



HONG KONG MEDICAL & HEALTHCARE DEVICE INDUSTRIES ASSOCIATION
APPLICATION FOR CERTIFICATE OF FREE SALES
APPLICATION FORM

A. Application's Information

Company Name (English) _____

Company Name (Chinese) _____

Business Reg. No. _____ Year Business Started in Hong Kong _____

Company Address (English): _____

Contact Person: _____ (Block Letters) Title: _____

Phone No.: _____ Fax No.: _____ E-mail: _____

Capacity of the Applicant in relation to the Product(s) (i.e. manufacturer, owner, authorized dealer, importer, wholesaler, retailer etc.): _____

B. Product Information

Product Name/s and pack size to be listed on the Certificate (maximum 6 products):

Manufacturer's Name: _____

Manufacturer's Address: _____

C. Name of the Country for which the Certificate will be used

D. Additional Information (if available):

For examples:

- Scientific papers on safety and efficacy of Products;
- ISO13485;
- FDA/CE Certificates;
- cGMP Certificate;
- 510K Certificate etc.

Declaration

I, _____ (name), _____ (title) duly authorized representative of _____ (company name) (“the Company”) hereby declare that all the information and materials submitted to the Hong Kong Medical and Healthcare Device Industries Association (“HKMHDIA”). For the purpose of this application are true, accurate and complete and the Company represents and warrants to HKMHDIA that HKMHDIA can rely on the information to be true complete and accurate. Further our company shall fully indemnify and keep fully indemnified the HKMHDIA against any claim, demand, liability, damage, loss and expenses of any nature in the event that the HKMHDIA is claimed or held liable by any third party in relation to any matter concerning the product(s), including but not limited to, product liability, personal injury or death, misrepresentation, intellectual property right infringement and/or other liability in contract (“actions”). Our company shall inform HKMHDIA of any demands or claims in relation to the above and if HKMHDIA is involved in actions, the Company shall use its best endeavors to cooperate with HKMHDIA.

Authorized Signatory:

Company Stamp:

Date:

Application Information

1. The application must be from a company registered in Hong Kong Special Administrative Region (“HKSAR”).
2. A photocopy of the application company's valid Business Registration Certificate must be attached to the Application Form.
3. The applicant must provide a sample of the packaging materials including the product label/s and insert(s) if available bearing the full name of the products, which name shall be printed on the Certificate of Free Sale.
4. The applicant must provide invoices indicating the sale of the product to at least two purchasers in Hong Kong during the most recent 12 months or at such period deemed appropriate by the Association. The applicant needs to submit the original invoice document(s) or the oath paper made at the Home Affairs Department of the Government of the HKSAR to confirm that the invoices are true and authentic.
5. The item "Additional Information" in the Application Form refers to, for example, but not limited to, any scientific data on product efficacy and safety, ISO13485, FDA/CE Certificate, cGMP, 510K Certificate etc. Further supporting materials may be required from the applicant.
6. The maximum number of product names can be included in the same certificate is six. Administration Fee payable for the first product for certification is HK\$1,000. For each additional product to be included in the same application, the charge will be HK\$600 per product.
7. Different package sizes of the same product name shall be treated as subsidiary products of the main or the first package size submitted at the same time. The Administration Fee payable for each subsidiary product is HK\$400. However, if the application for different package size is not made at the same time as the main or first product, it will be treated as a new application and full charge of HK\$1,000 will have to be paid.
8. One Certificate can only be used for one country. An additional administration fee of HK\$500 is payable for each additional certificate for any other country or place requested in the same application.

9. An additional administration fee of **HK\$500** is payable for each duplicate copy of certificate.
10. The total amount of Administration fees should be made payable by crossed bank check to " Hong Kong Medical & Healthcare Device Industries Association Limited" .
11. Processing time is approximately 4-6 weeks from the date of receipt of the application.
12. The Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA) shall not be obliged to issue the Certificate of Free Sale to any particular application or for any product. The decision to issue any Certificate of Free Sale is solely at the discretion of HKMHDIA. HKMHDIA shall have no responsibility to give any reason for refusing to issue any certificate and shall not be held liable to the applicant in any way for such refusal. Only 50% of the Administration fee will be refunded if the application is rejected by HKMHDIA.
13. HKMHDIA reserves the right to change the amount of Administration fee payable from time to time without giving any advance notice to the public. The applicant should enquire with HKMHDIA about the updated tariff immediately before submitting the application.
14. The application Form, Business Registration Certificate copy, product label/s, sales invoices, contact person's business card, Administration Fee and other supporting documents should be mailed to the Association's postal address below:

Hong Kong Medical & Healthcare Device Industries Association
Room 4, Unit 601, Core Building 1, Hong Kong Science Park, Pak Shek Kok,
New Territories, Hong Kong

**HONG KONG MEDICAL AND HEALTHCARE DEVICE
INDUSTRIES ASSOCIATION
APPLICATION FOR CERTIFICATE OF FREE SALE**

CHECKLIST

This is for your easy checking of the necessary materials to be sent to the Hong Kong Medical and Healthcare Device Industries Association for the application of Certificate of Free Sale.

Have you included the followings in your application package?

1. Original Application Form properly signed, dated and company seal affixed Photocopy of business registration certificate of the application company

2. Actual sale pack label/s of product/s for this application (different pack sizes)

3. Recent invoices indicating sale of each application products to at least two retail customers

4. The original invoice document(s) or oath paper/declaration/affirmation made at the Home Affairs Department of the Government of the HKSAR

5. Additional documents (if available)

6. Applicant's business card

7. Crossed bank check for full payment of Administration Fee