

Appendix 1

Requested Application mode	Manufacturer of Domestic Medical Devices	Manufacturer of Imported Medical Devices	
	On-site inspection	Desktop inspection ⁶ (QSD review)	Overseas On-site inspection
Basic information of the manufacturer		O	
Certificate of compliance equivalent to medical device QMS certification(ISO13485)		O	
Document demonstrating that the manufacturer is a legal entity ²			O
A photocopy of the medical device business permit	O		
Evidentiary documents showing the manufacturer's registration ³	O		
Letter of authorization and agreement from the original manufacturer ⁵			O
Manufacturer quality manual	O	▲ ¹	O
Document master list	O	O	O
Quality system procedural documents		▲ ¹	
Medical device file list ⁵	O	O	O
Plant layout diagram	O	O	O
Production area information for each type of product	O	O	O
Main manufacturing equipment and main testing equipment	O	O	O
Manufacturing process diagrams for each product item	O	O	O
Organizational chart	O		O
Suppliers of main raw materials and each component	O		O

Note:

1. ▲ shows in the case of applications for extension only need to submit the parts of revisions, the manufacturing license and the letter of revisions from the manufacturer.
2. The certification issued by medical device competent authority of the country where the manufacturer is located, ISO13485 certification or other document demonstrating that the manufacturer is a legal entity.

3. Pursuant to the Factory Management Act, or if such manufacture, as approved by the central competent health authority, is for research and development purposes are allowed exemption from factory registration.
4. Should clearly state that the original manufacturer authorizes the medical device firm in Taiwan to submit an application to the Food and Drug Administration, Ministry of Health and Welfare, R.O.C. (Taiwan), for overseas manufacturer inspection and related matters.
5. The medical device file is that established by manufacturer on the basis of article 11 of the Medical Device Quality Management System Regulations.
6. Medical device manufacturer falling with the scope of an agreement/established between other competent authorities with Taiwan (R.O.C), the requested documents could be substituted by other documents announced by the central competent authority.