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The Measures for the Administration of Medical Device Registration were passed by State Food and Drug Administration at the administration affairs meeting on May 28, 2004 and are hereby promulgated for implementation as of the date of promulgation.

Director General: Zheng Xiaoyu

Aug. 9, 2004

Measures for the Administration of Medical Device Registration

Chapter 1. General Provisions

Article 1

These Measures are formulated in accordance with the Regulations on the Supervision and Administration of Medical Devices to standardize the administration of medical device registration and guarantee the safety and effectiveness of medical devices.

Article 2

All the medical devices sold and used within the territory of the People's Republic of China shall be subject to application for registration in accordance with the provisions of these Measures. The medical devices whose registration fails to be approved shall not be sold or used.

Article 3

Medical device registration means the process of systematic evaluation of the safety and effectiveness of the medical devices to be sold and used in accordance with the legal procedures to decide whether the sale and use of such medical devices can be approved.

Article 4

China implements classified registration and administration of medical devices.

Category I domestic medical devices are subject to examination by municipal level (food) drug administration authorities of the administrative areas with districts, and medical device registration certificates will be issued after approval by such authorities.

Category II domestic medical devices are subject to examination by the (food) drug administration authorities of provinces, autonomous regions and municipalities, and medical device registration certificates will be issued after approval by such authorities.

Category III domestic medical devices are subject to examination by the State Food and Drug Administration (SFDA), and medical device registration certificates will be issued after approval by SFDA.

Foreign medical devices are subject to examination by SFDA, and medical device registration certificates will be issued after approval by SFDA.

Unless otherwise specified hereunder, medical devices from Taiwan, Hong Kong and Macao shall be registered by reference to the measures for the registration of foreign medical devices.

The valid period of each medical device registration certificate shall be four years.

Article 5

Medical device registration certificates shall be printed by SFDA in a centralized way, while the corresponding contents shall be completed by the (food) drug administration authorities responsible for examination and registration.

Registration numbers shall be arranged in the following form:

×(×)1(S)YJX(×2)Z××××3 No. ×4××5××××6, where,

×1 shall mean the abbreviation of the place where the registration examination and approval authority is located:

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The letter “G” shall be adopted for Category III domestic medical devices, foreign medical devices and medical devices from Taiwan, Hong Kong and Macao;
The abbreviation of the province, autonomous region or municipality where the registration examination and approval authority is located shall be adopted for Category II medical devices;
The abbreviation of the province, autonomous region or municipality where the registration examination and approval authority is located plus the abbreviation of the local municipal level administrative area with districts shall be adopted in the form of ××1 for Category I domestic medical devices (only the abbreviations of the local province, autonomous region or municipality shall be adopted if there is no corresponding municipal level administrative area with districts);
×2 shall indicate the form of registration (Z [approval], J [import] and X [permit]):
“Z” is applicable to domestic medical devices;
“J” is applicable to foreign medical devices;
“X” is applicable to medical devices from Taiwan, Hong Kong and Macao;
××××3 shall indicate the year of approval for registration;
×4 shall indicate the category of product administration;
××5 shall indicate the type code of product; and
××××6 shall indicate the serial number of registration.
The medical device registration record (see Appendix 1 of these Measures) attached to each medical device registration certificate shall be used together with the medical device registration certificate.

Article 6

A manufacturer applying for medical device registration shall undertake the corresponding legal obligations and hold a medical device registration certificate after the application is approved.
The person handling the matters related to application for medical device registration shall be subject to authorization by the manufacturer, have the corresponding professional knowledge and be familiar with the laws, rules, regulations and technical requirements on the administration of medical device registration.
Regarding application for the registration of foreign medical devices, the foreign manufacturer shall designate an organization located within the territory of China to act as the foreign manufacturer’s agent, who shall undertake the corresponding legal liability. The foreign manufacturer shall also entrust a corporate organization that is located within the territory of China and has the corresponding qualifications or entrust the manufacturer’s organ in China to undertake after-sale service for the medical devices.

Article 7

The medical device under application for registration shall have an applicable product standard, which may adopt a national standard, a professional standard or a registered product standard formulated by the manufacturer, but the registered product standard shall not be inferior to the relevant national standard or professional standard.
Registered product standards shall be formulated in accordance with the requirements of SFDA for the administration of the standards of medical devices.

Article 8

When a manufacturer applies for the registration of a Category II or III medical device, the manufacturer shall satisfy the production conditions specified by SFDA or meet the requirements of the relevant quality system.

Chapter 2. Test for Medical Device Registration

Article 9

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Categories II and III medical devices are subject to registration test by the medical device test organizations recognized by SFDA and the General Administration of Quality Supervision, Inspection and Quarantine. Such medical devices shall be proved conforming to the applicable product standards through test before the medical devices are used for clinical trial or an application is submitted for registration.

The list of the medical device test organizations recognized by SFDA and the General Administration of Quality Supervision, Inspection and Quarantine (hereinafter referred to "medical device test organizations") will be separately announced.

Article 10

The medical device test organizations shall conduct registration test to the proposed products and issue test reports within the scope of test approved by SFDA and the General Administration of Quality Supervision, Inspection and Quarantine and in accordance with the product standards proposed by the manufacturers (including the applicable national standards, professional standards or the registered product standards formulated by the manufacturers).

For the medical devices that have not been included in the authorized scope of test by the medical device test organizations, the corresponding registration examination and approval authority shall designate a test organization with the necessary test capacity to test such medical devices.

The registration test of foreign medical devices shall be conducted in accordance with the Regulations on the Registration Test of Foreign Medical Devices.

Article 11

The tested products in a same registration unit shall be typical products that can represent the safety and effectiveness of the other products in this registration unit.

Article 12

The similar products manufactured by a same manufacturer with the same raw materials may not be subject to biological compatibility test during the biological evaluation of the products for re-registration, provided that the production technology and the expected purpose of the products remain unchanged.

The similar products manufactured by a same manufacturer with raw materials that have passed biological evaluation may not be subject to biological compatibility test during the biological evaluation of the products for registration, provided that the production technology and the expected purpose of the products remain unchanged or there are no new potential biological risks.

Article 13

Application for the registration of a Category II or III medical device may be exempted from registration test if this medical device can satisfy all the following conditions:

(1) The basic principle, main function, structure, material, material quality and expected purpose of the medical device under application for registration are same as those of the manufacturer's medical device that has already been approved for registration;

(2) The manufacturer has passed the examination of quality management standard for medical device manufacturing or has passed the certification of quality system for medical devices, and the manufacturer can provide a test report recognized by the original production condition examination authority;

(3) The medical device under application for registration has seen no changes related to safety and effectiveness as compared with the manufacturer's similar product that has already been approved for registration and has passed registration test, or though there are changes related to safety and effectiveness, the changed parts and the other parts of the product with subsequent changes related to safety and effectiveness have passed test by a medical device test organization;

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(4) The manufacturer's similar product that has already been approved for registration has seen no adverse events during the monitoring of the adverse events of medical devices in accordance with the relevant regulations;
(5) The manufacturer's similar product that has already been approved for registration has no record of nonconformities as determined by the (food) drug administration authority during selective examination for product quality supervision within one year; and
(6) If the medical device under application is a foreign medical device, the sale of the medical device has been approved by the medical device administration authority of the relevant foreign government.

Article 14

Application for the re-registration of a Category II or III medical device may be exempted from registration test if this medical device can satisfy all the following conditions:

(1) The basic principle, main function, structure, material, material quality and expected purpose of the medical device under application for registration are same as those of the manufacturer's medical device that has already been approved for registration;
(2) The manufacturer has passed the examination of quality management standard for medical device manufacturing or has passed the certification of quality system for medical devices, and the manufacturer can provide a test report recognized by the original production condition examination authority;
(3) The medical device under application for re-registration has seen no changes related to safety and effectiveness as compared with the originally registered product that has passed registration test, or though there are changes related to safety and effectiveness, the changed parts and the other parts of the product with subsequent changes related to safety and effectiveness have passed test by a medical device test organization;
(4) The medical device under application for re-registration has seen no adverse events during the monitoring of the adverse events of medical devices in accordance with the relevant regulations within the valid period of the original medical device registration certificate; and
(5) The originally registered medical device has no record of nonconformities as determined by the (food) drug administration authority during selective examination for product quality supervision within one year.

Article 15

An application for the postponement of test may be submitted for large medical devices that have obtained sales approval from the medical device administration authority of the relevant foreign government, have special requirements for the site of installation and are difficult to be tested, and supplementary test shall be conducted for such medical devices after a medical device registration certificate is obtained.

For a product that is under application for the postponement of test and has been approved for registration in accordance with the provision of the above paragraph, the manufacturer must complete registration test after the first medical device is imported and before the medical device is put into use. The medical device shall not be used until the end of satisfactory test.

Chapter 3. Clinical Trial of Medical Devices

Article 16

Clinical trial documents shall be submitted for application for the registration of Categories II and III medical devices.

Clinical trial documents shall be submitted in the manner specified in the Classified Regulations on Clinical Trial Documents for Medical Device Registration (see Appendix 12 of these Measures).

Article 17

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The Regulations on the Clinical Trial of Medical Devices shall be strictly followed for the medical devices whose clinical trial is conducted within the territory of China.

Article 18

The clinical trial documents for a medical device whose clinical trial is conducted within the territory of China shall include a contract for clinical trial, a plan of clinical trial and a report of clinical trial.

When it's necessary at the (food) drug administration authority's discretion, the (food) drug administration authority may ask the manufacturer to submit the instructions on clinical trial, the letter of consent to clinical trial and the original record of clinical trial.

Chapter 4. Application for and Examination and Approval of Medical Device Registration

Article 19

To apply for medical device registration, the applicant shall, according to the classification of medical devices, submit an application to the corresponding (food) drug administration authority in accordance with the provisions of Article 4 of these Measures. The applicant shall complete a written application for medical device registration and submit application documents in accordance with the corresponding requirements of Appendix 2, 3, 6, 8 or 9 of these Measures. The application documents shall be made in Chinese; and the application documents translated on the basis of foreign documents shall be accompanied by the original documents.

The manual of medical device submitted by the applicant shall conform to the Regulations on the Administration of the Manuals, Labels and Packing Marks of Medical Devices.

The applicant shall be responsible for the truthfulness of all the contents of the application documents submitted by it.

Article 20

After a (food) drug administration authority receives an application, this authority shall dispose of the application respectively according to the following circumstances:

(1) If the matter under application is beyond the limits of the (food) drug administration authority's functions and powers, the (food) drug administration authority shall immediately decide to reject the application and notify the applicant to apply to the relevant administration authority;

(2) If the application documents have mistakes that can be corrected on the spot, the (food) drug administration authority shall allow the applicant to correct the mistakes on the spot;

(3) If the application documents are incomplete or do not meet the requirements of formal examination, the (food) drug administration authority shall issue a notice for the supplementation or correction of documents to the applicant on the spot or within five working days to inform the applicant of all the contents that need to be supplemented or corrected once and for all; the application documents shall be deemed to have been accepted from the date of receipt if the (food) drug administration authority fails to inform the applicant of the contents that need supplementation or correction within the time limit; or

(4) The (food) drug administration authority shall accept the application documents if the application documents are complete and meet the requirements of formal examination or the applicant has submitted all the necessary supplementary or corrective documents in accordance with the requirements.

After accepting or rejecting an application for medical device registration, the (food) drug administration authority shall issue a notice of acceptance or a notice of rejection that is affixed with the (food) drug administration authority's special seal and dated.

Article 21

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After a (food) drug administration authority accepts an application for medical device registration, the (food) drug administration authority shall conduct substantive examination of the application and make a written decision on whether to register the medical device under application for medical device registration. If the application is proved conforming to the regulations through examination and registration is approved, the (food) drug administration authority shall issue a medical device registration certificate to the applicant within 10 working days after the written decision of approval is made. If the application is proved nonconforming to the regulations, the (food) drug administration authority shall make a written decision of no registration, indicate the reason and inform the applicant of its right to apply for administrative reconsideration or bring an administrative lawsuit according to law.

Article 22

The municipal level (food) drug administration authority of an administrative area with districts shall decide to approve registration or not within 30 working days after accepting an application.

The (food) drug administration authority of a province, autonomous region or municipality shall decide whether to approve registration or not within 60 working days after accepting an application.

SFDA shall decide whether to approve registration or not within 90 working days after accepting an application.

If test, expert evaluation or hearing is needed during the examination of an application for registration, the period of test, expert evaluation or hearing shall not be included in the time limit specified in this Article. The (food) drug administration authority shall notify the applicant of the said period needed by writing.

Article 23

Application for the registration of a foreign medical device that has obtained no foreign sales license for medical devices shall be examined in accordance with the requirements of technical examination for the registration of similar domestic products (See Appendixes 8 and 9 of these Measures for the documents that need to be submitted).

Article 24

During the technical examination of application documents for medical device registration, if the (food) drug administration authority finds that the manufacturer needs to supplement documents, the (food) drug administration authority shall issue a notice for the supplementation of documents once and for all.

The manufacturer shall fully supplement the necessary documents once and for all within 60 working days in accordance with the requirements of the notice. The period used for supplementing materials shall not be included in the time limit for substantive examination by the (food) drug administration authority. The examination shall be terminated if the manufacturer fails to submit supplementary documents within the specified time limit without justified reasons.

Article 25

In case the examination of application for registration is terminated, the manufacturer shall put forth no new application within six months after the termination.

Article 26

If the manufacturer has any objection to the content of the notice for supplementing documents, the manufacturer may put forth its written opinions to the (food) drug administration authority within the specified time limit, indicate the reason of objection and provide technical support documents. The (food) drug administration authority shall make a decision after examining the documents submitted by the manufacturer.

Article 27

The registration units of medical devices shall be divided according to technical structures, performance indexes and expected purposes in principle.

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Article 28

For a medical device that is registered as a component, the applicant shall indicate the name, model and specifications of the product or component recommended for use together with the medical device.

The procedures of complete device registration must be gone through for a complete device that is composed of components that have been approved for registration.

For a medical device that is registered as a complete device, a list of its major components shall be provided during application for registration. The complete device shall be registered anew after the performance and specifications of a major component are changed.

A medical device that is registered as a complete device may be exempted from separate registration provided that the medical device's components set forth in the column "Performance, Structure and Components of the Product" in the attached table of the registration certificate for the medical device can be separately sold on the condition of no changes in the form of assembly and the expected purpose.

Article 29

A (food) drug administration authority shall make public the necessary conditions, procedure and time limit for the corresponding medical device registration, a list of all the documents that need to be submitted and a demonstrative text of application in the administration authority's website and the medical device registration office.

Article 30

A (food) drug administration authority shall make public the process and the result of examination and approval during the examination of an application for medical device registration. The applicant and the interested party may present their opinions and defend themselves on the matters directly related to their major interests.

Article 31

SFDA shall regularly announce in its website the catalogue of the medical devices that have been approved for registration for public consultation.

Article 32

In case an application for medical device registration directly touches upon the relationship of major interests between the applicant and another party, the (food) drug administration authority shall tell the applicant and the interested party that they have the right to apply for hearing in accordance with laws, regulations and the other regulations of SFDA; during the examination of an application for medical device registration, the (food) drug administration authority shall publicly announce and hold a hearing of the major licensing matters that touch upon public interests at the (food) drug administration authority's discretion.

Chapter 5. Re-registration of Medical Devices

Article 33

If a manufacturer holding a medical device registration certificate needs to continuously sell or use the relevant medical device after the registration certificate expires, this manufacturer shall apply for re-registration within six months before the valid period of the medical device registration certificate expires. If the manufacturer fails to apply for re-registration within the time limit, the product shall be subject to registration test for re-registration.

Article 34

In case any of the following items in a medical device registration certificate is changed, the manufacturer shall apply for re-registration of the relevant product within 30 days from the date of change:

(1) Model;
(2) Address of manufacturing site;
(3) Product standard;

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(4) Performance, structure and components of the product; or
(5) Indications.

Article 35

If the category of product administration is changed within the valid period of the medical device registration certificate, the manufacturer shall, according to the category after change, apply to the corresponding (food) drug administration authority for re-registration within six months.

Article 36

To apply for the re-registration of a medical device, the applicant shall complete a written application for medical device registration and submit the application documents to the (food) drug administration authority in accordance with the corresponding requirements of Appendix 4, 5 or 7 of these Measures.

The relevant provisions of Chapter 4 of these Measures shall apply to the procedures of application acceptance, examination and approval for re-registration if such procedures are not separately specified in this Chapter.

Article 37

A medical device shall not be reregistered in any of the following circumstances:

(1) The applicant fails to meet the requirements specified by the (food) drug administration authority in accordance with SFDA's relevant regulations at the time of approval for sale;
(2) The medical device is obsolete as indicated by the result of reevaluation by SFDA; or
(3) The medical device registration certificate for the medical device has been cancelled in accordance with the Regulations on the Supervision and Administration of Medical Devices.

Chapter 6. Modification and Re-issuance of Medical Device Registration Certificate

Article 38

In case the items in a medical device registration certificate see any of the following changes, the manufacturer shall apply for the modification of medical device registration certificate within 30 days after the date of change:

(1) Change of the manufacturer's name but no change of the manufacturer's entity;
(2) Change of the manufacturer's registered address;
(3) Literal change of the address of manufacturing site;
(4) Literal change of product name or trade name;
(5) Literal change of model or specifications;
(6) Literal change of the name or code of product standard;
(7) Change of agent; or
(8) Change of after-sale service provider.

Article 39

To apply for the modification of a medical device registration certificate, the applicant shall complete an written application for the modification of medical device registration certificate and submit the relevant documents and explanations to the original registration examination and approval authority in accordance with the requirements of Appendix 10 of these Measures. The original registration examination and approval authority shall conduct formal examination of the application documents and inform the applicant of all the contents that need to be supplemented or corrected once and for all on the spot or within five working days. A notice of acceptance shall be issued to the applicant if the application documents meet the requirements.

Article 40

The original registration examination and approval authority shall decide by writing whether to approve the modification or not within 20 working days after accepting the application. If the modification is proved

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conforming to the regulations through examination, the original registration examination and approval authority shall issue a modified medical device registration certificate and nullify the original one. If the modification is proved nonconforming to the regulations through examination, the original registration examination and approval authority shall decide by writing to reject the application for modification, indicate the reason and tell the applicant that it has the right to apply for administrative reconsideration or bring an administrative lawsuit according to law.

The modified medical device registration certificate shall adopt the original serial number, and the word "Modified" in brackets shall be added at the end of the serial number.

The expiry date of the modified medical device registration certificate shall be same as that of the original certificate, and the certificate holder shall apply for re-registration upon expiry of the valid period.

Article 41

In case a manufacturer's medical device registration certificate is lost or damaged, the manufacturer shall apply to the original registration examination and approval authority for re-issuance by submitting the relevant documents and explanations in accordance with the requirements of Appendix 11 of these Measures.

Chapter 7. Supervision and Administration

Article 42

The (food) drug administration authorities in charge of examination and approval for medical device registration shall conduct examination and approval in accordance with the specified procedures and decide whether to approve registration or not. Those who approve registration in violation of the regulations shall undertake the relevant administrative liability.

Article 43

In case a local (food) drug administration authority at municipal level or above of an administrative area with districts implements medical device registration in violation of the provisions of these Measures, the (food) drug administration authority directly superior to the said local (food) drug administration authority shall order the latter to correct its fault within a particular time limit. If the local (food) drug administration authority fails to conduct correction within the time limit, the superior (food) drug administration authority may make a public announcement to directly cancel the relevant medical device registration certificate. The medical device whose medical device registration certificate has been cancelled shall be not continuously sold or used; and the local (food) drug administration authorities of county level or above shall be responsible to supervise the manufacturer to dispose of the products that have already been sold or used.

Article 44

The (food) drug administration authorities at provincial level or above shall conduct technical reevaluation to the medical devices on the market and, according to the result of technical reevaluation, decide to cancel the medical device registration certificates of the medical devices whose expected purposes cannot be reached or whose safety and effectiveness cannot be guaranteed. The (food) drug administration authorities shall publicly announce the medical devices whose certificates have been cancelled. The medical devices whose medical device registration certificate have been registered shall be not continuously sold or used; and the local (food) drug administration authorities at county level or above shall be responsible to supervise the manufacturers to dispose of the products that have already been sold or used.

Article 45

In any of the circumstances specified in Article 70 of the Administrative License Law of the People's Republic of China, the original registration examination and approval authority shall cancel the relevant medical device registration certificate according to law.

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Chapter 8. Legal Liability

Article 46

If a manufacturer provides false certification, document or sample in violation of the provisions of these Measures during application for medical device registration, or attempts to obtain a medical device registration certificate by such improper means as fraudulence and bribery, the registration examination and approval authority shall reject this manufacturer's application or refuse to register this manufacturer's product and give the manufacturer a warning, and shall not accept this manufacturer's application for medical device registration within one year; if the manufacturer has already obtained a medical device registration certificate, the registration examination and approval authority shall cancel the certificate, shall not accept the manufacturer's application for medical device registration within two years, and shall punish the manufacturer in accordance with the provisions of Article 40 of the Regulations on the Supervision and Administration of Medical Devices.

Article 47

If a manufacturer alters, sells, leases or lends its medical device registration certificate or illegally transfers its medical device registration certificate in other forms, the local (food) drug administration authority at county level or above shall order this manufacturer to correct its fault and concurrently impose on the manufacturer a fine less than RMB 30,000.

Article 48

If a manufacturer violates the provisions of Article 33, 34 or 35 of these Measures by selling medical device before going through the procedures of medical device re-registration according to law, or selling medical device inconsistent with that specified in the registration certificate, or selling medical device whose manual, label and packing mark are inconsistent with those specified in the registration certificate, the local (food) drug administration authority at county level or above shall punish this manufacturer in accordance with the penalty provisions of the Regulations on the Supervision and Administration of Medical Devices for the sale of medical devices without registration certificate.

Article 49

If a manufacturer violates the provisions of Article 38 of these Measures by failing to apply for the modification of its medical device registration certificate according to law, the local (food) drug administration authority at county level or above shall order this manufacturer to correct its fault within a particular time limit or give this manufacturer a warning; if the manufacturer fails to conduct correction within the time limit, the (food) drug administration authority may impose upon the manufacturer a fine more than RMB5,000 but less than RMB10,000.

Article 50

If the manufacturer of a product that shall be tested after application for registration in accordance with Article 15 of these Measures puts the product into use before registration test is completed in accordance with the regulations, SFDA shall cancel the medical device registration certificate, announce the cancellation and record the matter in the manufacturer's credit file.

If a product is proved unqualified through registration test, SFDA shall cancel the medical device registration certificate.

Chapter 9. Supplementary Provisions

Article 51

Manufacturers mean the organizations that put their products on the market in their own names and undertake final legal liability for their products.

Article 52

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Registered products mean the products that have been approved for registration and the products whose manuals, labels and packing marks are consistent with those specified in the corresponding medical device registration certificate.

Article 53

All the medical devices manufactured within the valid period of the corresponding medical device registration certificate shall be deemed products with certificates.

Article 54

SFDA shall separately formulate the regulations on the administration of the registration of external diagnosis reagents that are registered and administered as medical devices.

Article 55

SFDA shall be responsible to interpret these Measures.

Article 56

These Measures shall be implemented as of the date of promulgation, when the Measures on the Administration of Medical Device Registration promulgated by the State Drug Administration on Apr. 5, 2000 shall be abolished at the same time.

Appendixes:

1. Form of Medical Device Registration Record
2. Requirements on Application Documents for the Registration of Category I Domestic Medical Devices
3. Requirements on Application Documents for the Registration of Categories II and III Domestic Medical Devices
4. Requirements on Application Documents for the Re-registration of Category I Domestic Medical Devices
5. Requirements on Application Documents for the Re-registration of Categories II and III Domestic Medical Devices
6. Requirements on Application Documents for the Registration of Foreign Medical Devices
7. Requirements on Application Documents for the Re-registration of Foreign Medical Devices
8. Requirements on Application Documents for the First Registration of Category I Foreign Medical Devices without Foreign Sales License for Medical Devices
9. Requirements on Application Documents for the First Registration of Categories II and III Foreign Medical Devices without Foreign Sales License for Medical Devices
10. Requirements on Application Documents for the Modification of Medical Device Registration Certificate
11. Requirements on Application Documents for the Re-issuance of Medical Device Registration Certificate
12. Classified Regulations on Clinical Trial Documents for Medical Device Registration

(Appendixes 1-5, not need translation)

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Appendix 6:
Requirements on Application Documents for the Registration of Foreign Medical Devices

(1) An written application for the registration of foreign medical devices
(2) Qualification certificate of the medical device manufacturer
(3) Duplicate of the applicant's business license and the manufacturer's letter of authorization for registration by agent
(4) Certification document evidencing the relevant foreign government's medical device administration authority's approval or permit of the sale of the product on the market of that country (region) as medical device
(5) Applicable product standard

When a national standard or professional standard of China is adopted as the applicable standard for the product, the text of the national standard or professional standard of China shall be provided; the registered product standard shall be signed and sealed by the manufacturer or its representative office in China or by the standard drafting organization entrusted by the manufacturer. In the manufacturer's letter of authorization for entrusted standard drafting it shall be clearly indicated that "the manufacturer is responsible for product quality".

The manufacturer shall submit a statement of its product's compliance with China's national standard and professional standard, a statement of the manufacturer's liability for the quality of the product after the product is put on the market, and instructions on the classification of the models and specifications of the product.

In this Appendix, the words "seal and sign" mean sealing by the relevant organization, or signing by its legal representative or person in charge, or signing plus sealing (same as below when foreign medical devices are mentioned).

(6) Manual of medical device

The manual of a Category II or III medical device shall be signed and sealed by the manufacturer or its representative office in China; the manual of a Category I medical device may not be sealed and signed.

(7) Test report for product registration issued by a medical device test organization (applicable to Categories II and III medical devices)

For the medical devices that are subject to clinical trial, a test report issued by a medical device test organization within half a year before the beginning of clinical trial shall be submitted; for the medical devices that are not subject to clinical trial, a test report issued by a medical device test organization within one year before the application for registration is accepted shall be submitted.

When the provisions of Articles 11, 12, 13 and 14 of these Measures are applicable, the corresponding explanatory documents shall be provided.

When the provisions of Article 15 of these Measures are applicable, the manufacturer shall put forth an application for the postponement of test. In the application the manufacturer shall undertake to complete registration test before the first medical device is put into use within the territory of China.

(8) Documents about the clinical trial of medical device (see Appendix 12 of these Measures for the particular manner of submission)
(9) Product quality guarantee issued by the manufacturer

The manufacturer shall guarantee that the quality of the product registered for sale and use in China is completely consistent with that of the same product that has been approved for sale by the medical device administration authority of the relevant foreign government.

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(10) The manufacturer's letter of authorization for its agent in China, and the agent's letter of commitment, business license or organization registration certificate

The content of commitment indicated in the agent's letter of commitment shall be consistent with the matter entrusted by the manufacturer's letter of authorization. In the letter of commitment, the agent shall also undertake to report the adverse events of medical devices and be responsible for contact with the (food) drug administration authority.

(11) Letter of authorization for the designated after-sale service provider in China, the authorized service provider's letter of commitment and qualification certificate

The letter of authorization for after-sale service shall be issued by the manufacturer and indicate the name of the product. In case of multi-level authorization, the authorizer at each level shall provide a document of approval by the manufacturer.

The content of commitment indicated in the after-sale service provider's letter of commitment shall be consistent with the matter entrusted by the letter of authorization.

The after-sale service provider's qualification certificate shall be its business license (the scope of business of the after-sale service provider shall cover the corresponding item of technical service) or the registration certificate of the manufacturer's organ in China.

(12) The manufacturer's statement to guarantee the truthfulness of the documents submitted

The statement shall be issued by the manufacturer or its representative office in China. The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability.

All the above documents shall have Chinese texts. The certification documents specified in Items (2) and (4) of this Appendix may be copies, but the copies shall be signed and sealed by the original issuing authority or notarized by the local notary office. Unless otherwise specified in these Measures, the other documents required by this Appendix shall be originals signed and sealed by the manufacturer or its office in China.

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Appendix 7:
Requirements on Application Documents for the Re-registration of Foreign Medical Devices

(1) A written application for the registration of foreign medical devices
(2) Qualification certificate of the medical device manufacturer
(3) The original medical device registration certificate

In the circumstance specified in Article 33 of these Measures, a copy of the original medical device registration certificate shall be submitted. In the circumstances specified in Articles 34 and 35 of these Measures, the original medical device registration certificate shall be submitted.

(4) Certification document evidencing the relevant foreign government's medical device administration authority's approval or permit of sale of the product on the market of that country (region) as medical device.
(5) Applicable product standard and instructions

When a national standard or professional standard of China is adopted as the applicable standard for the product, the text of the national standard or professional standard of China shall be provided; the registered product standard shall be signed and sealed by the manufacturer or its representative office in China or by the standard drafting organization entrusted by the manufacturer. In the manufacturer's letter of authorization for entrusted standard drafting it shall be clearly indicated that "the manufacturer is responsible for product quality".

The manufacturer shall submit a statement of its product's compliance with China's national standard and professional standard, a statement of the manufacturer's liability for the quality of the product after the product is put on the market, and instructions on the classification of the models and specifications of the product.

(6) Manual of medical device

The manual of Category II or III medical devices shall be signed and sealed by the manufacturer or its representative office in China; the manual of Category I medical devices may not be sealed and signed.

(7) Test report for product registration issued by a medical device test organization (applicable to Categories II and III medical devices)

For the medical devices that are subject to clinical trial, a test report issued by a medical device test organization within half a year before the beginning of clinical trial shall be submitted; for the medical devices that are not subject to clinical trial, a test report issued by a medical device test organization within one year before the application for registration is accepted shall be submitted.

When the provisions of Articles 11, 12, 13 and 14 of these Measures are applicable, the corresponding explanatory documents shall be provided.

When the provisions of Paragraph (2) of Article 10 of the Regulations on the Registration Test of Imported Medical Devices are applicable, the corresponding report of recognition shall be submitted.

(8) Product quality tracing report

The quality tracing report issued by the manufacturer's agent after the product is used in the medical institutions of China shall include a description of the monitoring of the adverse events of medical devices.

(9) Product quality guarantee issued by the manufacturer

The manufacturer shall guarantee that the quality of the product registered for sale and use in China is completely consistent with that of the same product that has been approved for sale by the medical device administration authority of the relevant foreign government.

(10) The manufacturer's letter of authorization for its agent in China, and the agent's letter of commitment, business license or organization registration certificate

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The content of commitment indicated in the agent's letter of commitment shall be consistent with the matter entrusted by the manufacturer's letter of authorization. In the letter of commitment, the agent shall also undertake to report the adverse events of medical devices and be responsible for contact with the (food) drug administration authority.

(11)Letter of authorization for the designated after-sale service provider in China, the authorized service provider's letter of commitment and qualification certificate

The letter of authorization for after-sale service shall be issued by the manufacturer and indicate the name of the product. In case of multi-level authorization, the authorizer at each level shall provide a document of approval by the manufacturer.

The content of commitment indicated in the after-sale service provider's letter of commitment shall be consistent with the matter entrusted by the letter of authorization.

The after-sale service provider's qualification certificate shall be its business license (the scope of business of the after-sale service provider shall cover the corresponding item of technical service) or the registration certificate of the manufacturer's organ in China.

(12)In the circumstance specified in Article 34 of these Measures, a corresponding description of the circumstance and a certification document shall be provided

(13)The manufacturer's statement to guarantee the truthfulness of the documents submitted

The statement shall be issued by the manufacturer or its representative office in China. The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability.

All the above documents shall have Chinese texts. The certification documents specified in Items (2) and (4) of this Appendix may be copies, but the copies shall be signed and sealed by the original issuing authority or notarized by the local notary office. Unless otherwise specified in these Measures, the other documents required by this Appendix shall be originals signed and sealed by the manufacturer or its office in China.

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Appendix 8:

Requirements on Application Documents for the First Registration of Category I Foreign Medical Devices without Foreign Sales License for Medical Devices

(1) A written application for the registration of foreign medical devices
(2) Qualification certificate of the medical device manufacturer
(3) Applicable product standard and instructions

When a national standard or professional standard of China is adopted as the applicable standard for the product, the text of the national standard or professional standard of China shall be provided; the registered product standard shall be signed and sealed by the manufacturer or its representative office in China or by the standard drafting organization entrusted by the manufacturer. In the manufacturer's letter of authorization for entrusted standard drafting it shall be clearly indicated that "the manufacturer is responsible for product quality".

The manufacturer shall submit a statement of its product's compliance with China's national standard and professional standard, a statement of the manufacturer's liability for the quality of the product after the product is put on the market, and instructions on the classification of the models and specifications of the product.

(4) Full performance test report for the product
(5) A description of the manufacturer's existing resources and conditions for manufacturing the product and the manufacturer's quality management capability (including the means of test)
(6) Manual of medical device (no signing and sealing are required)
(7) The manufacturer's letter of authorization for its agent in China, and the agent's letter of commitment, business license or organization registration certificate

The content of commitment indicated in the agent's letter of commitment shall be consistent with the matter entrusted by the manufacturer's letter of authorization. In the letter of commitment, the agent shall also undertake to report the adverse events of medical devices and be responsible for contact with the (food) drug administration authority.

(8) Letter of authorization for the designated after-sale service provider in China, the authorized service provider's letter of commitment and qualification certificate

The letter of authorization for after-sale service shall be issued by the manufacturer and indicate the name of the product. In case of multi-level authorization, the authorizer at each level shall provide a document of approval by the manufacturer.

The content of commitment indicated in the after-sale service provider's letter of commitment shall be consistent with the matter entrusted by the letter of authorization.

The after-sale service provider's qualification certificate shall be its business license (the scope of business of the after-sale service provider shall cover the corresponding item of technical service) or the registration certificate of the manufacturer's organ in China.

(9) The manufacturer's statement to guarantee the truthfulness of the documents submitted

The statement shall be issued by the manufacturer or its representative office in China. The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability.

All the above documents shall have Chinese texts. The certification document specified in Item (2) of this Appendix may be a copy, but the copy shall be signed and sealed by the original issuing authority or notarized by the local notary office. Unless otherwise specified in these Measures, the other documents required by this Appendix shall be originals signed and sealed by the manufacturer or its office in China.

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Appendix 9:
Requirements on Application Documents for the First Registration of Categories II and III Foreign Medical Devices without Foreign Sales License for Medical Devices

(1) A written application for the registration of foreign medical devices
(2) Qualification certificate of the medical device manufacturer
(3) Technical report for the product

The report shall at least include technical indexes or the grounds for determining the performance requirements.

(4) Safety risk analysis report

The report shall be prepared in accordance with the requirements of the standard YY0316 Analysis of the Risks of Medical Devices. The report shall include the analysis of energy hazards, biological hazards, environmental hazards, the hazards related to the use of the product and the hazards that may arise out of functional failure, improper maintenance and aging, as well as the corresponding preventive measures.

(5) Applicable product standard and instructions

When a national standard or professional standard of China is adopted as the applicable standard for the product, the text of the national standard or professional standard of China shall be provided; the registered product standard shall be signed and sealed by the manufacturer or its representative office in China or by the standard drafting organization entrusted by the manufacturer. In the manufacturer's letter of authorization for entrusted standard drafting it shall be clearly indicated that "the manufacturer is responsible for product quality".

The manufacturer shall submit a statement of its product's compliance with China's national standard and professional standard, a statement of the manufacturer's liability for the quality of the product after the product is put on the market, and instructions on the classification of the models and specifications of the product.

(6) Report of product performance test by the manufacturer

The items of product performance test by the manufacturer shall be the items of product test specified in the registered product standard, and the report shall be signed by the chief inspector or the person in charge of inspection and the examiner. When a national standard or professional standard is implemented, the manufacturer shall supplement the items of factory test determined by the manufacturer itself.

(7) Test report for product registration issued by a medical device test organization

For the medical devices that are subject to clinical trial, a test report issued by a medical device test organization within half a year before the beginning of clinical trial shall be submitted; for the medical devices that are not subject to clinical trial, a test report issued by a medical device test organization within one year before the application for registration is accepted shall be submitted.

When the provisions of Articles 11, 12, 13 and 14 of these Measures are applicable, the corresponding explanatory documents shall be provided.

(8) Documents about the clinical trial of medical device (see Appendix 12 of these Measures for the manner of submission)
(9) Manual of medical device (shall be signed by the manufacturer or its representative office in China)
(10) Effective certificate of the examination (certification) of the quality system for product manufacturing
(11) The manufacturer's letter of authorization for its agent in China, and the agent's letter of commitment, business license or organization registration certificate

The content of commitment indicated in the agent's letter of commitment shall be consistent with the matter entrusted by the manufacturer's letter of authorization. In the letter of commitment, the agent shall also

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undertake to report the adverse events of medical devices and be responsible for contact with the (food) drug administration authority.

(12)Letter of authorization for the designated after-sale service provider in China, the authorized service provider's letter of commitment and qualification certificate

The letter of authorization for after-sale service shall be issued by the manufacturer and indicate the name of the product. In case of multi-level authorization, the authorizer at each level shall provide a document of approval by the manufacturer.

The content of commitment indicated in the after-sale service provider's letter of commitment shall be consistent with the matter entrusted by the letter of authorization.

The after-sale service provider's qualification certificate shall be its business license (the scope of business of the after-sale service provider shall cover the corresponding item of technical service) or the registration certificate of the manufacturer's organ in China.

(13)The manufacturer's statement to guarantee the truthfulness of the documents submitted

The statement shall be issued by the manufacturer or its representative office in China. The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability.

All the above documents shall have Chinese texts. The certification document specified in Item (2) of this Appendix may be a copy, but the copy shall be signed and sealed by the original issuing authority or notarized by the local notary office. Unless otherwise specified in these Measures, the other documents required by this Appendix shall be originals signed and sealed by the manufacturer or its office in China.

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Appendix 10:
Requirements on Application Documents for the Modification of Medical Device Registration Certificate

1. Requirements on application documents for the change of enterprise name:
   (1) The original medical device registration certificate (a copy shall be submitted when an application for modification is submitted; the original certificate shall be handed back when the modified medical device registration certificate is received);
   (2) The new license for the manufacturer (applicable to Categories II and III domestic medical devices);
   (3) The new business license (applicable to domestic medical devices);
   (4) The manufacturer's new legal qualification certificate (applicable to foreign medical devices);
   (5) The new product standard (applicable to the change of the main content of standard);
   (6) The manufacturer's explanation of the change and the relevant certification;
   (7) The manufacturer's statement to guarantee the truthfulness of the documents submitted:

The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability. For the modification of a registration certificate for foreign medical devices, the statement shall be issued by the manufacturer or its representative office in China.

2. Requirements on application documents for the literal change of product name or trade name, the literal change of the product's model or specifications and the literal change of the name or code of product standard:
   (1) The original medical device registration certificate (a copy shall be submitted when an application for modification is submitted; the original certificate shall be handed back when the modified medical device registration certificate is received);
   (2) The new product standard;
   (3) The manual of medical device
   (4) The manufacturer's explanation of the change and the relevant certification;
   (5) The manufacturer's statement to guarantee the truthfulness of the documents submitted:

The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability. For the modification of a registration certificate for foreign medical devices, the statement shall be issued by the manufacturer or its representative office in China.

3. Requirements on application documents for the change of the manufacturer's registered address and the literal change of the address of manufacturing site:
   (1) The original medical device registration certificate (a copy shall be submitted when an application for modification is submitted; the original certificate shall be handed back when the modified medical device registration certificate is received);
   (2) The new license for the manufacturer (applicable to Categories II and III domestic medical devices);
   (3) The new business license (applicable to domestic medical devices);
   (4) The manufacturer's explanation of the change and the relevant certification;
   (5) The manufacturer's statement about the change of address (applicable to foreign medical devices);
   (6) The manufacturer's statement to guarantee the truthfulness of the documents submitted:

The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability. For the modification of a registration certificate for foreign medical devices, the statement shall be issued by the manufacturer or its representative office in China.

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4. Requirements on application documents for the change of after-sale service provider in the certificate of registration for foreign medical devices:
   (1) The original medical device registration certificate (a copy shall be submitted when an application for modification is submitted; the original certificate shall be handed back when the modified medical device registration certificate is received);
   (2) The manufacturer's statement about the change or addition of after-sale service provider;
   (3) The manufacturer's letter of authorization for the changed or new after-sale service provider;
   (4) The manufacturer's arrangement of and commitment for after-sale service for the products that have already been sold;
   (5) The business license or organization registration certificate of the changed or new after-sale service provider;
   (6) The changed or new after-sale service provider's letter of commitment to be responsible for after-sale service;
   (7) The manufacturer's statement to guarantee the truthfulness of the documents submitted

The statement shall be issued by the manufacturer or its representative office in China. The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability.

5. Requirements on application documents for the change of agent in the certificate of registration for foreign medical devices
   (1) The original medical device registration certificate (a copy shall be submitted when an application for modification is submitted; the original certificate shall be handed back when the modified medical device registration certificate is received);
   (2) The manufacturer's statement about the change of agent;
   (3) The manufacturer's letter of authorization for the changed agent;
   (4) The agent's business license or organization registration certificate;
   (5) The agent's commitment to accept the authorization and undertake the corresponding liability;
   (6) The manufacturer's statement to guarantee the truthfulness of the documents submitted

The statement shall be issued by the manufacturer or its representative office in China. The statement shall contain a list of the documents submitted and the manufacturer's promise to undertake legal liability.

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Appendix 11:

Requirements on Application Documents for the Re-issuance of Medical Device Registration Certificate

(1) Explanation of the reason of application for the re-issuance of medical device registration certificate;
(2) The applicant's qualification certificate;
(3) Copies of the medical device registration certificate and its appendixes;
(4) The manufacturer's statement to guarantee the truthfulness of the documents submitted

The statement shall contain a list of the documents submitted and the manufacturer's commitment to undertake legal liability. For the re-issuance of a certificate of registration for foreign medical devices, the statement shall be issued by the manufacturer or its representative office in China.

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Appendix 12:
Classified Regulations on Clinical Trial Documents for Medical Device Registration

Category of product	Basic circumstances	Existing conditions	Submission of clinical trial documents
Category III products	1. In all circumstances	The medical device administration authority of the relevant foreign government has not approved the sale of the product in that country (region).	Documents about clinical trial in China shall be submitted.
Category III implantation products	1. The manufacturer has no product sold on the Chinese market.	For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region).	Documents about clinical trial in China shall be submitted.
	2. The manufacturer already has product(s) sold on the Chinese market	A. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The manufacturer's quality system has been examined by Chinese government, but the quality system does not cover the product under application.	For a domestic product, the corresponding clinical trial documents specified shall be submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product shall be submitted, and the documents shall be recognized by the expert group organized by Chinese government.
		B. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The quality system approved by Chinese government covers the product	For a domestic product, the corresponding clinical trial documents specified shall be submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product

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		under application and is still valid; 3. The manufacturer's other product(s) sold on the Chinese market has a record of no complaint in four or more years. Note: Item A shall be applicable if there is any record of complaint.	shall be submitted.
	3. The manufacturer already has product(s) sold on the Chinese market, and the product under application is of a same type but different models with the registered product(s).	A. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The quality system approved by Chinese government does not cover the product under application.	For a domestic product, the corresponding clinical trial documents specified shall be submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product shall be submitted, and the documents shall be recognized by the expert group organized by Chinese government.
		B. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The quality system approved by Chinese government covers the model under application and is still valid; 3. The manufacturer's similar product(s) sold on the Chinese market has a record of no complaint in four or more years. Note: Item A shall be applicable if there is any record of complaint.	For a domestic product, the clinical trial documents prepared at the time when the manufacturer's similar product(s) is registered for sale shall be submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of similar product(s) shall be submitted.
	4. The manufacturer already has product(s) sold on the Chinese	A. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the	For a domestic product, the corresponding clinical trial documents specified shall be submitted; for a foreign product, the clinical trial documents

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	market, and the product under application is of a same model but different specifications with the registered product (s).	relevant foreign government has approved the sale of the product in that country (region); 2. The quality system approved by Chinese government does not cover the product under application.	prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product shall be submitted, and the documents shall be recognized by the expert group organized by Chinese government.
		B. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The quality system approved by Chinese government covers the product under application and is still valid; 3. The manufacturer's similar product(s) sold on the Chinese market has a record of no complaint in four or more years. Note: Item A shall be applicable if there is any record of complaint.	For a domestic product, the clinical trial documents prepared at the time when the manufacturer's similar product(s) is registered for sale shall be submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of similar product(s) shall be submitted.
Other Category III products	1. The manufacturer has no product sold on the Chinese market.	For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region).	For a domestic product, the corresponding clinical trial documents specified shall be submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product shall be submitted, and the documents shall be recognized by the expert group organized by Chinese government.
	2. The manufacturer already has	A. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a	For a domestic product, the corresponding clinical trial documents specified shall be

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	product(s) sold on the Chinese market, but the product under application has never been sold on the Chinese market.	foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The product is a therapeutic device that uses ultrasound, microwave, laser, X-ray, gamma ray or other radioactive particulate as therapeutic source.	submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product shall be submitted, and the documents shall be recognized by the expert group organized by Chinese government.
		B. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The product is a diagnostic product or a therapeutic device that does not use ultrasound, microwave, laser, X-ray, gamma ray or other radioactive particulate as therapeutic source. 3. The manufacturer's other product(s) sold on the Chinese market has a record of no complaint in four or more years. Note: Item A shall be applicable if there is any record of complaint.	For a domestic product, the corresponding clinical trial documents specified shall be submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product shall be submitted.
	3. The manufacturer already has product(s) sold on the Chinese market, and the product under application is of a same type as the registered product(s).	A. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The product is a therapeutic device that uses ultrasound, microwave, laser, X-ray, gamma ray or other radioactive particulate as therapeutic source.	For a domestic product, the corresponding clinical trial documents specified shall be submitted; for a foreign product, the clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product shall be submitted, and the documents shall be recognized by the expert group organized by

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			Chinese government.
		B. All the following conditions: 1. For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region); 2. The manufacturer's similar product(s) sold on the Chinese market has a record of no complaint in four or more years. Note: Item A shall be applicable if there is any record of complaint.	The clinical trial documents prepared at the time when the manufacturer's similar product(s) is registered for sale shall be submitted.
Category II products	1. In all circumstances	For a domestic product, the sale of the product has not been approved; for a foreign product, the medical device administration authority of the relevant foreign government has not approved the sale of the product in that country (region).	The documents about clinical trial in China shall be submitted.
	2. The product has never been sold on the Chinese market	A. The medical device administration authority of the relevant foreign government has approved the sale of the product in that country (region).	The clinical trial documents prepared at the time when the medical device administration authority of the relevant foreign government approves the registration and sale of the product shall be submitted.
		B. For a domestic product, Chinese government has approved the sale of similar products in China.	The clinical trial documents for the similar product(s) and a statement of comparison shall be submitted.
		C. The product is a medical device used for test or diagnosis in accordance with the relevant national standard or professional standard.	No clinical trial documents are required.

Notes:

1. "Similar products" mean the products that are same in basic principle, main function, structure, material, material quality and expected purpose. The catalogue of similar products shall be formulated and promulgated by SFDA.

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2. “Products of a same model” mean the products whose basic principles, major functions and structures are same and whose supplementary functions have same principles and same structures.
3. “Products of same specifications” mean the products whose basic principles, major functions and structures are same, whose supplementary functions have same principles and same structures, and whose major performance parameters, indexes and physical dimensions are also same.
4. “Complaint” means an adverse event that has been heard by SFDA or the (food) drug administration authority a province, autonomous region or municipality and has arisen out of the quality defects of product as determined by technical means.
5. When documents about clinical trial in China need to be submitted, the manufacturer shall, in accordance with the Regulations on the Clinical Trial of Medical Devices, provide the documents about clinical trial in two or more clinical trial bases.