Appendix 4: Documents and information that shall be submitted for an application of change, re-issuance, or replacement of medical device license

Item to be Changed / Documents and Information to be Submitted		Chinese product name	English product name	Labels, Instructions, or Packaging	Ingredients, Materials, Structures, Specifications, or Model number	Effectiveness, Intended Use, or Indication	Name of the Manufacturer	Address of the Manufacturer or Country of Manufacture	License Holder	Name of the License Holder	Re-issuance or Replacement of a Lost or Damaged License	Manufacturing license number
1	Application form for change of medical device license	○	○	○	○	○	○	○	○ Note 9	○	○	○
2	Application form for medical device registration and market approval	×	×	×	×	×	×	×	×	×	△ Note 13	×
3	Original license	○	○	○	○	○	○	○	○	○	△ Note 14	○

4	Copy of the originally approved labels, instructions, or packaging stamped with tally impression of the central competent authority	×	×	○	△ Note 2	○	×	×	×	×	△ Note 15	×
5	Two copies of draft labels, instructions, or packaging	×	×	○	△ Note 3	○	×	×	×	×	△ Note 16	×
6	Copy of the medical device business permit	×	×	×	×	×	△ Note 5	△ Note 5	○ Note 10	○ Note 12	×	×
7	Original of the manufacture and free sale certificate of the country of origin	×	△ Note 1	×	△ Note 4	△ Note 4	△ Note 4	△ Note 6	×	×	×	×
8	Original of the foreign original manufacturer authorization letter	×	×	×	△ Note 4	△ Note 4	△ Note 4	△ Note 4	△ Note 11	×	×	×
9	Document verifying that medical device manufacturer conforms to the Medical Device Quality Management System Regulations	×	×	×	×	×	○	○	×	×	×	○

10	Test specifications and methods of preclinical testing and quality control conducted by the original manufacturer, the original test records, and the test reports	×	×	×	△ Note 3	○	×	△ Note 7 Note 8	×	×	×	×
11	Documents relating to product structures, materials, specifications, functions, intended uses, and drawings	×	×	×	△ Note 3	○	×	△ Note 7 Note 8	×	×	×	×
12	Clinical evidence information	×	×	×	△ Note 3	△	×	×	×	×	×	×
13	Radiation safety information for equipment generating ionizing radiation	×	×	×	△ Note 3	×	×	×	×	×	×	×
14	Original of the manufacturer's letter that explains the change	×	○	○	△ Note 3	○	○	○	×	×	×	×
15	Comparison table of changed and originally approved content	×	×	○	△ Note 3	○	×	×	×	×	×	×

16	Transfer statement co-signed by the transferor and transferee	×	×	×	×	×	×	×	○	×	×	×
17	Statement from the medical device firm receiving the transferred license (transferee) affirming the responsibility for the transferred medical device	×	×	×	×	×	×	×	○	×	×	×
18	Statement from the medical device firm after name change affirming the responsibility for every item on the changed license	×	×	×	×	×	×	×	×	○	×	×
19	Statement claiming that change in the name of a medical device firm holding the medical device license does not involve transfer of rights	×	×	×	×	×	×	×	×	○	×	×
20	Other documents and information designated by the	△	△	△	△	△	△	△	△	△	△ Note 17	△

	central competent authority											
21	Samples for testing	╳	╳	╳	△ Note 18	╳	╳	△ Note 18	╳	╳	╳	╳

Instructions:

I. ○: Indicates document for this item shall be submitted. △: Indicates it would be dependent on the case. ╳: Indicates document for this item shall not be required for submission.

II. Please refer to the instructions of Appendix 2 for relevant regulations on: draft labels, instructions, or packaging; copy of the medical device business permit; manufacture and free sale certificate of the country of origin; foreign original manufacturer authorization letter; document verifying that medical device manufacturer conforms to the Medical Device Quality Management System Regulations; test specifications and methods of preclinical testing and quality control conducted by the original manufacturer; original test records and test reports; documents relating to product structure, materials, specifications, functions, intended uses, and drawings; clinical evidence information; radiation safety information for equipment generating ionizing radiation; other documents designated by the central competent authority; and samples for testing.

Notes:

1. The manufacture and free sale certificate of the country of origin shall be able to indicate that the changed product and the originally approved product are the same. For domestically manufactured medical devices, it is exempt from submission.
2. This is exempt from submission if the change of specifications does not involve changing the originally approved labels, instructions, or packaging.
3. This is exempt from submission for deletion of specifications.
4. For domestically manufactured medical devices, this is exempt from submission. For deletion of specifications, this is exempt from submission.
5. For domestically manufactured medical devices, a copy of new firm's medical device manufacturing permit shall be submitted. For imported medical devices, this is exempt from submission.
6. For domestically manufactured medical devices, this is exempt from submission. If

the change of manufacturer's address was due to house numbering system change, this document may be exempt but certificate document issued by a government agency shall be submitted; in the case of imported medical devices, it shall be notarized by ROC overseas representative office.

7. If the application for change involves a Class 3 in vitro diagnostic medical device, this information shall be attached. For applications for change of other products, the central competent authority may, when necessary, order submission of this document.
8. For medical devices that require testing as announced by the central competent authority, two copies of this document shall be submitted.
9. The change of license holder shall be applied jointly by the transferor and transferee.
10. This refers to a copy of the transferee's medical device business permit.
11. The foreign original manufacturer authorization letter shall explain in detail about termination of the rights of the transferor, and bestowing of such rights to the transferee, and shall state the product name and the names and addresses of transferor and transferee. For domestically manufactured medical devices, it is exempt from submission.
12. This refers to a copy of the transferee's medical device business permit after name change.
13. This document shall be submitted when applying for re-issuance or replacement of a lost or damaged license. It is exempt from submission when applying for re-issuance or replacement of lost or damaged labels, instructions, or packaging.
14. This is exempt from submission when applying for re-issuance of a lost license.
15. This document shall be submitted when applying for replacement of damaged labels, instructions, or packaging. It is exempt from submission when applying for re-issuance or replacement of a lost or damaged license and re-issuance of lost labels, instructions, or packaging.
16. This document shall be attached when applying for re-issuance or replacement of lost or damaged labels, instructions, or packaging. It is exempt from submission

when applying for re-issuance or replacement of a lost or damaged license.

17. When applying for re-issuance of a lost license, a statement declaring that the original license has indeed been lost shall be submitted. When applying for re-issuance or replacement of lost or damaged labels, instructions, or packaging, a statement declaring that the original labels, instructions, or packaging has indeed been lost shall be submitted.
18. 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.