



Medical Devices in Thailand



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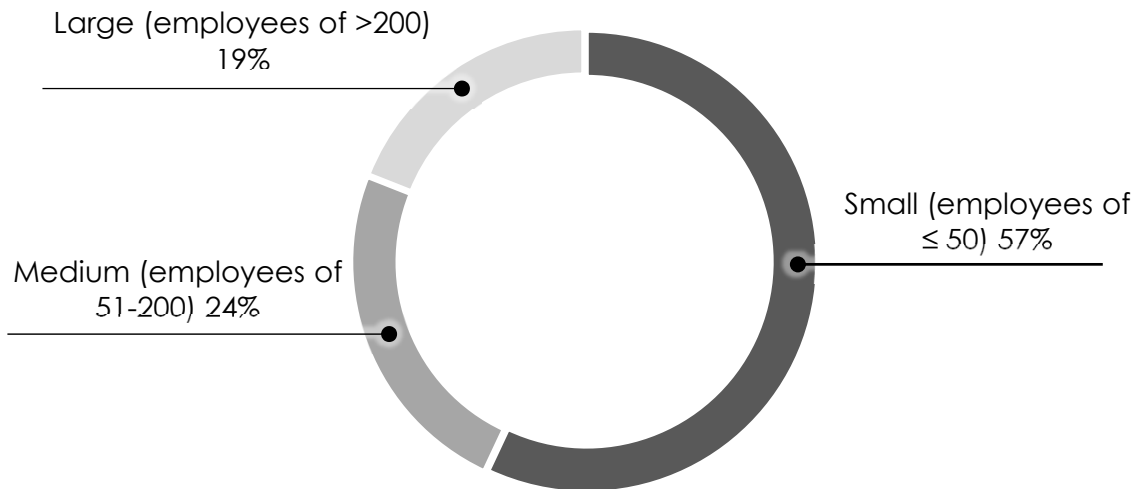
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Medical Devices Production in Thailand

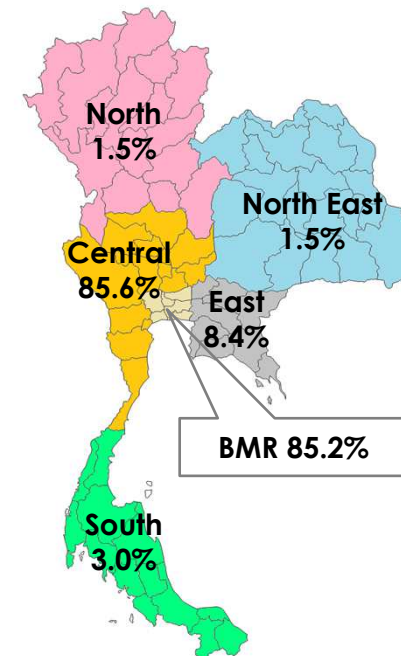
- According to the Thailand FDA, around 39.5 billion baht of medical devices and equipment are produced each year, about 70% are exported and 30% are for the local market.
- There are 565 medical devices and equipment manufacturers in Thailand. Most production facilities are in Bangkok and vicinity.
- More than 80% of the manufacturers are SMEs. The large manufacturers are multinational companies that mainly produce and export back to their parent companies.
- The local medical devices manufacturers mostly produce consumable and basic medical products, such as medical rubber gloves, syringes, catheters, autoclave, and X-ray device which do not require advanced technology.

Medical Device Manufacturers in Thailand

By Size (2019)



By Location (2019)

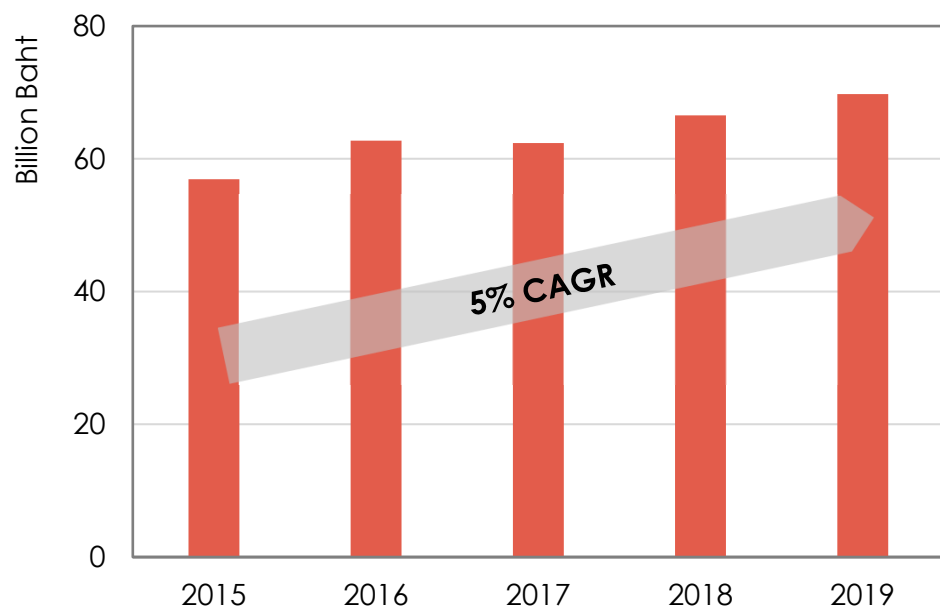


Source: Food and Drug Administration, Medical Devices Intelligence Unit (MedIU)

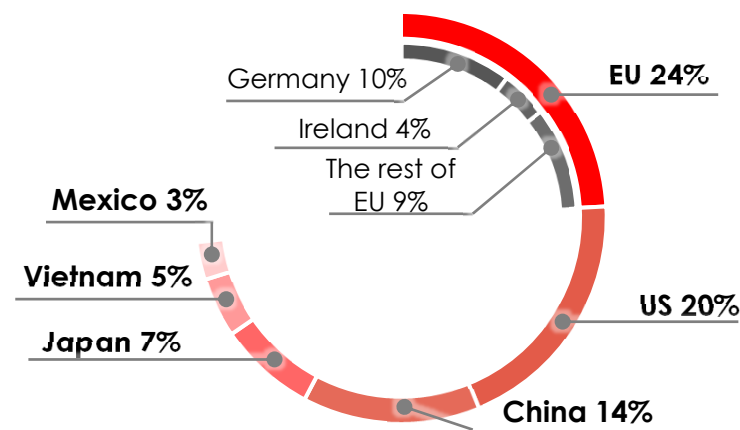
Thailand's Import of Medical Devices (1)

- The increasing number of hospitals and clinics and medical tourists have boosted the demand for medical devices in Thailand.
- Thailand is the major importer of medical devices in ASEAN with an import value of 70 billion baht in 2019.
- US, China, Germany, and Japan are the primary sources of imported medical devices & equipment in Thailand with a share of more than half of overall imported value in 2019.
- According to the FDA, there are around 2,500 medical devices importers currently operating in Thailand.

Thailand's Medical Devices Import Trend



Major Import Suppliers of Medical Devices in 2019

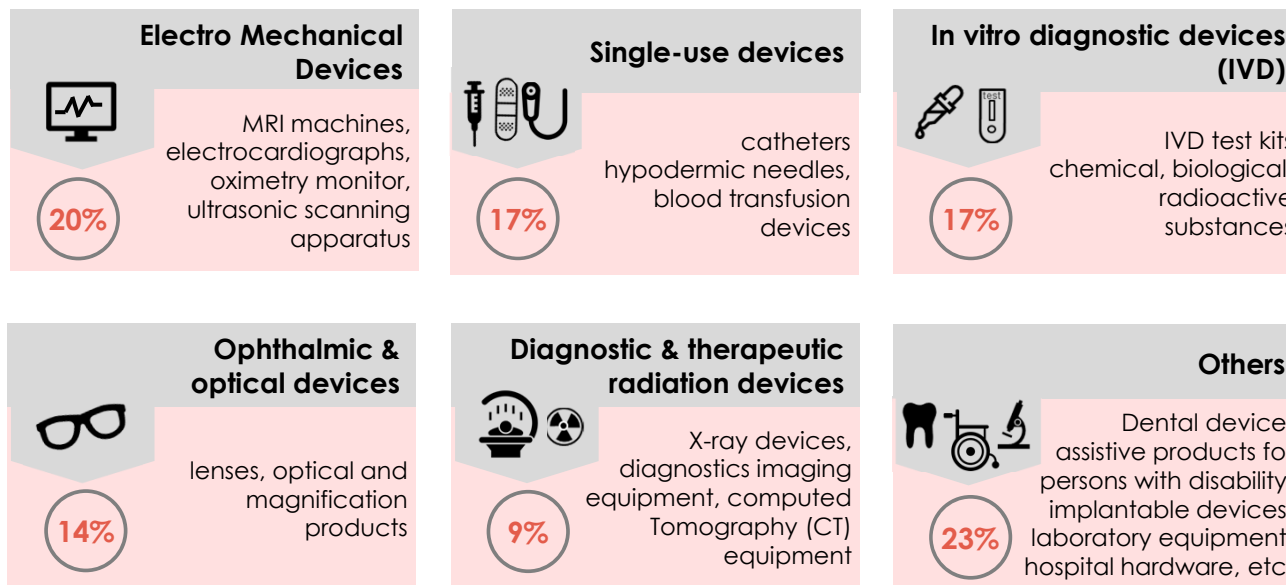


Source: Medical Devices Intelligence Unit (MedIU), Office of Industrial Economics (OIE)

Thailand's Import of Medical Devices (2)

- Thailand relies heavily on importing high-tech medical equipment, including electro-mechanical medical devices, ophthalmic and optical devices, and radiation devices. These high-tech equipment require high cost of R&D.
- Despite the manufacturing base of single-use device (i.e. surgical glove, face mask), Thailand still relies on the imported high-quality catheters and needles products. The demand for disposable medical supplies and protective equipment has been growing in line with the increasing number of hospitals and patient visits, driving import growth.
- Some medical devices (i.e. equipment for emergency department, ventilator) need to be imported as the limited local demand does not lead to domestic production.

Share of Major Imported Medical Devices by Products in 2019



Share to total import of medical devices

Growth of Thailand's Medical Device Import

GMDN	CAGR 2015-19
Electro mechanical medical devices	1%
Single-use devices	8%
In vitro diagnostic devices (IVD)	8%
Ophthalmic and optical devices	-1%
Diagnostic and therapeutic radiation devices	10%
Hospital hardware	8%
Dental devices	3%
Non-active implantable devices	7%
Assistive products for persons with disability	10%
Active implantable devices	3%
Complementary therapy devices	2%
Laboratory equipment	17%
Others	8%
Total import of medical devices	5%

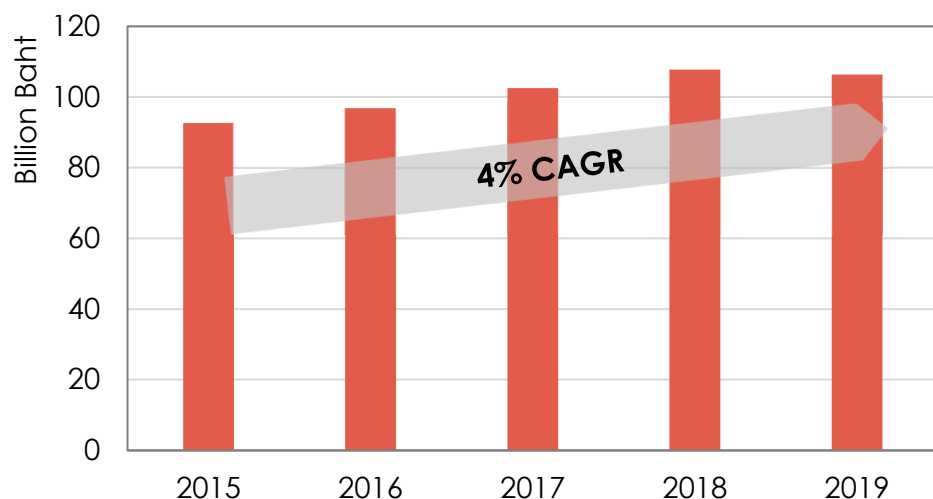
Note: * GMDN is Global Medical Device Nomenclature Codes

Source: Medical Devices Intelligence Unit (MedIU), Office of Industrial Economics (OIE)

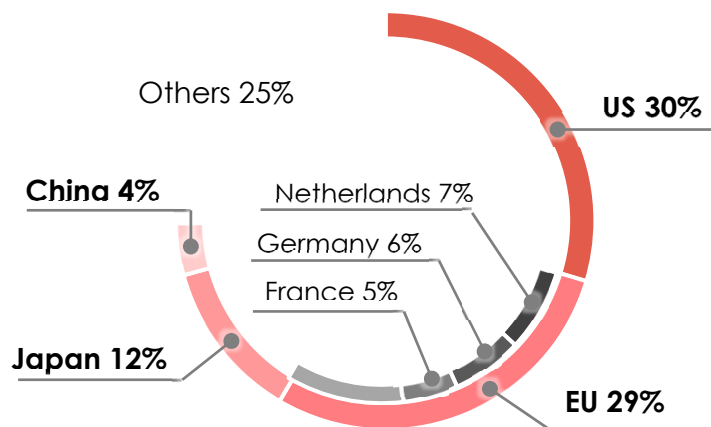
Thailand's Export of Medical Devices (1)

- Thailand's export of medical devices has exceeded 100 billion baht since 2017.
- Major export destinations of Thailand's medical devices are the US, EU, and Japan, which accounted for more than 70% of total export in 2019.
- The foreign companies from those major export destinations use Thailand as their OEM production base to export back to their countries.

Thailand's Medical Devices Export Trend



Major Export Destinations of Medical Devices in 2019



Source: Medical Devices Intelligence Unit (MedIU)

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International Medical Devices with Manufacturing Facilities in Thailand

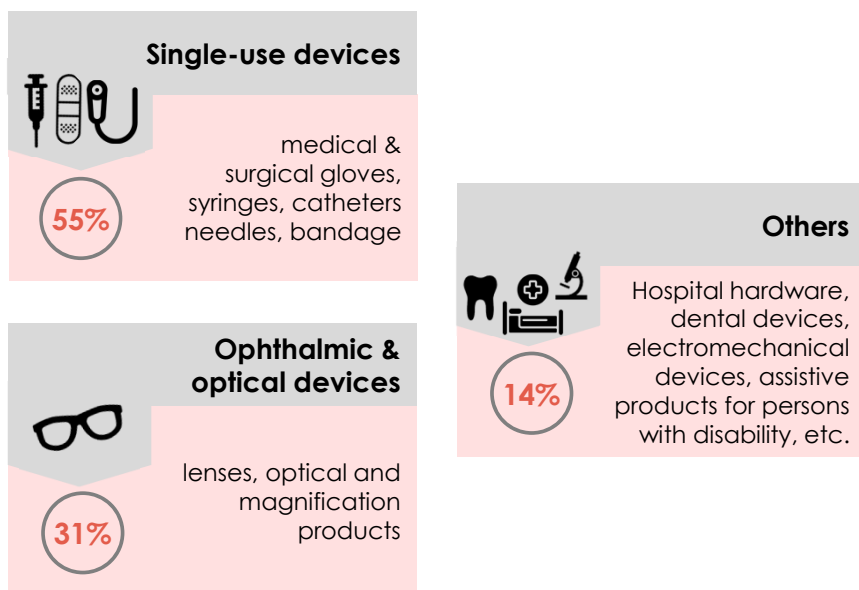
Company	Products
Nipro	Blood tubing set, PTA balloon catheter, hypodermic needles, and syringe
Hoya	Glass molded lenses, preforms, glass polished lenses
Kawasumi	Hemodialysis, plasmapheresis, blood banking and transfusion, infusion therapy
Asahi Intecc	Ultra-fine stainless steel wire ropes
Hakuzo	Infection control product, adhesive plasters, push swab, sterile product, eyes stick for an eye operation
Mizuho	Operation tables, sub assembly parts of operation tables
Essilor	Ophthalmic-lenses
Molnlycke Health Care	Single-use surgical gown, surgical drape & set and wound dressing
Cardinal Health	Surgical and specialty medical gloves
Greiner Bio-One	High-quality plastic laboratory products
Reckitt Benckiser	Antiseptic, ingestion remedy, immune support supplement
Quasar	Catheters, electronics and disposables
Ansell	Medical gloves, surgical gloves
Forme Medical	Functional examination couches, treatment tables
Mercator Medical	Medical disposable gloves
Synergy Health	Gamma Irradiation facility
Karma	Wheel chair, walker
Biotem	Dental implant system
Infus	Bone cement mixing, blood transfusion products, apheresis products, drainage products
Metron	Treatment tables
GE Healthcare	EP recording, maternal-infant products, ultrasound, radiography, mammography, ventilator

Source: BOI, Companies website

Thailand's Export of Medical Devices (2)

- The main export items are single-use devices, such as medical rubber gloves, catheters, medical tubing, syringes, needles, bandages, and ophthalmic and optical devices.
- Thailand is the world's leading producer of rubber glove. According to Fitch Solutions Inc., Thailand was the third top supplier of surgical gloves globally, behind Malaysia and China.
- The foreign medical devices manufacturers in Thailand mainly produce single-use devices. More than 60% of foreign BOI-promoted companies in medical devices business are the single-use devices manufacturers, especially the producers of catheters and syringes, according to Kasikorn Research.
- There has been a rapid growth in the export of IVD and assistive products for disability thanks to the growing proactive healthcare and ageing population worldwide.

Share of Major Exported Medical Devices by Products in 2019



Share to total export of medical devices

Source: Medical Devices Intelligence Unit (MedIU), Office of Industrial Economics (OIE)

Growth of Thailand's Medical Device Export

GMDN*	CAGR 2015-19
Single-use devices	6%
Ophthalmic and optical devices	2%
Electro-mechanical medical devices	-11%
Dental devices	-2%
Hospital hardware	0%
In vitro diagnostic devices (IVD)	80%
Assistive products for persons with disability	29%
Diagnostic and therapeutic radiation devices	5%
Non-active implantable devices	38%
Complementary therapy devices	-27%
Active implantable devices	-26%
Laboratory equipment	13%
Others	10%
Total export of medical devices	4%

Note: * GMDN is Global Medical Device Nomenclature Codes

Impact of COVID-19 Pandemic towards Thailand's Medical Devices Market

During COVID-19 outbreak

- **Supply Chains Disruption:** Like other products, COVID-19 has disrupted medical devices' global supply chain. This disruption has caused significant fall in the import and export of medical devices since the first quarter of 2020.
- **Lower Demand for Durable Devices:** The pandemic and country's lockdown measure has significantly impacted the hospital's financial performance. According to the Thai Medical Device Technology Industry Association, the number of patients visiting the private hospitals dropped around 40-50% during the COVID-19 period. The private hospital's lower profitability led to cost management and delayed investments in the new medical equipment.
- **A Surge in Demand to Diagnose, Prevent, and Treat Disease:** Despite slow demand for several devices, the personal protective equipment (PPE), i.e. surgical mask, N95 mask, face shield, disposable glove, gown, and PPE suit, as well as diagnostic test kit, thermo-scan, respirator and ventilator have observed optimistic growth during the pandemic. The market for these products expected to grow until there is a vaccine for COVID-19.

Post COVID-19 outbreak

- The COVID-19 outbreak and social distancing practice have accelerated digital technology in the medical service business.
- Demand for some particular types of medical devices, such as telemedicine, electronic medical records, remote health monitoring increased during the pandemic and is expected to grow rapidly to help remedy the physician shortage and reduce the expense of hospital visits.
- During COVID-19, Thailand's well-preparedness in handling the pandemic has increased investor's confidence in its medical industry.

Opportunities in Thailand's Medical Devices Industry

Private Hospitals



- Increasing no. of hospitals and medical facilities
- > 1,400 public and private hospitals nationwide
- Leads ASEAN with 66 JCI-accredited hospitals
- New players entering into hospital business (it was estimated that there will be 10-20 new hospitals opening during 2019-2024)

Increasing demand for high-tech medical devices, hospital hardware, etc.

Aging population



- Ageing population in Thailand will reach 15 million in 2025 and 20 million in 2038.
- World's population aged 60 years and older is expected to total 2 billion by 2050.
- Increasing NCDs patients, i.e. diabetes, hypertensive diseases, diabetes, stroke, cardiovascular diseases, cancer, etc.

Increasing demand for assistive products to support elderlies, IVD test kits, monitoring equipment, and devices used to treat and assist those with heart disease, strokes, diabetes, etc.

Health tourism surge



- 2.5 million medical tourist arrivals in 2018
- The medical treatment expenditure grew by 31% CAGR during 2016-2018.
- The cosmetic surgery, dental treatment, health checkup, hip/knee replacement are popular among medical tourists.

Increasing demand for high-tech medical devices, orthopedic devices, dental equipment, etc.

Supporting Factors



- Government-supporting policies, i.e. medical and wellness hub, BOI incentives, EEC, E-health, medical tourist visa, long stay visa, etc.
- Strong supporting industries i.e. rubber, plastic, E&E, textile & fiber, etc.
- ASEAN's emerging middle-income class, which will increase from 24% to 65% of total population in 2030, will boost the demand for medical devices. ASEAN's import of medical devices exceeded one trillion baht in 2019.

Increasing local supplies of high quality raw materials and investment incentives will lead to enhancing the competitive advantage of the manufacturers, meanwhile the rising demand in ASEAN will lead to economy of scale.

Thailand's Medical Hub Policies

- Initiated in 2004, the Thai government has continued to develop the country as an international medical hub with several supportive measures and policies, ranging from the investment incentives to the issuance of special visas to promote medical tourism.
- A 10-year medical hub strategic plan (2016-2025) acted as a guideline for related agencies to work together and develop the advanced medical industry ecosystem. The four major hubs are medical service hub, wellness hub, academic hub, and product hub.

Major Elements of Thailand's Medical & Wellness Hub Policy

Academic hub:

- Professional & post graduate education
- Skill labor training (i.e. therapist, care worker)
- Research center
- International conference

Key strategies:

- Enhance the academy capability to provide international program for health sciences and related field
- Promote the academy to produce more physicians in the field to meet future needs
- Establishment of medi-tech & health centers

Product hub:

- Medicine
- Thai herb medicines
- Healthy food, supplements
- Medical devices (i.e. innovated consumable device, high technology equipment, 3D printed medical model)

Key strategies:

- Develop the quality of Thai herb medicines and marketing to meet the international standards
- Promote the investment in medicine, medical devices, R&D, and innovation in related products



Medical service hub:

- Medical treatment (i.e. medical check up center, dental clinic, cosmetic surgery, anti-aging, infertility center, joint replacement, elderly care)
- Alternative medicine
- Laboratory services for testing/ R&D

Key strategies:

- Promote the hospitals to achieve national and international accreditations
- Offer investment incentives for medical services business
- Establish efficient patient transferring and interpretation centre to facilitate international patients

Wellness hub:

- Health spa
- Massage
- Health resort & long stay
- Rehabilitation center

Key strategies:

- Promote spa products and services to the international market
- Enhance the local health spa and traditional Thai massage to achieve international standard
- Promote the collaboration between government and private sector in human resource development

Thailand's Medical Hub Policies: Investment Incentives for Manufacture of Medical Devices

BOI-Investment Privileges for Manufacture of Medical Devices

	CIT exemption
Manufacture of high-risk or high-technology medical devices: e.g. <ul style="list-style-type: none"> ▶ x-ray machine ▶ MRI machine, ▶ CT scan machine ▶ implants ▶ medical devices that are commercialized from public sector research or collaborative public-private sector research 	8 years*
Manufacture of other medical devices (except for medical devices made of fabrics or fibers)	5 years
Manufacture of medical devices made of fabrics or fibers: e.g. <ul style="list-style-type: none"> ▶ Gowns ▶ Drapes ▶ Caps ▶ Face masks ▶ Gauze and cotton wool 	3 years
Manufacture of non-woven fabric or hygienic products made of non-woven fabric <ul style="list-style-type: none"> ▶ Non-woven fabric, i.e. spunbond, meltblown, which used as raw materials for production of medical masks or medical devices 	5 years**
<ul style="list-style-type: none"> ▶ Other non-woven fabrics or hygienic products made of non-woven fabric 	3 years



Additional 50% CIT reduction for 3 years after the expiration of CIT exemption***

Exemption of import duties on machinery

Exemption of import duties on raw materials used in production for export

Non-tax incentives (i.e. land ownership rights, visa & work permit facilitation)

The adjustment of existing production lines to manufacture medical devices or parts will also get the import duties exemption on machinery, with the condition that the application must be submitted by September 2020 and the equipment must be imported within 2020.

Note: * In case projects include R&D and innovation, the CIT exemption will be uncapped.

** The period of CIT exemption was revised from 3 years to 5 years to encourage the investment in medical supplies to serve the rising demand from COVID-19 pandemic.

*** Conditions are as follow:

- (1) The projects are required to apply for the promotion between 1 January and 30 June 2020.
- (2) The projects must start production and generate income by 31 December 2020.
- (3) Distribution or donation domestically of at least 50% of the output must take place in 2020-2021.

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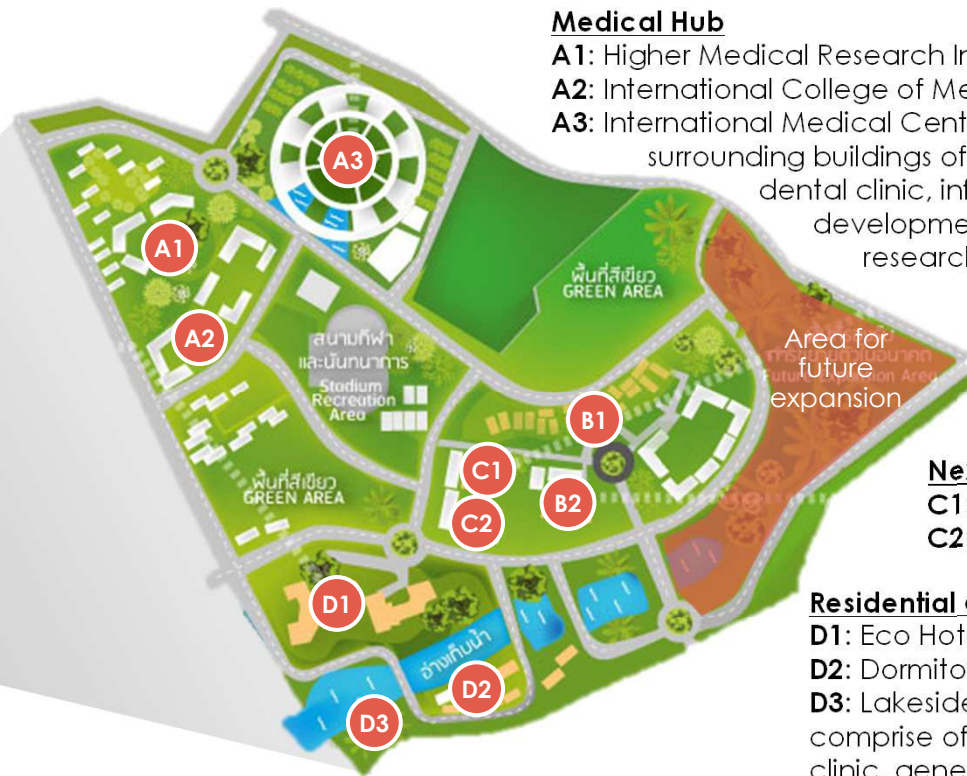
Thailand's Medical Hub Policies: EECmd for Manufacture of Medical Devices

EECmd Facilities and Investment Incentives

- The EECmd or Thailand's Medical Hub, located at Thammasat University Pattaya Campus, has been promoted since February 2019.
- The project area, which covers around 566 rai, will be divided into four main zones including medical hub (Zone A), Digital Innovation Hub (Zone B), Next Generation Automotive Hub (Zone C), and Residential and Service area (Zone D). The
- The investment in EECmd will be eligible to basic incentives plus a 50% deduction of corporate income tax on the net profits for 2 years from the expiry date of corporate income tax exemption period.

EECmd Master Plan

Location	Banglamung District in Chonburi Province
Project area	566 Rai (~ 91 hectare)



Medical Hub

- A1:** Higher Medical Research Institute
- A2:** International College of Medicine
- A3:** International Medical Center: comprise of a hospital and 10 surrounding buildings of specialized medical clinics i.e. digital dental clinic, infertility clinic, hemodialysis center, health development center for aging, pharmaceutical research center, etc.

Digital Innovation Hub

- B1:** Thammasat Innovation Hub
- B2:** Pattaya Cyberport

Next-Generation Automotive Hub

- C1:** Next-Generation Automotive Hub
- C2:** Electric Vehicle Learning Laboratory

Residential and Service Area

- D1:** Eco Hotel with 75 rooms
- D2:** Dormitory
- D3:** Lakeside Premier Complex (Senior complex): comprise of residential units, anti-aging medicine clinic, general clinic, dental clinic, and rehabilitation clinic

Source: Thammasat University Pattaya Campus

Market Entry Requirements

- The production, import, and marketing activities of the medical devices and equipment are under the supervision of Food and Drug Administrative office (FDA), which is the organization under Ministry of Public Health.
- Prior to manufacture, sell, import, and advertisement of the medical devices, the premise and product registration or license is required.
 - **Establishment Registration:** The medical devices entrepreneurs have to register the manufacturing and importing establishment before the operation. The premise location, production place, production equipment, storage area, shall be in good condition and hygienic.
 - **Product Registration:** The process of registration and permission depends on the product categories, which are classified into 3 categories according to the risk-based classification system.

Categories	Licensed medical devices	Notified medical devices	General (Listing) medical devices
Products	High risk level: Syringes, contact lens, IVDs, condoms, surgical glove, blood bags for human, etc.	Moderate risk level: Physical therapy devices, alcohol detector devices, methamphetamine test kits, silicone breast implants, ophthalmic viscosurgical device (OVD), concentrate for hemodialysis	Low risk level: <ul style="list-style-type: none"> ▪ Other medical devices which are not licensed or notified medical devices ▪ This category includes about 90% of medical devices
Requirements for registration	(1) Submit the dossier* (2) Obtain license and registration before production, importation, or sales	(1) Submit the dossier* (2) Do not require the sales license (3) Obtain the product notification from FDA before manufacturing or importation	(1) Do not require dossier submission, but Certificate of Free Sale (CFS) and / or Certificate of Quality System for manufacturer(s) from the country of origin (2) Product catalogue or details of the product specified in the Certificate of Free Sale (3) Require ISO certificate and technical data specifications for some devices, such as sterile products and laser equipment
Approval timeliness	8-10 months	6-8 months	2-6 days
Validity of license/certification	5 years	5 years	Depends on the validity of Free sale Certificate

Source: FDA, MOPH, KPMG

Note: *The documents according to the Common Submission Dossier Template (CSDT), which must be prepared. The dossier includes the medical devices information, namely relevant essential principles and method used to demonstrate conformity, medical device description (i.e. feature, materials, intended purposes, instruction for use, warnings, potential adverse effects, etc.), a summary of design verification and validation documents (pre-clinical studies, clinical evidence), medical devices labelling, risk analysis, and physical manufacturer information.

Conclusion

- Thailand is a major production base with huge domestic demand for medical devices. Among the ASEAN member countries, Thailand has the highest value of import and export of medical devices.
- Thailand's medical devices market is expected to grow due to several driven factors, including the increasing need for medical services, the influx of medical tourists, and its ageing population. ASEAN's emerging middle class will also offer a vast opportunity for the import of medical devices.
- Meanwhile, the country's reliance on medical devices import, especially electromechanical devices and sophisticated equipment, represents an excellent opportunity for the multinational manufacturers to produce locally to meet this demand. For non-durable medical devices and hospital hardware (i.e. hospital bed, examination table), the manufacturers make can use of large volume of local materials and strong supporting industries, i.e. plastics, rubber, auto parts, etc.
- Despite the opportunities, challenges remain. Thailand continues to face the shortage of qualified medical workforce and low level of R&D commercialisation.
- However, the medical industry has been designated as one of the country's targeted industries. Favourable initiatives and support from the government offer advantages to foreign investors, especially investments in advanced technology, innovation, and R&D, to enhance its value-addedness.

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