Appendix 1: Documents and information that shall be submitted for an application of registration and market approval to manufacture or import Class 1 medical devices

Item	Application Category	Manufacture	Import
1	Application form for Class 1 medical device registration and market approval	○	○
2	Copy of the medical device business permit	○	○
3	Document verifying that medical device manufacturer conforms to the Medical Device Quality Management System Regulations	△	△
4	Instructions of product from the original manufacturer	△	△
5	Test specifications and methods for preclinical testing and the test reports	△	△
6	Other documents and information designated by the central competent authority	△	△

Instructions:

1. ○: Indicates document for this item shall be submitted. △: Indicates it would be dependent on the case.
2. 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 shall 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.
3. Document verifying that medical device manufacturer conforms to the Medical Device Quality Management System Regulations: This document refers to a copy of the certification document issued by the central competent authority stating that the medical device manufacturer conforms to the Medical Devices Quality Management Systems Regulations. However, this shall not be required for items that, as product items announced by the central competent authority, do not need to obtain manufacturing license.
4. Instructions of product from the original manufacturer: They shall include the instructions for use, function, working principle, explanation of product composition (or ingredients), and the contents of which shall be sufficient to determine that the medical product meets the identification of Class 1 classification.

5. Test specifications and methods of preclinical testing and the test reports: These documents shall be submitted if the product performance/specifications have been described in the identification provisions of Class 1 medical device product items or announced by the central competent authority pursuant to Article 30 of the Act.
6. The central competent authority may, depending on the circumstances of the case, request relevant documents and information be submitted:
   (1) 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 firm, a consent letter issued by the firm shall be submitted.
   (2) 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.