

## Appendix 5: Documents and information that shall be uploaded for an application for a listing to manufacture or import Class 1 medical devices

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

### Instructions:

- : Indicates document for this item shall be submitted. △: Indicates it would be dependent on the case.
- Copy of the medical device business permit:
  - Those who manufacture medical devices shall upload a copy of the medical device manufacturing permit. Those who import medical devices shall upload a copy of the medical device dealer permit showing that the business category includes “medical device import”.
  - For domestic contract manufacturing, both the contract party and the contract manufacturer's medical device business permits shall be uploaded.
- 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 Device Quality Management System Regulations. However, this is shall not be required for items that, as product items announced by the central competent authority, do not need to obtain manufacturing license.
- 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. For items designated by the listing system, this document should be uploaded.

5. Test specifications and methods of preclinical testing and the test reports: These documents shall be uploaded 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. Other documents and information designated by the central competent authority:
  - (1) If the product name bears a trademark, relevant information related to trademark registration shall be uploaded. If the product name bears the name or trademark of another firm, a consent letter issued by the firm shall be uploaded.
  - (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 a listing from the central competent authority.
  - (3) If the name 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 uploaded.