

Guide to Taiwan Wholesale and Retail Sales of Medical Devices License

According to the definition stipulated in “Regulations for Governing the Management of Medical Device” and “Enforcement Rules of Medical Devices Act”, medical devices include instruments, substances, software, in vitro diagnostic reagents and other related articles in Taiwan. The design and usage of the devices are aimed to achieve diagnosis, treatment or improvement of human bodies and human diseases by means of pharmacological, immunological, metabolic or chemical methods. If a company is intended to engage in wholesale or retail sales of the above-mentioned devices, it must apply for the Wholesale and Retail Sales of Medical Devices License with the Taiwan Ministry of Health and Welfare.

Ministry of Health and Welfare is the authority responsible for the issue and supervision of the Wholesale and Retail Sales of Medical Devices License.

Applicants shall fulfill certain criteria in order to apply for the license, including the business address of the company should be able to register for business activity code of medical devices wholesale and retail sales. Also, government officer will conduct onsite inspection on the business address.

In general, if the submitted documents and information are correct, the license will be issued with 4-6 weeks by the Ministry of Health and Welfare.

Kaizen’s service fee for the application of Wholesale and Retail Sales of Medical Devices License is HKD 12,000, which includes the application fees and other fees incurred from miscellaneous items. The service will start upon the receipt of service fee and application fee.

Wholesale and Retail Sales of Medical Devices License does not require a yearly renewal. However, if there are changes of business address, company representative and business activities, the company should report to the Ministry of Health and Welfare within one month and renew the license.

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1. Application Fees of Taiwan Wholesale and Retail Sales of Medical Devices License

Our service fees for applying the Taiwan Wholesale and Retail Sales of Medical Devices License are HKD 12,000. The service fees include:

- a) Provide advice to clients regarding the application of the license
- b) Prepare the required documents for application
- c) Submit the documents to the Ministry of Health and Welfare
- d) Liaise between clients and the authority regarding the license application
- e) Settle the application fee for clients
- f) Receive the licence for clients

The aforementioned service fees include the application fees and delivery fee of documents to related authority.

2. Payment

After taking the case from client officially, Kaizen will issue and provide clients with the invoice and guideline of payment via e-mail. While proceeding the payment, please leave our invoice reference or document number on the remark of your proof of remittance. After settling the payment, please send over the proof to our e-mail, so as to track your amount of payment more smoothly. Based on the policy, the service fees shall be charge fully in advance. Except for the special conditions, the request of refund is not accepted from the start of service.

The payment is accepted in the format of cash, bank transfer, remittance and Paypal (credit card). In the condition of payment proceed in Paypal, the extra 5% processing fees will be incurred.

3. Businesses Required Taiwan Wholesale and Retail Sales of Medical Devices License

According to the definition stipulated in “Regulations for Governing the Management of Medical Device” and “Enforcement Rules of Medical Devices Act”, medical devices include instruments, substances, software, in vitro diagnostic reagents and other related articles in Taiwan. The design and usage of the devices are aimed to achieve diagnosis, treatment or improvement of human bodies and human diseases by means of pharmacological, immunological, metabolic or chemical methods. Medical equipment dealers are referring to sellers of the above-mentioned medical devices, including wholesale, retail, import, export, rental, and repair of medical devices.

In brief, any company which plans to engage in wholesale and retail of medical devices in Taiwan shall apply for the license with the Ministry of Health and Welfare in Taiwan.

4. Application Requirements

Before submitting an application of Wholesale and Retail Sales of Medical Devices License to Ministry of Health and Welfare, the applicant shall meet the following requirements:

a) Business Registration

To whom plans to run their business as medical device dealer must finish the business registration at first. Regarding the procedure and processing fees of business registration in detail, please refer to the “Procedure and Fees of Business Registration in Taiwan”. Foreign incorporation is also able to register their business in branch company to offer the employment services.

b) Business Registered Address Requirement

The business address of the company should be able to register for business activity code of medical devices wholesale and retail sales, floorplan shall also be provided for the authority’s review. The address does not limit to actual office or virtual officer, however government authority will conduct an onsite inspection.

c) Professional Technician Requirement

If the company intends to import medical devices to Taiwan, it shall hire at least one professional medical device technician, with the following qualifications:

i) Graduated from Taiwan public or private college or above or foreign college or above which conforms to the Taiwan Ministry of Education recognition and obtained a graduation certificate.

ii) Engaged in the medical device manufacturing or sales industry for more than one year and took part in medical device manufacture or the preparation, management and submission of medical device inspection registration documents.

iii) Completed at least 20 hours of training in Taiwan, which shall include related acts and regulations of Taiwan medical device, medical device product manufacturing quality management system, inspection and registration documents preparation and progress management, practical delivery of inspection registration documents and management of medical devices products after launch.

5. Procedures of Application

The following procedures are quoted based on Kaizen’s service for the application:

- a) Client confirms Kaizen’s service and provide required materials to Kaizen
- b) Kaizen prepares and shares the required signing documents with guidelines with client (The documents will be sent over to client via e-mail, hard copy with wet signature should be mailed to Kaizen afterwards.)
- c) After the documents are received, Kaizen will submit for pre-screening to the Ministry of Health and Welfare
- d) After the company is registered, Kaizen will submit for license application to the Ministry of Health and Welfare
- (5) Kaizen will settle the license payment and receive the license.

6. Materials for Application

The following documents are required before submitting the application of Wholesale and Retail Sales of Medical Devices License:

- a) Fill out and sign the application form
- b) Business registered address and floorplan
- c) A copy of company name reservation and business activities approval letter
- d) A copy of certificate of business registration, articles of incorporation and passport or Taiwan ID of the company representative.

7. Estimated Processing Time

The license application has been divided into 2 phases: the first phase is the pre-screening, second phase is the license issuance after the company is registered. In general, if the required documents and materials are well prepared, it will take 4-6 weeks for approval at the earliest.

8. Renewal

Wholesale and Retail Sales of Medical Devices License does not require a yearly renewal. However, if there are changes of business address, company representative and business activities, the company should report to the Ministry of Health and Welfare within one month and renew the license.

If you wish to obtain more information or assistance, please visit the official website of Kaizen CPA Limited at www.kaizencpa.com or contact us through the following and talk to our professionals:

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