glove Sdn. Bhd.	Surgical and examination gloves	Selangor
Kossan Latex Industries (M) Sdn. Bhd.	Surgical and examination gloves	Selangor

- Foreign Companies:

Company	Products	Origin	Location
B.Braun Medical Industries Sdn. Bhd.	Infusion and transfusion sets, sutures, intravenous cannula, large volume parenterals, hemodialysis concentrates, peritoneal dialysis solution, bloodlines, surgical instruments, hypodermic needles, spinal needles, AV fistula epidural anaesthesia sets	Germany	Penang
St. Jude Medical Operations	Cardiac rhythm management e.g. pacemakers, defibrillators and leads	USA	Penang
Symmetry Medical Malaysia Sdn Bhd	Medical sterilising cases, medical instruments and orthopaedic implants	USA	Penang
Ciba Vision Johor Sdn. Bhd. (Novartis Group)	Contact lenses	USA	Johor
Teleflex Medical Ltd.	Catheters, blood pressure bags, blood pressure bulbs, penrose drains. PVC endotracheal tubes, red rubber tracheal tubes and nasal cannulae. Rebreathing bags, Heat and moisture exchanger and filters for breathing system and tracheostomy tubes.	USA	Perak
Steripack Medical Asia Sdn. Bhd.	Medical device R&D services, medical device packaging, orthopaedic implants	Ireland	Selangor
Bard Sdn. Bhd.	Foley catheters and procedural kits	USA	Kedah

Company	Products	Origin	Location
Ambu Sdn. Bhd.	Disposable medical electrodes	Denmark	Penang
Haemonetics Malaysia Sdn. Bhd.	Whole Blood Devices & Apheresis Devices	USA	Penang
Medipro Mfg. (M) Sdn. Bhd.	Single use hospital theatre surgical gowns and draping system	Japan	Selangor
Meditop Corporation (M) Sdn. Bhd	Extension tube, scalp vein set, infusion set, I.V. catheters, urinary bag, suction catheters	Japan	Selangor
Mediquip Sdn. Bhd.	Latex Foley Catheters	USA	Perlis
Ansell (M) Sdn. Bhd.	Household, examination and surgical gloves	Australia	Kedah

- List of Associations for Medical Devices Industry as below:

	Association Of Malaysian Medical Industries (AMMI)	Malaysia Medical Device Association (MMDA)
Name of Current President	Mr. Hitendra Joshi	Mr. Yong Tuan Heng
Membership	62 members	180 members
Address	Level 32 Menara Prestige No. 1 Jalan Pinang 50450 Kuala Lumpur	Suite A-807, Level 8, Block A, Kelana Square No: 17 Jalan SS7/26, 47301 Kelana Jaya, Selangor
Contact Detail	T:010 4040 662 F:6032178 4347 Email: secretariat@ammi.com.my	T:03-7804 4468 F:60378054469 Email: secretariat@mmda.org.my
Roles	AMMI continue to be the growth base of the medical device industry in Malaysia and consist of three main types of industry players: manufacturers; suppliers of raw materials and services to the medical devices manufacturing companies; and importers and exporters of medical devices, all of whom employ a sizable workforce in their production facilities.	The Malaysia Medical Device Association or commonly known as MMDA has a diversity of members comprising of local manufacturers, local authorised representatives, importers, suppliers, distributors, multi-national corporations and service providers involved in the distribution and sales of medical devices and related healthcare products and equipment within Malaysia.

I. PROMOTED ACTIVITIES & TARGETED PRODUCTS

- **Promoted Activities under Promotion Investment Act (1986)**

- General List
- High Technology List
- Strategic Project Incentives
- Reinvestment Allowance
- Automation Capital Allowance Expenditure (ACA)

- **Targeted products**

- Electromedical equipment
- Cardiovascular devices
- Orthopaedic devices
- In-vitro diagnostic products
- Wound care management products
- Products from convergence of technology (medical devices/ pharmaceutical/ electronics/ ICT/IoT/ 3D Printing)

II. POLICIES

- **Medical Device Act, 2012**

- 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. 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	Surgical Retractors, Tongue Depressors
B	Low-moderate Risk	Hypodermic Needles, Suction Equipment
C	Moderate-high Risk	Lung Ventilator, Bone Fixation Plate
D	High Risk	Heart Valve, Implantable Defibrillator

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III. TRADE IN MEDICAL DEVICES INDUSTRY

• Export

Year	Total (RM million)
2013	RM 11,900
2014	RM 13,400
2015	RM 15,533
2016	RM 15,841
Top 5 Major Export Items	Total (RM million) 2016
1. Surgical and examination gloves	RM 7,882
2. Other Medical Instruments, Apparatus and Appliances	RM 3,802
3. Catheters, syringes, needles and sutures	RM 2,135
4. Electro medical equipment	RM 1,122
5. Ophthalmic lenses, including contact lenses	RM 771

• Import

Year	Total (RM million)
2013	RM 3,417
2014	RM 3,943
2015	RM 4,424
2016	RM 4,544
Top 5 Major Import Items	Total (RM million) 2016
1. Other Medical Instruments, Apparatus and Appliances	RM 2,336
2. Electro medical equipment	RM 563
3. Catheters, syringes, needles and sutures	RM 617
4. Electro medical equipment	RM 540
5. Medical and surgical x-ray apparatus	RM 247

- Total trade for 2016 was valued at RM20.4billion. In terms of trade, exports of medical devices in 2016 amounted to RM15.8 billion, an increase of 2% as compared to RM15.5 billion in 2015. Major exports in 2016 were:
 - surgical and examination gloves (RM7.9 billion);
 - other medical instruments, apparatus and appliances (RM3.8 billion);
 - catheters, syringes, needles and sutures (RM2.1 billion);
 - electro medical equipment (RM1.1billion); and
 - ophthalmic lenses, including contact lenses (RM0.8 billion).

- Top 5 export destinations in 2016 were the US (RM4.1 billion), Germany (RM1.7 billion), Belgium (RM1.6 billion), Japan (RM1.2 billion), and Singapore (RM1 Billion)

- Imports of medical devices in 2016 amounted to RM4.5 billion, an increase of 3% as compared to RM4.4 billion in 2015. Major imports in 2016 were:
 - other Medical Instruments, Apparatus and Appliances (RM2.3 billion).
 - catheters, Syringes, Needles and Sutures (RM0.6 billion); and
 - ophthalmic Lenses, Including Contact Lenses (RM0.6 billion);
 - electro medical equipment (RM0.5 billion); and
 - medical and surgical x-ray apparatus (RM0.2 billion)

- Top 5 import destinations in 2016 were the US (RM0.9 billion), Singapore (RM0.7 billion), China (RM0.6 billion), Germany (RM0.5 billion), and Japan (RM0.4 billion).

IV. INVESTMENT

Approved Investment (2013 – 2016)

	2013	2014	2015	2016	Total
No of projects	43	42	30	41	156
Employment	18,302	7,300	7,872	7,386	40,860
Domestic Investment (RM mil.)	1,330 (27.7%)	1,225 (54.5%)	1,200 (66.7%)	1,279 (44.6%)	5,034
Foreign Investment (RM mil.)	3,391 (72.3%)	1,000 (45.5%)	603 (33.3%)	1,588 (55.4%)	6,582
Total (RM mil.)	4,721	2,225	1,803	2,867	11,616

Implemented Projects (2013 - 2015)

	2013	2014	2015
No of projects	31	27	19
Domestic Investment (RM mil.)	3,100	552	479
Foreign Investment (RM mil.)	1,400	543	191
Total (RM mil.)	4,500	1,095	670

- In 2015, a total of 30 projects with investments orth RM1.8 billion were approved. Of this, 19 projects (RM670 million) have been implemented. While in 2016, a total of 41 projects were approved.