Appendix 2: Documents and information that shall be submitted for an application of registration and market approval to manufacture or import Class 2 or Class 3 medical devices

Application Category / Documents and Information to be Submitted		Class 2 Medical Devices		Class 3 Medical Devices		Same Product with Different Product Names		Exclusively for Export
		Manufacture	Import	Manufacture	Import	Manufacture	Import	Manufacture
1	Application form for medical device registration and market approval	○	○	○	○	○	○	○
2	Two copies of draft labels, instructions, or packaging	○	○	○	○	○	○	×
3	Copy of the medical device business permit	○	○	○	○	○	○	○
4	Original of the manufacture and free sale certificate of the country of origin	×	△	×	△	×	○	×
5	Original of the foreign original manufacturer authorization letter	×	○	×	○	×	○	×
6	Document verifying that medical device manufacturer conforms to the Medical Device Quality Management System Regulations	○	○	○	○	×	×	○

7	Test specifications and methods of preclinical testing and quality control conducted by the original manufacturer, the original test records, and the test reports	△	△	○	○	×	×	×
8	Documents relating to product structures, materials, specifications, functions, intended uses, and drawings	○	○	○	○	×	×	×
9	Clinical evidence information	△	△	△	△	×	×	×
10	Radiation safety information for equipment generating ionizing radiation	△	△	△	△	×	×	×
11	Essential Principles (EP) of Safety and Performance of Medical Devices and Summary Technical Documentation (STED)	×	△	○	○	×	×	×
12	Original of the manufacturer's letter explaining that the product is the same product with different product names	×	×	×	×	○	○	×

13	Copy of the originally approved labels, instructions, or packaging stamped with tally impression of the central competent authority	╳	╳	╳	╳	○	○	╳
14	Copy of the originally approved medical device license	╳	╳	╳	╳	○	○	╳
15	Other documents and information designated by the central competent authority	△	△	△	△	△	△	△
16	Samples for testing	△	△	△	△	╳	╳	╳

Instructions:

1. ○: Indicates document for this item shall be submitted. △: Indicates it would be dependent on the case. X: Indicates document for this item shall not be required for submission.
2. Draft labels, instructions or packaging:
   (1) For those who manufacture medical devices, the Chinese labels, instructions, or packaging and draft color pictures of the actual product appearance.
   (2) For those who import medical devices, the original labels, instructions, or packaging, the draft detailed Chinese instructions and draft color pictures of the actual product appearance.
3. Copy of the medical device business permit:
   (1) Those who manufacture medical devices shall attach a copy of the medical device manufacturing permit. Those who import medical devices should attach a copy of the medical device dealer permit showing that the business category includes “medical device import.”
   (2) For domestic contract manufacturing, both the contract party and the contract manufacturer's medical device business permits shall be submitted.
4. Manufacture and free sale certificate of the country of origin:
   (1) This document shall record the following particulars:

① Name and specifications and/or model number of the medical device.
② Manufacturer's name, address, manufacturing status, and actual status for domestic sale as approved in that country.

(2) This document may be replaced by a document issued by other authorities or another document in accordance with the following provisions:
① If the medical device is not regulated by the highest health authority in manufacturer's country, this document may be issued by the local health agency or an organization approved by the central competent authority of the Republic of China (Taiwan).
② If the medical device is commissioned to be manufactured, this document may be issued by the highest health authority in the country where the contract party or the contract manufacturer is located.
③ If the medical device involves contract manufacturing and it is not sold in the country where the contract manufacturer is located, this document may be replaced by a free sale certificate issued by the highest health authority in the country where the contract party is located, and a manufacture certificate issued by the government of the country where the contract manufacturer is located.
④ This document may be replaced by a manufacture certificate issued by the government of manufacturer's country and a free sale certificate issued by the highest health authority of the United States of America or of a European Union Member State.
⑤ If the medical device is a world's first product with no predicate, a report from the central competent authority after conducting an on-site inspection of the foreign medical device manufacturer and a report of medical device clinical trials carried out in the Republic of China (Taiwan) shall be submitted for the exemption from submitting the manufacture and free sale certificate of the country of origin.

(3) This document shall remain valid for two years from the date of issuance, and shall be notarized by the Republic of China's (Taiwan's) overseas embassy or consulate, representative office, other official office stationed in the region, or overseas organization authorized by the Ministry of Foreign Affairs (hereafter referred to as the ROC overseas representative office). If the certification document is not issued in English, a Chinese or English translation shall be submitted at the same time and the translation shall be notarized. However, those issued by the highest health authority of a country that has established technical cooperation agreement with the Republic of China (Taiwan) for the premarket review of medical devices or those recognized by the central competent authority are exempt from notarization.

5. Foreign original manufacturer authorization letter:
   (1) This document shall record the following particulars:
      ① The original manufacturer authorizes an agent in the Republic of China (Taiwan) to apply for registration and market approval and agrees to coordinate with the agent in the Republic of China (Taiwan) to comply with relevant medical device regulatory requirements.
      ② It specifies the name and address of medical device firm commissioned or authorized to register, as well as the name and specifications and/or model number of medical device.
   (2) This document may be replaced by other documents in accordance with the following provisions:
      ① A certification document for authorized agent issued by the headquarter company of the imported medical devices that authorizes the agent in the Republic of China (Taiwan) to apply for registration and market approval. Its contents explicitly state the name and address of manufacturer and specify the name and address of medical device firm commissioned or authorized to register, as well as the name and specifications and/or model number of medical device.
      ② The original manufacturer of imported medical devices issues a certification document stating its foreign agent, and then the foreign agent issues a certification document for authorized agent, which authorizes the agent in the Republic of China (Taiwan) to apply for registration and market approval and explicitly states the name and address of medical device firm commissioned or authorized to register, as well as the name and specifications and/or model number of medical device.
   (3) This document shall remain valid for one year from the date of issuance. If it is not issued in English, a Chinese or English translation shall also be submitted at the same time.
6. Document verifying that medical device manufacturer conforms to the Medical Device Quality Management System Regulations:
   (1) This document refers to the certification document issued by the central competent authority stating that the medical device manufacturer conforms to the Medical Device Quality Management System Regulations.
   (2) For medical devices that were originally regulated as pharmaceuticals and within three years from the date of announcing the regulatory change to medical devices, this document may be replaced by a copy of the certification document showing conformance to the Good Manufacturing Practices for Pharmaceuticals.
7. Test specifications and methods of preclinical testing and quality control conducted

by the original manufacturer, the original test records, and the test reports:

(1) This document shall include information on safety and performance testing that has been conducted to ensure the claimed efficacy, structure, materials, design, and quality of the product.

(2) For Class 2 medical devices with predicate device(s) that have been approved for marketing by the central competent authority, this document may be replaced by one of the following documents:

① Marketing approval certification document issued by the government of a country that has established technical cooperation agreement with the Republic of China (Taiwan) for the premarket review of medical devices, as well as Essential Principles (EP) of Safety and Performance of Medical Devices and Summary Technical Documentation (STED).

② Affidavit of preclinical testing conformity for medical device that is a product announced by the central competent authority whose manufacturer has a predicate device of the same classification and approved for marketing by the central competent authority.

(3) For Class 2 medical devices in Appendix 3, if the applicant has obtained the license showing that the same medical device manufacturer has manufactured a predicate device of the same item and the license is still within the validity period, this document may be replaced by the Class 2 medical device product comparison and preclinical test data conformity statement, with the exception of medical devices containing medicine.

(4) For medical devices that require testing as announced by the central competent authority, two copies of this document shall be submitted.

(5) Commissioned laboratories that conduct the biocompatibility, electrical safety, and electromagnetic compatibility (EMC) testing shall conform to any of the following requirements:

① Conform to the provisions of ISO/IEC 17025.

② Conform to the provisions of Good Laboratory Practice for Nonclinical Laboratory Studies (GLP).

8. Documents relating to product structures, materials, specifications, functions, intended uses, and drawings: For instrument products, the operation manual and maintenance manual that cover these documents may replace them.

9. Clinical evidence information:

(1) This document includes:

① Academic and theoretical bases, relevant research reports and data.

② Clinical evaluation report or clinical trial report.

(2) The central competent authority shall determine or announce whether or not the medical device applying for registration and market approval requires clinical

trials in the Republic of China (Taiwan) by considering the medical device product item, individual case, and data submitted by applicant.

(3) For medical devices with predicate device(s) that have been approved for marketing by the central competent authority, unless it is necessary to verify their safety and effectiveness with clinical evidence, this document may be exempt from submission.

(4) For Class 2 medical devices without predicate device, unless otherwise specified, the clinical trial report may be replaced by supporting data that meets all the following conditions:

① There are no ethnic differences in the expected effectiveness of this product.

② There are no serious adverse reports related to the claimed intended use or indication for such type of product in foreign countries, and the product has not been required to be removed from the market.

③ Preclinical data (including trial) may be used to demonstrate that the differences between the product and domestic products that have been approved for marketing will not affect the product's safety and effectiveness; or marketing approval certification documents of the United States of America and the European Union may be provided and the indication under application does not exceed the scope approved by the United States of America and the European Union.

10. Radiation safety information for equipment generating ionizing radiation: For medical devices generating ionizing radiation, this document shall be submitted.

11. Essential Principles (EP) of Safety and Performance of Medical Devices and Summary Technical Documentation (STED):

(1) The format of this document shall follow the announcement of the central competent authority.

(2) For Class 2 medical devices under application with the circumstances in Paragraph (2) ① of Section 7, this document shall be submitted.

12. Manufacturer's letter explaining that the product is the same product with different product names: It shall explain that the product for which a new application has been made and the originally approved product are identical products, and indicate clearly the medical device license number that was originally approved.

13. Other documents and information designated by the central competent authority:

(1) For medical devices using bovine or ovine/hircine tissues, an explanation of animal raw material source control procedures and proof of raw material source from the original manufacturer shall be submitted in order to verify that the processes associated with the medical device and the ultimate finished product do not use any bovine or ovine/hircine product from the bovine spongiform encephalopathy (BSE) epidemic areas announced by the Council of Agriculture,

Executive Yuan, and have not been contaminated by BSE pathogens. However, for applications conforming to the announcement from the central competent authority regarding the exemption from submitting the aforementioned documentation after considering the international regulatory guidelines for controlling bovine or ovine/hircine tissues in accordance with the risk of contamination of the tissues by BSE pathogen, this provision shall not apply.

(2) If the product name bears a trademark, relevant information related to trademark registration shall be submitted. If the product name bears the name or trademark of another medical device firm, a consent letter issued by the firm shall be submitted.

(3) In line with the Consolidated List of Commodities Subject to Import Restriction and Commodities Assisted by Customs for Import Examination announced by the Bureau of Foreign Trade of the Ministry of Economic Affairs, medical devices imported from China shall first obtain permit for import from the Bureau of Foreign Trade of the Ministry of Economic Affairs before applying for registration and market approval from the central competent authority.

(4) For medical devices exclusively for export, the instructions for use, function, working principle, and explanation of product composition (or ingredients) shall be submitted, and the contents of which shall be sufficient to determine that this product meets the identification of the product item under application.

(5) If the name, the label, instructions or packaging of the product bears a proper noun for performance/specification of a specific country or international organization standards, supporting documents issued by the country or the region, a third-party validation agency, or the international organization should be attached.

14. Samples for testing: For items announced in Paragraph 2 of Article 3, the applicant shall follow the testing notice, pay the testing fee by the designated deadline, and submit sufficient samples for testing to conduct testing procedures.