

MEDICAL DEVICE INDUSTRY IN THAILAND







Why Thailand for the Medical Device Industry?

Local and Regional Demand

Thailand's medical devices sector is one of the most well-known and well-established sectors in ASEAN countries. To better illustrate, the trade value for this industry is 19.93 billion US dollars. In terms of export and import, Thailand is ranked in the first and second ranks compared within ASEAN countries.

For domestic consumption, Thailand also consumes lots of medical device items. This is because of the expansion of medical services. For example, medical devices produced in Thailand particularly those of single-use type are more produced each year. However, other advanced ones such as ophthalmic or optical devices are imported. This is because of unavailability in domestic production.

Persistent Hike of Demand for Medical Devices Due to COVID-19

Because of the Covid-19 pandemic, the medical devices sector was contracting at 10.2 percent in 2020. However, the prediction from Krungsri Research Center¹ shows that the industry will be grown steadily at 6.5 percent per year in 2022–2023. This hike in demand, especially in the long-term, corresponds to main 5 factors, which are:

- The rising incidences of both communicable and non-communicable diseases (NCDs) among Thai population.
- The increasing size of the geriatric market due to Thailand's aging population.
- The rebound of foreign patients seeking treatment in Thai hospitals once the vaccine has been injected.
- The need of new devices from expansion of new buildings from many private hospitals.
- The support from the government to promote Medical Tourism.

Supply-Side Supporting Factor

Thailand has abundance of raw materials used for medical devices production, especially for single-use item type, such as rubber and plastic. Moreover, some institutions and regulations supported, from the R&D process to intellectual protection, ensure that the producer can be commercialized their items.

Government and BOI Support

The Thailand Board of Investment offers many highly attractive investment incentives, which, among others, include exemption of import duties on machinery, exemption of import duties on raw materials used in production for export, and other non-tax incentives such as BOI business facilitation services. Moreover, the incentives are highly competitive compared to the rest of ASEAN, especially the necessary items to include R&D and innovation to develop the products. In order to incentivize these kinds of things, some measures such as corporate income tax exemption can be applied for maximum 8 years.

¹ Source : Industry Outlook 2020–22: Medical Devices , Krungsri Research Center

Overview of Thailand's Medical Devices Market

The medical devices industry is one of the most well-known and high-potential sectors in Thailand. In 2019, this sector accounted for 4.47 percent of national GDP. Moreover, Thailand has long been the most significant medical device market in ASEAN countries. In 2020, the trade value is 19.93 billion US dollars, followed by Singapore, Malaysia, and Indonesia, respectively. In terms of export, Thailand is ASEAN's largest exporter of medical device according to Thailand's Medical Device Intelligence Unit.

Table 1: Export Value of ASEAN-5 Countries

Country	2016	2017	2018	2019	2020
Thailand	18.53	17.17	16.74	17.33	13.94
Singapore	11.93	12.79	12.65	15.00	13.08
Malaysia	8.77	8.70	9.71	11.24	12.14
Indonesia	4.47	4.63	4.43	6.06	4.17
Philippines	0.88	0.90	0.83	0.98	0.83

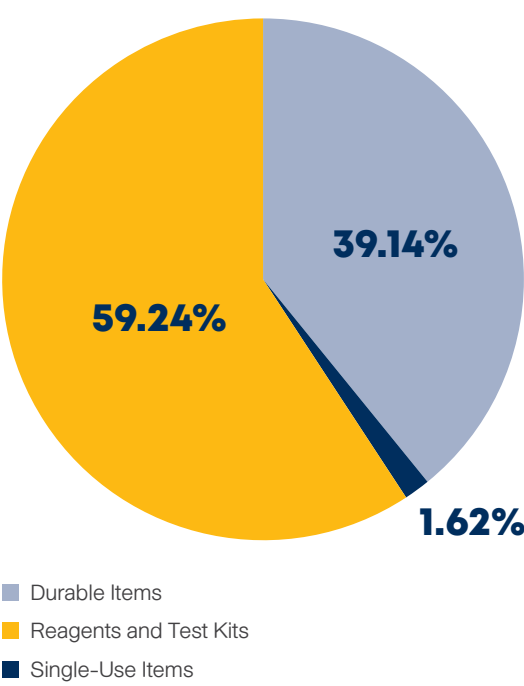
(Unit: USD, Billion)
Source: Medical Devices Intelligence Unit, data as of February 2021
Note: Exchange Rate 1 USD = 29.99 THB (As of Feb 2021, Bank of Thailand)

Single use items are the most exported Thai medical device product. The segment's value accounted for 59.24 percent of all medical devices export in 2020. This is due to the availability of raw materials, such as rubber and plastic. Moreover, export of other medical device products such as durable item and reagents and test kits account for 39.14 and 1.62 percent of its total export in medical devices sector, respectively.



Figure 1: Thailand's Exports of Medical Devices by Product Types

Exports of Medical Device by Product Type in 2020



Source: Medical Devices Intelligence Unit, data as of February 2021

In the other hand, the import value product from medical device sector is approximately 5.99 billion USD. This number are considered as the second rank of importer in ASEAN.

Table 2: Import Value of ASEAN-5 Countries

Country	2016	2017	2018	2019	2020
Thailand	6.82	6.12	6.62	8.00	5.99
Singapore	10.52	10.10	9.92	10.65	9.94
Malaysia	5.90	5.16	5.44	6.52	4.25
Indonesia	4.46	4.22	4.11	4.63	4.22
Philippines	5.83	6.41	5.39	5.66	2.96

(Unit: USD, Billion)
Source: Medical Devices Intelligence Unit, data as of February 2021
Note: Exchange Rate 1 USD = 29.99 THB (As of Feb 2021, Bank of Thailand)

Business Opportunities

The medical devices sector is expected to grow steadily at 6.5 percent per year in 2022-2023. This significant number of the growth comes from the following reasons.

- Lucrative market size as an ASEAN medical hub. Thailand demand for medical devices increase rapidly once the government strategize itself as medical hub in ASEAN. To understand characteristics and needs of end users in high growth ASEAN emerging markets, it is worth for investor to relocate medical device production into Thailand.
- Enormous investment incentive in Thailand for medical device sector. The government of Thailand offers a huge support of this sector via BOI channel. The measurements are extremely high especially in medical device production which necessarily need to research and development before inventing the products. The incentive for these items such as corporate income tax exemption will be implemented to the business for 8 years.
- Utmost potential production base in ASEAN market. Thailand also established the infrastructure, such as industrial parks, utilities and logistics system, which will be supported



investor from Research and development the items to export-oriented activities. In addition, Thailand has a pool of trained workforce from electrical and electronic industry. These group of high skill labors are ready to move forward to produce semi-hi tech and hi-tech medical instruments.

Moreover, Thailand tends to have high growth rate of market in medical devices sector in the long term. The reason comes from main 5 factors which will be described by the following.



- Rising incidences of cases in both communicable and non-communicable diseases (NCDs). The most common diseases are diarrhea, pneumonia, hypertension, diabetes, chronic obstructive pulmonary disorder, and coronary heart disease. Moreover, the number of patients has been forecasted to rise around 1.5 times in 2030. These would increase demand for modern, hi-tech medical equipment, especially for diagnostic purposes.

- The increase of Thailand's aging population. The Office of the National Economic and Social Development Council forecasts the population over 60 years old in Thailand will increase from 11.2 million in 2018 to 13.5 million by 2023. Moreover, healthcare costs for these people will increase to 230 billion Thai baht (2.8% of GDP) in 2022.

- The rebound of foreign patients seeking treatment in Thai hospitals once the vaccine has been vaccinated. The main reason is Thailand can offer high-quality care and services at its hospitals. Domestic care facilities for the elderly are also competitive in terms of spending. Using the health care services in Thailand is cheaper than its neighbors, such as Singapore and Malaysia. These two factors support Thailand

to be one of the preferred destinations for medical tourism.

- The increase of new buildings from many private hospitals. Many private hospitals plan to construct the new building to serve the rise in demand from Thai and foreign patients. To better illustrate, Bangkok hospital plans to increase its network from 49 sites to 50 by 2023 and expand its capacity by 172 beds. In sum, the construction's overall supply is projected to increase at least 2,000 beds by 2022. These construction buildings will undoubtedly increase demand for medical device products and equipment.

- The support from the government to promote Medical Tourism. Medical tourism is considered as a potential sector to generate income for the country. The medical industry's quality in Thailand attracts many foreign patients worldwide, with steady growth over time from 1.2 million foreign patients in 2014 to a forecasted 2.11 million foreign patients in 2021. Also, the reputation ranked as the fifth-largest medical tourism market. The majority of foreign patients in Thailand are from East Asia, Europe, and the Middle East. This group of patients often have high purchasing power.

For these reasons, Thailand continues to welcome new production of medical devices in all categories.

Technology and business opportunities.

For domestic production, most Thai manufacturers are small enterprises. Also, most medical devices produce in Thailand are using low and middle technology and innovation. The statistics from the previous session shown that Thailand has single-use devices as the most significant portion. Moreover, most domestic production is exported.

On the other hand, Thailand heavily imports high technology and innovation products for domestic consumption. This means that the country has a high demand for high technology and innovative medical device items. Thus, the government are welcome all investment for supporting our demand. By implementing this idea, firstly, the Medical devices sector has been prioritized to be supported due to the National Strategy and National Reform Plan. Moreover, to attract medical devices' production using advanced technology and innovation, the government uses measurements to aim this goal, such as tax exemption incentives via the BOI channel.

Government and BOI Support

Area of focus

Thailand welcomes all medical-related investment. However, there are some areas of focus which provide extra incentive in medical devices sector in the following.

- Thermoscaner and thermometer
- Personal protective equipment, such as the N95 mask
- Ventilator, respirators, or negative pressure units
- Testing apparatus, such as mobile lab testing equipment or COVID-19 kit test
- Devices for the ageing society, such as hearing aid, prosthetics and Orthopedic Devices
- Other single-use devices

Related institution

There are many institutions and research centers where medical technological breakthroughs and development are adequately supported. Moreover, the support from these agencies is covered from R&D process to Manufacturing. The lists of supporting institutions are as followed.

R&D Center / Facilitation

- National Science and Technology Development Agency (NSTDA)
- The National Center for Genetic Engineering and Biotechnology (BIOTEC)
- Thailand Center of Excellence for Life Sciences (TCELS)
- Thailand Institute of Scientific and Technological Research (TISTR)

R&D Facilitation

- Thailand Science Park (TSP)
- Science Park Promotion Agency (SPA)

Regulator

- Thailand Food and Drug Administration (FDA Thailand)

Policy and Knowledge Support

- Health Systems Research Institute (HSRI)

Funding and Acceleration

- National Innovation Agency (NIA)

Industrial Support & Promotion

- Thailand Board of Investment (BOI)
- Office of Industrial Economics (OIE)

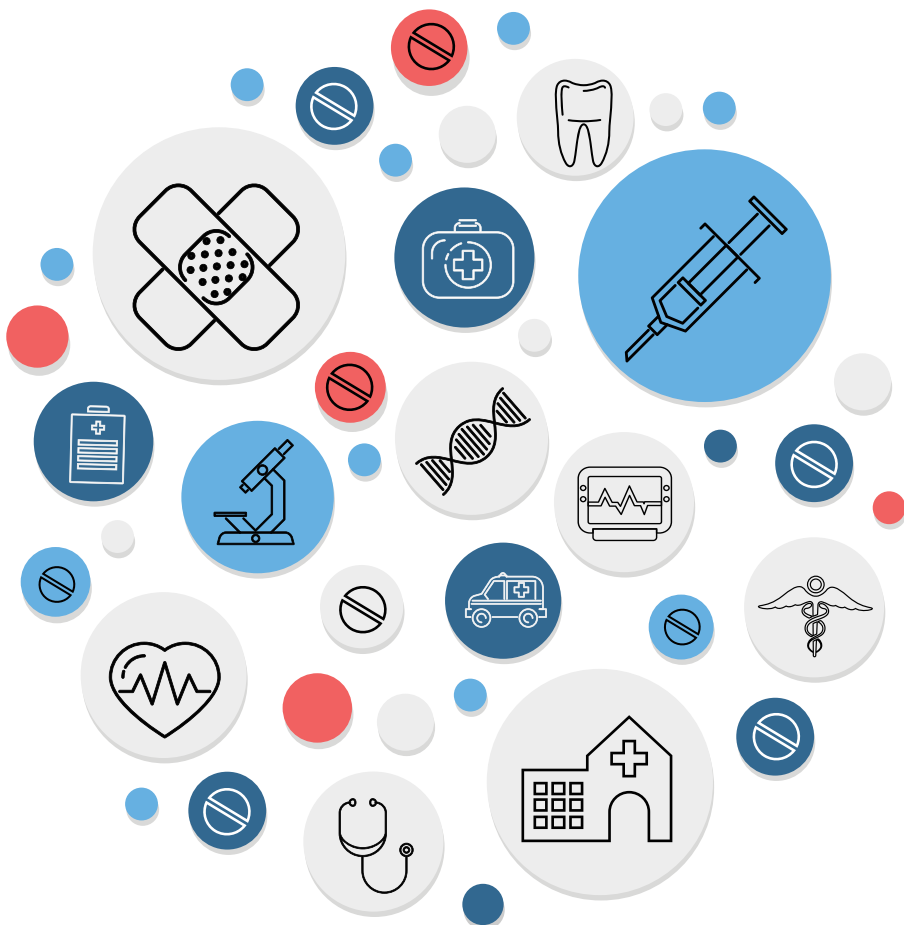


BOI Incentives

The Thailand Board of Investment offers many highly attractive investment incentives, which, among others, include exemption of import duties on machinery, exemption of import duties on raw materials used in production for export, and other non-tax incentives such as BOI business facilitation services. However, the chief incentive the BOI provides is the exemption on corporate income tax, which varies according to the level of risk associated with the different types of medical devices.

<p>Manufacture of high-risk or high-technology medical devices, (e.g. x-ray machine, MRI machine, CT scan machine and implants) or medical devices that are commercialized from public sector research or collaborative public-private sector research</p>	<p>8-year CIT exemption (no limit on maximum exemptible CIT for projects involving with R&D and innovation)</p>
<p>Manufacture of other medical devices (except for medical devices made of fabrics or fibers)</p>	<p>5-year CIT exemption</p>
<p>Manufacture of medical devices made of fabrics or fibers, e.g. gowns, drapes, caps, face masks, gauze and cotton wool</p>	<p>3-year CIT exemption</p>

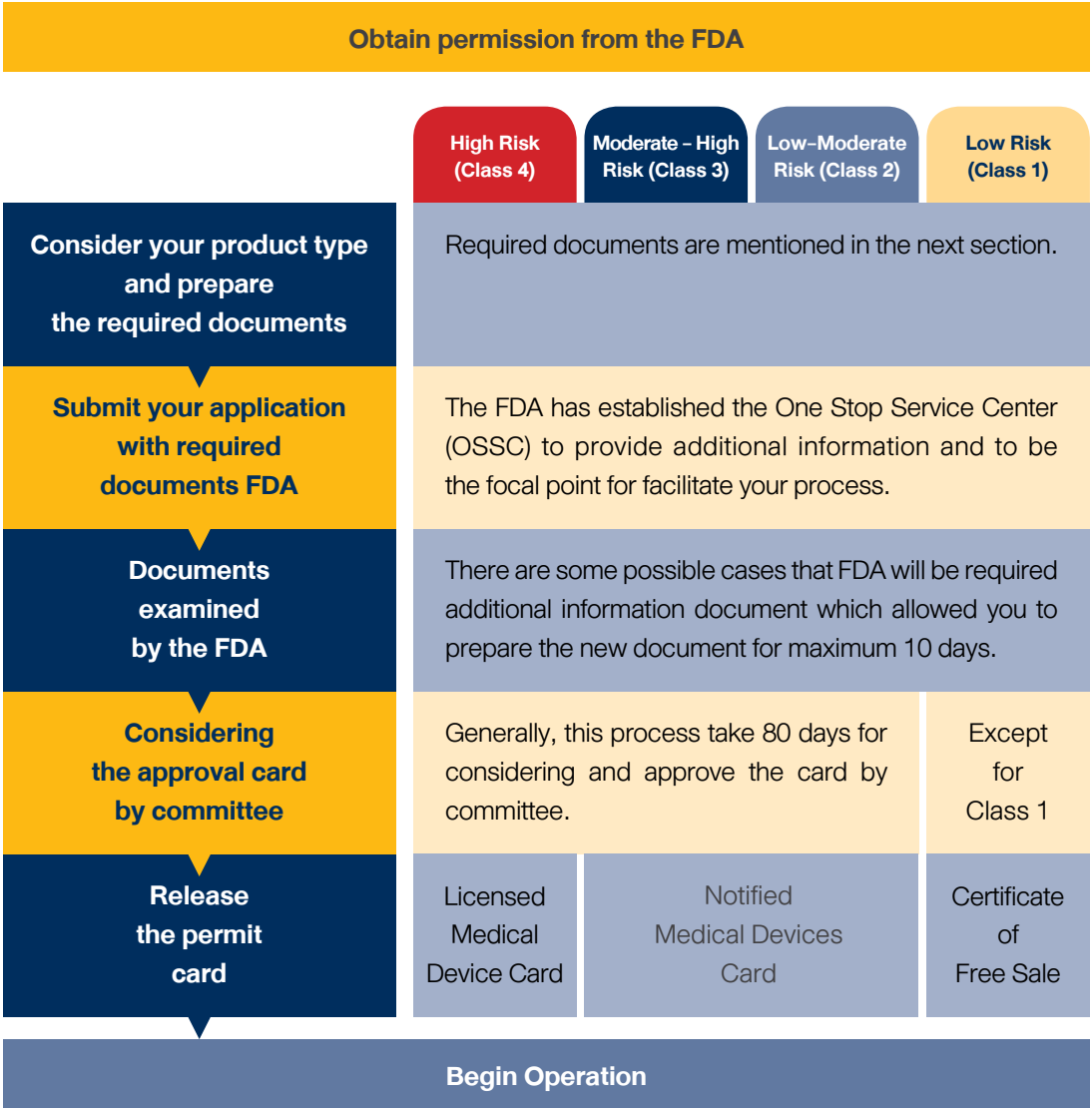
Source: Thailand Board of Investment



Regulatory Process

The following flowcharts summarize the entire process of starting your medical device business in Thailand. Production of medical devices are regulated under the provisions of the Medical Devices Act B.E. 2551 (2008) and the amended Medical Device Act (No.2), B.E. 2562 (2019). Observe the second chart for the specifics of FDA approval.





How to Operationalize Your Business Operation

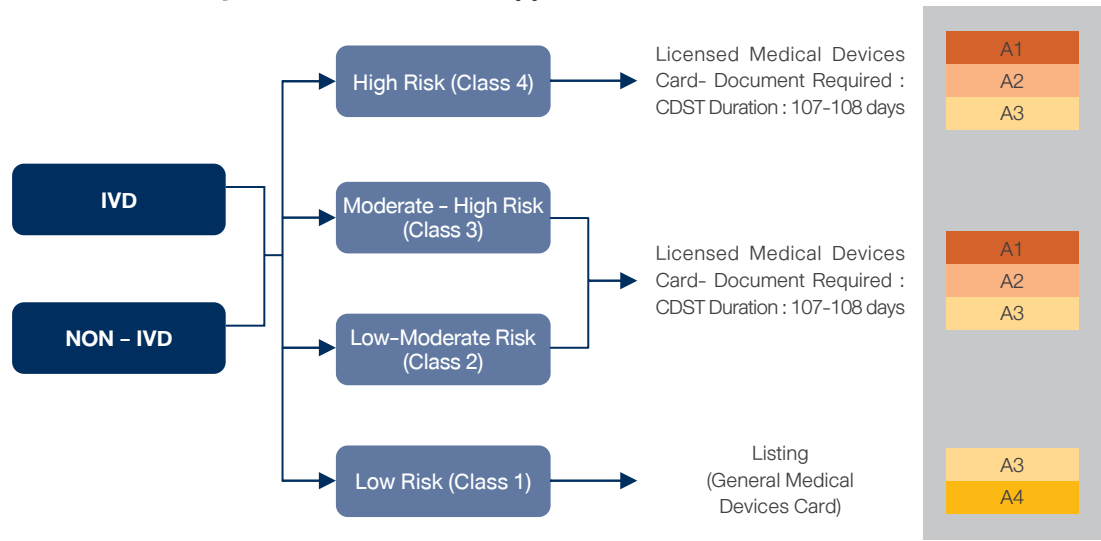
Per above illustration, apart from obtaining the BOI incentives and certificates, allow the BOI to assist you on the following processes.

Process	Details and Contact Point
Dealing With Construction Permits	<ul style="list-style-type: none">● Building Permit and Occupancy Permit: submit building permit application at the Civil Works department of the area you are building your establishment.● Telephone: TOT Public Company Limited● Water: connect with Provincial or Metropolitan Waterworks Authority depending on your location
Getting Electricity	<ul style="list-style-type: none">● Connect with the Metropolitan Electricity Authority or the Provincial Electricity Authority depending on your location
Registering Property	<ul style="list-style-type: none">● Submit your documents at the Land Office, Department of Lands.● All corporate documents used in this process must be certified copies.
Recruitment	<ul style="list-style-type: none">● Key takeaways in understanding labor laws in Thailand: protections, hours and holiday, compensation, social security, cessation of operation, termination, and minimum wage● Understand incentives for labor skill training
Manufacturing License	<ul style="list-style-type: none">● Apply for Authorization to Use Land, Authorization for New Factory Construction or Rental Factory Renovations, and Authorization to begin factory● Connect with either the Industrial Estate Authority of Thailand (IEAT) or the Ministry of Industry (MOI) Provincial Offices (Dept. of Industrial Works) depending on the location of your establishment
Import And Export License	<ul style="list-style-type: none">● Use of e-Custom system for importing and exporting
Foreign Business License/Certificate	<ul style="list-style-type: none">● Obtain foreign business license if required per business type

Medical Device-Specific Regulatory Process

The most important aspect of which is approval process for production and importing of medical devices which will be shown following.

Risk-based Policy For Medical devices Approval



First, you must know your product type before entering this process. Thailand’s FDA categorization closely resembles that of the ACCD; hence the Thai FDA has categorized medical devices into 4 groups which are as follows.

Class	IVD, Risk Level	Non-IVD, Risk Level	Group of Control
1	Low risk to individual and public health, e.g., examination gloves, enema devices	Low, e.g., adhesive bandages, gauze dressing, incision drapes, dental patient chair	Listing (Required to make the notification)
2	Moderate risk to individual or low risk to public health, e.g., urinary catheters, stents, dental aspirator tips	Low to Moderate, e.g., hydrogel dressing, devices to remove carbon dioxide from the blood and/or adding oxygen	Notified (Required to make the declaration of specifications)
3	High risk to individual or moderate risk to public health, e.g., bone cement, stents and valves (Pulmonary), Intraocular lenses	Moderate to High, e.g., haemodialysers, dressing for severe wound	
4	High risk to individual and public health, e.g. cardiovascular catheters	High	Licensing (Required to be granted permission)

For High-risk products, you need to have Licensed Medical Devices Card from FDA before commercializing. The processes for getting license are required some essential documents as follow.

Required Documents

- Registration certificate of the original company
- Executive summary
- Essential Principles of Safety and Performance of Medical Device and method used to demonstrate conformity.
- Device description
- Summary of design verification and validation documents
- Device labeling
- Risk analysis
- Manufacturer information
- Certificate of free sale
- GMP or quality system certificate
- Declaration of conformity
- Letter of authorization for authorized representatives
- Destroying approaches (if possible)

Duration: Approximately 107.5 days

For Moderate-high and Low-moderate risk products, you need to have Notified Medical Devices Card before selling. The process for getting notified are required some essential documents as follow.

Required Documents

- Registration certificate of the original company
- executive summary
- Essential Principles of Safety and Performance of Medical Device and method used to demonstrate conformity
- Device description
- Summary of design verification and validation documents
- Device labeling
- Risk analysis
- Manufacturer information
- Certificate of free sale
- GMP or quality system certificate
- Declaration of conformity
- Letter of authorization for authorized representatives
- Destroying approaches (if possible)

Duration: Approximately 107.5 days

For General Medical Device products, you need to have the certificate of free sale before selling. The process for getting certificate are required some essential documents as follow.

Required Documents

- A letter from company requesting to verify the Certificate of Free Sale
- Original document of the Certificate of Free Sale and/or Certificate of Quality System for manufacturer(s) with two photocopies.
- Copy of the company's registration issued by the Ministry of Commerce within the six months stating the objectives of the company.
- Letter of authorization
- Product catalogue or details of the product specified in the Certificate of Free Sale
- Copy of the establishment for importation license.
- Detail of products in the Certificate of Free Sale indicating medical devices' code.

For all permit cards, the debrief process are as follow.

1) You should submit your application with required documents to One Stop Service Center (OSSC), FDA.

2) Then, the medical devices department will examine your documents. If they want some additional information, they will inform you to submit some additional documents. Generally, you will have 10 days for submitting the additional.

3) Next, the department will consider your document before submitting to the committee. If your devices need to be scrutinized by specific expert, the department will submit to the specific experts. (This process is except for Low-risk (class 1) equipment.)

4) Lastly, the department will estimate and record all documents and release the permit card.





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