

Provisions for Medical Device Registration (Order of China Food and Drug Administration No. 4)

Issued on July 30, 2014

Order of China Food and Drug Administration

No. 4

The Provisions for Medical Device Registration that were adopted at the meeting of China Food and Drug Administration on June 27, 2014, is hereby promulgated and shall come into force as of October 1, 2014.

Minister Zhang Yong
July 30, 2014

Provisions for Medical Device Registration

Chapter I General Provision

Article 1 To normalize the administration over the registration and record of the medical device and ensure the safe and effectiveness thereof, The Administrative Measures for the Medical Device Registration (hereinafter referred to the "Measures") are hereby enacted according to the *Regulations for the Supervision and Administration of Medical Devices*.

Article 2 All medical device sold and used within the territory of the People's Republic of China shall be subject to application for registration or filing.

Article 3 Medical device registration is a process under which the food and drug regulatory authority carries out the systematic review towards the safety, validation study and the related result of the medical device of the applicant of medical device registration which is planned to be on the market according to the legal procedures to decide whether such application could be approved.

Medical device filing is a process where the person who put the medical device for record submits the filing materials to the food and drug regulatory authority and the food and drug regulatory authority keeps the submitted materials in the archives for future reference.

Article 4 Medical device registration and filing shall be subject to the principles of openness, justice and equity.

Article 5 The Class I medical device shall be subject to the record management. The Class II and Class III medical device shall be subject to the registration management.

For the filing of the Class I domestic medical device, the person who files for record shall submit the filing materials to the food and drug regulatory authority at city level of a district city.

The food and drug regulatory authority at each province, autonomous region and municipality directly under the Central Government shall review the Class II domestic medical device and issue the medical device registration certificate upon the approval.

China Food and Drug Administration shall review the Class III domestic medical device and issue the medical device registration certificate upon the approval.

For the filing of the Class I imported medical device, the applicant shall submit the filing materials to China Food and Drug Administration.

China Food and Drug Administration shall review the Class II and Class III imported medical device and issue the medical device registration certificate upon the approval.

The registration and filing for the imported medical device shall apply mutatis mutandis to those for the medical device of Hong Kong, Macao and Taiwan regions.

Article 6 The registrant and the person who files for record for medical device releasing the product to market in his/her own name shall bear the legal liability for such product.

Article 7 The food and drug regulatory authority shall timely publish the information related to the

registration and filing of the medical device according to the law. The applicant may refer to the examination and approval progress and the public the approval results.

Article 8 The State encourages the research and innovation of medical device and carries out a special examination and approval towards the innovative medical device to promote the popularization and application of new technologies of medical device and the development of medical device industry.

Chapter II Basic Requirements

Article 9 The applicant and the person who files for record of medical device registration and shall establish the quality management system related to the product development and production and maintain the effective operation of such system.

As for the registration application of the domestic medical device which are approved according to the special approval process of innovative medical device, if the manufacturing of the sample is entrusted to other enterprises, such enterprises shall have corresponding production range; as for the registration application of the domestic medical device which are not approved according to the special approval process of innovative medical device, the sample production of such devices shall not be entrusted to other enterprises.

Article 10 The personnel transacting the registration or the filing of medical device shall have the related specialized knowledge and be familiar with the laws, regulations, rules and technical requirements of medical device registration or filing management.

Article 11 The applicant or the person who files for record shall carry out the registration application or filing according to the basic requirements for the safety and effectiveness of the medical device and ensure the normalization of design cycle and the authenticity, integrity and traceability of all data.

Article 12 The materials of registration application or filing shall be made in Chinese. Should such materials be translated from foreign language, the originals shall be also provided. Should the document literature that is not published be quoted, the documentary evidence proving the licensed use as approved by the owner of such document literature shall be provided.

The applicant and the person who files for record shall be responsible for the authenticity of the materials.

Article 13 The imported medical device applied for registration or filing shall have been proved for market at the country (region) of the registration place or production address of the applicant or the person who files for record.

Should the product be not managed by the country (region) of the registration place or production address of the applicant or the person who files for record as medical device, the applicant or the person who files for record shall offer the related documentary documents, including the documentation of authorized sale of the product at the country (region) of the registration place or production address.

Article 14 The overseas applicant or person who files for record shall cooperate with the overseas applicant or person who files for record to carry out the related work through its representative organization established within the territory of China or the business entity within the territory of China appointed by it.

Besides the transaction of medical device registration or filing, the agency shall also undertake the following responsibilities:

(I) Contact with the related food and drug regulatory authorities, the overseas applicant or the person who files for record;

(II) Truthfully and accurately provide the applicant or the person who files for record with the related laws and regulations as well as technical requirements;

(III) Collect the post-marketing medical device administration events, feedback such information to the overseas registrant or the person who files for record and report to the related food and drug

regulatory authorities;

(IV) Coordinate the product recall after the marketing of medical device and report to the related food and drug regulatory authorities; and

(V) Other several liability with respect to the quality products and after-sale services.

Chapter III Product Technical Requirements and Registration Inspection

Article 15 The applicant or the person who files for record shall prepare the product technical requirements for the medical device to be registered or filed. The product technical requirements for the Class I medical device shall be submitted by the person who files for record to the food and drug regulatory authorities at the filing. The product technical requirements for the Class II and III medical device shall be approved along with the registration by the food and drug regulatory authorities.

The product technical requirements mainly include the performance index and the inspection method of the finished medical device, among which the performance index refers to the product functionality and security index as well as other indexes related to the quality control that can be objectively determined.

Medical device listed at China shall accord with the technical requirements of the registered or filed product.

Article 16 The registration application for the Class II and III medical device shall be subject to registration inspection. The medical device inspection body shall carry out the registration inspection towards the related product according to the product technical requirements.

The production of the sample of registration inspection shall accord with the related requirements of the medical device quality management system; the product passing the registration inspection may be subject to clinical test or registration application.

As for the filing of Class I medical device, the person who files for record may submit the product self-inspection report.

Article 17 As for the registration inspection, the applicant shall provide the inspection body with the related technical materials, the sample for registration inspection and the product technical requirement necessary for the registration inspection.

Article 18 The medical device inspection body shall have the qualifications for medical device inspection, inspect within the scope of inspection and carry out the pre-assessment towards the product requirements submitted by the applicant. The pre-assessment opinions shall be provided to the applicant along with the registration inspection report.

The medical device that are not included in the inspection scope of the medical device inspection body shall be inspected by the eligible inspection body appointed by the relevant registration review organization.

Article 19 The safety and validity of an inspected product in a registration unit can represent the safety and validity of other products in the same unit.

Chapter IV Clinical Assessment

Article 20 The clinical assessment of medical device is a process where the applicant or the person who files for record confirms the conformity of the product with the operating requirement or the range of application through information such as clinical literatures, clinical empirical data and clinical test.

Article 21 Clinical assessment document refers to the document formed through the clinical assessment carried out by the applicant or the person who files for record.

Where it is necessary to carry out the clinical test, the clinical assessment document submitted shall include the clinical test scheme and clinical test report.

Article 22 The clinical test is not required for Class I medical device when the filing thereof is handled. The registration application of Class II and III medical device shall be subject to clinical test.

The clinical test may be exempted under any of the following circumstances:

(I) The medical device with clear working mechanism, determined design and mature manufacturing process; the clinical application of medical device of the same variety on sale has been conducted for years and there is no record of serious adverse event for such kind of medical device, and the general application has not been changed;

(II) The medical device can be proven to be safe and effective by non-clinical assessment;

(III) The safety and validity of the medical device can be proven through the analysis evaluation of the data obtained through the clinical test of the clinical use of other medical device of the same variety.

The list of the medical device free from the clinical test shall be prepared, adjusted and published by China Food and Drug Administration. If the safety and validity of the products which are not included in the list of the medical device that are free from the clinical test can be confirmed by the analysis evaluation of the data obtained through the clinical test of the clinical use of other medical device of the same variety, the applicant may state such circumstance during the registration application and submit the related documentation.

Article 23 The clinical test of medical device shall be conducted by the qualified clinical test organization according to the requirements of quality management practice of medical device clinical test. The production of clinical test sample shall accord with the related requirements of quality management system for medical device.

Article 24 If the human body will take a higher risk during the clinical test of Class III medical device, such test shall be approved by China Food and Drug Administration. The list of the Class III medical device subject to the clinical test shall be prepared, adjusted and published by China Food and Drug Administration.

Article 25 Clinical test assessment is a process where China Food and Drug Administration carries out the comprehensive analysis towards the degree of risk, the clinical test scheme, the clinical benefits and the risk contrastive analysis report of the medical device to be subject to clinical test according to the application of the applicant so as to decide whether to carry out such clinical test.

Article 26 Where the approval of the medical device clinical test is necessary, the applicant shall submit the declaration materials to China Food and Drug Administration according to the related requirements.

Article 27 China Food and Drug Administration shall deliver the declaration materials to the technical review organization of medical device within 3 working days after its acceptance of the application for approval of the medical device clinical test.

The technical review organization shall complete the technical review within 40 working days. China Food and Drug Administration shall make a decision within 20 working days after the completion of the technical review. Should the clinical test be approved, China Food and Drug Administration shall issue the approval letter for medical device clinical test; otherwise, the related reasons shall be made clear in writing.

Article 28 In the event that the applicant is required to supplement and correct the application materials during the technical review process, the technical review organization shall inform all the

necessary materials at one stroke. The applicant shall offer the supplementary information on a lump-sum basis within 1 year according to the requirement of the notice thereof. The technical review organization shall complete the technical review within 40 working days from its receipt of the supplementary information. The time for supplementing materials by the applicant is not counted in the time limit of review.

In the event that the applicant fails to submit supplementary materials within the required time limit, the technical review organization shall terminate the technical review and offer a proposal of rejecting the test, which is examined and approved by China Food and Drug Administration prior to its decision of rejecting the test.

Article 29 China Food and Drug Administration shall repeal the issued approval documents for the clinical test of medical device under any of the following circumstances:

- (I) The declaration materials of clinical test are false;
- (II) The ethicality and scientificity of the clinical test which has been approved has been proven to be problematic by the latest research; and
- (III) Other circumstances where the approval documents shall be repealed.

Article 30 The clinical test of medical device shall be conducted within 3 years after the approval; should such test fail to be carried out within the specified period, the original approval documents shall be terminated automatically; where the clinical test is still required, the applicant shall apply for the same again.

Chapter V Product Registration

Article 31 To apply for medical device registration, the applicant shall submit the application materials to the food and drug regulatory authority in accordance with the relevant requirements.

Article 32 The food and drug regulatory authorities conduct formal examination for the application materials after receiving application and respectively handle it according to the following situations:

- (I) Where items of application fall within the terms of reference of the authorities and the application materials are complete and conform to the requirements of formal examination, the application shall be accepted;
- (II) Where there are some mistakes that are correctable on the spot in the application materials, the applicant shall be permitted to correct them on the spot;
- (III) Where the application materials are not complete or do not conform to the requirements of formal examination, the applicant shall be informed of all necessary supplementary materials at one time within 5 working days; the materials receiving date shall be deemed as the acceptance date in the case of failure to inform the same within the specified time limit; and
- (IV) Where items of application fall out of the terms of reference of the authorities, the applicant shall be informed promptly that the application is rejected.

The food and drug regulatory authorities shall provide a dated acceptance or rejection notice with the special seal of the authorities regarding whether the application for medical device registration is accepted or not.

Article 33 The food and drug regulatory authorities who accept the registration application shall deliver the application materials to the technical review organization within 3 working days after the receipt.

The technical review organization shall complete the technical review of Class II medical device registration within 60 working days, as well as that of Class III medical device registration within 90 working days.

In the event that external experts are needed and the medical device combination products need jointly reviewing with the drug review organization, the time will not be counted in the above time limit and the technical review organization shall inform the applicant of the required time in writing.

Article 34 The food and drug regulatory authorities may consult the original research materials and organize examination against the quality management system related to the products research and production by the applicant when organizing the technical review of products.

The food and drug regulatory authorities of provinces, autonomous regions and municipalities directly under the Central Government conduct the quality management system examination of domestic Class II and Class III medical device registration. With respect to the quality management system examination of domestic Class III medical device registration, the technical review organization of China Food and Drug Administration shall inform the corresponding food and drug regulatory authorities of provinces, autonomous regions and municipalities directly under the Central Government to conduct the examination and shall participate in the examination if necessary. The food and drug regulatory authorities of provinces, autonomous regions and municipalities directly under the Central Government shall complete the system examination in accordance with the relevant requirements within 30 working days.

When conducting technical review of imported Class II and Class III medical device, the technical review organization of China Food and Drug Administration shall, if quality management system examination is deemed to be necessary, inform the technical organization of quality management system examination of the China Food and Drug Administration to conduct examination in accordance with relevant requirements and the technical review organization shall participate in the examination if necessary.

The time for the quality management system examination is not counted in the time limit of review.

Article 35 In the event that the applicant is required to supplement and correct the application materials during the technical review process, the technical review organization shall inform all the necessary supplementary materials at one stroke. The applicant shall provide the supplementary materials in accordance with the requirements of the said notification within 1 year on a lump-sum basis; the technical review organization shall complete technical review within 60 working days after receiving the supplementary materials. The time for the material supplementation is not counted in the time limit of review.

In the event of any objections to the material supplementation notification, the applicant may present written comments to corresponding technical review organization, stating reasons and providing corresponding technical supporting materials.

In the event that the applicant fails to submit supplementary materials within the required time limit, the technical review organization shall terminate the technical review and propose to refuse registration, which is examined and approved by the food and drug regulatory authorities prior to their decision of registration rejection.

Article 36 The food and drug regulatory authorities who accept the registration application shall make a decision within 20 working days after finishing the technical review. Those applications conforming to safety and effectiveness requirements are granted registration; the relevant authorities shall grant with registration certificate within 10 working days after the approval decision and send the examined products technical requirements in attachment to the applicant. The authorities shall state the reasons in writing for the refusal of registration while notifying the applicant of its right of applying for re-examination and administrative reconsideration pursuant to laws or instituting administrative litigation.

Medical device registration certificate is valid for 5 years.

Article 37 Medical device registration items include licensing items and registering items. Licensing items include product name, model, specification, structure and components, indications, product technical requirements, manufacturing address of imported medical device and registering items

include name and address of the applicant, name and address of the agent and the manufacturing address of domestic medical device.

Article 38 For those medical device that are used to cure orphan diseases and respond to the emergent needs of outburst public health events, the food and drug regulatory authorities may require the applicant to further complete related work when approving the medical device registration and specify the requirements in the medical device registration certificate.

Article 39 In the case of any of following circumstances regarding the accepted registration application, the food and drug regulatory authorities issue registration rejection and inform the applicant:

- (I) Where the applicant is unable to prove the products are safe and effective regarding the research and its result of the safety and effectiveness of the medical device ready to come into the market;
- (II) Where the registration application materials are false;
- (III) Where the registration application materials are confusing and inconsistent;
- (IV) Where the contents of registration application materials obviously fail to conform to the applying item; and
- (V) Other circumstances where the registration is refused.

Article 40 The applicant may apply for withdrawal of the accepted registration application and related materials and state reasons for it to the food and drug regulatory authority that accepts the application before the administrative license decision is made.

Article 41 In the event that there is evidence showing the registration application materials for the accepted registration application may be false, the food and drug regulatory authorities may suspend the examination and approval. Through verification, the authorities may continue to examine and approve or issue registration rejection according to the verification result.

Article 42 In the event that the applicant has objection to the food and drug regulatory authorities' registration rejection, he/she may present application for re-examination to the food and drug regulatory authority that makes the approval decision within 20 working days after receiving the notice of registration rejection. The contents of re-examination application are limited to the original applying item and application materials.

Article 43 The food and drug regulatory authorities shall make re-examination decision within 30 working days after accepting the re-examination application and inform the applicant in writing. In the event the decision remains the same as before, the food and drug regulatory authorities will not accept a second re-examination application from the applicant any more.

Article 44 In the event that the applicant has objection to the food and drug regulatory authorities' registration rejection and has applied for administrative reconsideration or instituted administrative litigation, the food and drug regulatory authorities will not accept its re-examination application.

Article 45 In the event that the medical device registration certificate gets lost, the registrant shall promptly publish lost certificate statement on the media appointed by the original license-issuing authority. The applicant may apply for reissuing the certificate by the original license-issuing authority 1 month after the release of the lost certificate statement and the original license-issuing authority shall reissue the certificate within 20 working days.

Article 46 If the application for registration of medical device is directly related to the important interests between the applicant and other parties, the food and drug regulatory authorities shall inform the applicant and the interested party of their right to apply for hearing according to laws and regulations, and other provisions of China Food and Drug Administration; when conducting examination on the application for registration of medical device, the food and drug regulatory authorities shall make known to the public and hold hearing if they deem that the application involves the approval for important matters related to the public interests.

Article 47 For the newly invented medical device that have not been listed in the classified catalogue, the applicant may directly apply for Class III medical device registration or may apply for registration of product or put the product on records after determining the classification of the product according to the rules of classification and applying for the verification of the product classification from China Food and Drug Administration.

If the application is made directly for Class III medical device registration, China Food and Drug Administration shall determine the classification according to the degree of risks. In the case that domestic medical device have been determined as Class II, China Food and Drug Administration shall transfer the application data to local food and drug regulatory authorities of the province, autonomous region and municipality directly under the central government for examination and approval of the review; in the case that domestic medical device have been determined as Class I, China Food and Drug Administration shall transfer the application data to local food and drug regulatory authorities with districts at the city level for record.

Article 48 The patent disputes occurring during the process of examination for the registration application and after the approval of the application, if any, shall be handled according to the provisions of the relevant laws and regulations.

Chapter VI Change of Registration

Article 49 For the registered Class II and Class III medical devices, if medical devices registration certificate and the contents listed in the attachment have changed, the registrant shall apply for change of registration to the original registration department and submit the declaration materials according to the related requirements.

If product name, model, specification, structure and composition, applicable scope, product technical requirements and the production address of imported medical devices have changed, the registrant shall apply for change of licensed matters to the original registration department.

If the registrant name and domicile, and the agent name and domicile have changed, the registrant shall apply for change of registration to the original registration department; in the event that the production address of domestic medical devices has changed, the registrant shall handle change of registration after the corresponding change of production permit.

Article 50 In case that the change materials of the registered items are consistent with the requirements, the food and drug regulatory authority shall issue the document of registration changes for medical devices within ten (10) working days. In case that the change materials of the registered items are not complete or inconsistent with the requirements of formal examination, the food and drug regulatory authority shall in one time inform of all contents required to be supplemented and corrected.

Article 51 For the change of licensed matters, the technical review organization shall focus on the changed parts for review, and estimate whether the changed product is safe and effective or not.

The food and drug regulatory authority which accepts the application for change of licensed matters shall organize technical examination within the time limit as stipulated under Chapter V of the Measures.

Article 52 The registration change document for medical devices and the original registration certificate of medical devices shall be combined for use and the valid period of the change document is the same as the registration certificate. After receiving the registration change document, the registrant shall modify the technical requirements, specification and label of the product according to the changed contents.

Article 53 For the acceptance and approval process of the application for change of licensed matters which is not stated in this Chapter, shall be subject to the relevant provisions under Chapter V of the Measures.

Chapter VII Extension of Registration

Article 54 If the registration certificate of medical devices is expired and an extension of registration is required, the registrant shall apply for the extension of registration and submit the application materials as required to the food and drug regulatory authority six (6) months before the expiration of the valid period of the registration certificate of medical devices.

Except under the circumstances as specified under Article 55 of the Measures, the food and drug regulatory authority which has accepted the application of extending registration shall make a decision for granting the registration extension prior to the expiration of the valid period of the registration certificate of medical devices. Failure in making a decision within the specified period will be deemed to grant the extension of registration.

Article 55 The extension of registration shall not be accepted in any of the following circumstances:

- (I) The registrant fails to propose the application for extension of registration within the specified time limit;
- (II) The mandatory standard of medical devices has been revised and such medical devices fail to meet the new requirements;
- (III) For those medical devices which are used to cure orphan diseases and urgently needed in response to any sudden public health event, when the medical devices are approved to appear in the market by the registration approval department, the registrant fails to complete the matters expressly stated on the registration certificate of medical devices as required by the registration approval department within the specified time limit.

Article 56 For the acceptance and approval process of the application for extension of registration of medical devices which is not stated in this Chapter, such process shall be subject to the relevant provisions under Chapter V of the Measures.

Chapter VIII Filing of the Product

Article 57 The Class I medical devices shall be filed prior to the manufacture.

Article 58 The person who files for record shall, in accordance with Article 9 of the *Regulations for the Supervision and Administration of Medical devices*, submit the filing materials.

If the filing materials are qualified, food and drug regulatory authority shall file them on the spot. If the filing materials are not complete or do not comply with the stipulated format, food and drug regulatory authority shall notify the person who files for record all contents required to be supplemented and amended, and such person shall supplement and amend the filing materials.

Food and drug regulatory authority shall, in accordance with the relevant required format, make the filing certificates with respect to the filed medical devices, and publish the information listed in the filing information table on its website.

Article 59 In case of any change to the contents of the filing information table and technical requirements of the product with respect to the filed medical devices, the person who files for record shall submit the explanation and the relevant supporting documents for such change and apply to the original filing department for changing the filing information. If the filing materials comply with the required format, food and drug regulatory authority shall state the change in the change information and keep the filing materials for record.

Article 60 In case of any adjustment for the management category of the filed medical devices, the person who files for record shall propose the cancellation of the original filing to food and drug regulatory authority. And if the management category is changed to the Class II or Class III medical devices, application for registration in accordance with the Measures is needed.

Chapter IX Supervision and Management

Article 61 China Food and Drug Administration shall be responsible for the supervision and management of the registration and filing of medical devices nationwide. And it also shall be responsible for the supervision and direction of the registration and filing of medical devices of local

food and drug regulatory authorities.

Article 62 Food and drug regulatory authorities of provinces, autonomous regions and municipalities shall be responsible for supervising and managing the registration and filing of medical devices within its own administrative region, organizing and carrying out supervision and inspection work, and reporting the relevant situation to China Food and Drug Administration in time.

Article 63 Food and drug regulatory authorities of provinces, autonomous regions and municipalities shall, in accordance with the principle of territorial jurisdiction, carry out routine supervision and management for relevant registration and filing work of the agent who files imported medical devices.

Article 64 Food and drug regulatory authorities of a city with sub-districts shall regularly inspect the filing work and report the relevant information to the food and drug regulatory authorities of provinces, autonomous regions and municipalities in time.

Article 65 In case of any cancellation of registered medical devices in accordance with the laws and regulations, or the registrant cancels such registered medical devices prior to the expiry of the registration certificate, food and drug regulatory authorities shall cancel such registered medical devices in accordance with the laws and publish such cancellation to the public.

Article 66 In the event that the management category of the registered medical devices is adjusted to a lower category from a higher category, the registration certificate shall remain in full effect within the effective term. In case that any extension is needed, the registrant shall, 6 months prior to the expiry of the medical devices registration certificate, apply to the food and drug regulatory authorities for registration extension or filing based on the changed category.

In the event that the management category of the registered medical devices is adjusted to a higher category from a lower category, the registrant shall, in accordance with Chapter V of the Measures, apply to the food and drug regulatory authorities for registration based on the changed category. China Food and Drug Administration shall specify the time limit for the adjustment in the notice of adjustment for management category.

Article 67 In case of any breach of the Measures by food and drug regulatory authorities of provinces, autonomous regions and municipalities in registering medical devices, China Food and Drug Administration shall order them to rectify within a stipulated period. Should such authorities fail to rectify within the stipulated period, China Food and Drug Administration may cancel such medical devices registration certificate directly and publish such cancellation to the public.

Article 68 Food and drug regulatory authorities, relevant technical institutions and their staff shall be responsible for keeping confidential experimental data and technical secrets submitted by the applicant or the person who files for record.

Chapter X Legal Liabilities

Article 69 In the event that the registrant obtains medical devices registration certificate through providing fake materials or conducting other cheating behaviors, such registrant shall be punished in accordance with Paragraph 1, Article 64 of the *Regulations for the Supervision and Administration of Medical devices*.

In the event that the person who files for record provides fake materials during filing, such person shall be punished in accordance with Paragraph 2, Article 65 of the *Regulations for the Supervision and Administration of Medical devices*.

Article 70 In the event that the person who forges, changes, purchases, sells, rents or borrows medical devices registration certificate, such person shall be punished in accordance with Paragraph 2, Article 64 of the *Regulations for the Supervision and Administration of Medical devices*.

Article 71 In the event that the person who fails to change the filing of Class I medical devices or change the registration items of Class II and Class III medical devices in accordance with the Measures, such person shall be punished based on the situations of relevant non-filing in accordance with the *Regulations for the Supervision and Administration of Medical devices*.

Article 72 In the event that the person who fails to change the licensed matters of medical devices registration in accordance with the Measures, such person shall be punished based on the situations of failing to obtain the medical devices registration certificate in accordance with the *Regulations for the Supervision and Administration of Medical devices*.

Article 73 In the event that the applicant fails to conduct clinical tests in accordance with the Measures and the *Regulations for the Supervision and Administration of Medical Devices*, such applicant shall be ordered to rectify by the food and drug regulatory authorities above the county level and may be fined 30,000 yuan or below; and if the circumstance is serious, the clinical tests shall be stopped promptly and the approved documents of clinical tests shall be cancelled.

Chapter XI Supplementary Provisions

Article 74 The units of medical devices registration or filing shall be divided in accordance with the technical principle, structure and composition, performance index and application scope in principle.

Article 75 The combination components stated in the column "structure and composition" of medical devices registration certificate, which are used in the original registered products for the purposes of changing consumables, after-sale service and maintenance, can be sold separately.

Article 76 The format of the medical devices registration certificate shall be unified and formulated by China Food and Drug Administration.

The registration certificate number shall be arranged as follows:

x1XZx2xxxx3x4xx5xxxx6, in which:

x1: short name of location of registration approval department

"Guo" is for domestic Class III medical devices, imported Class II and Class III medical devices

The short names of provinces, autonomous regions and municipalities of registration approval department are for domestic Class II medical devices.

x2: the form of registration:

"Zhun" is for domestic medical devices;

"Jin" is for the imported medical devices;

"Xu" is for the medical devices of Hong Kong, Macao and Taiwan region;

xxxx3: the first year of registration;

x4: management category of the products;

x5: category number of the products;

xxxx6: serial number of the first registration.

In case of registration extension, the number of xxxx3 and xxxx6 shall be kept the same. In case that the management category of the products is changed, the registration certificate number of such devices shall be renumbered.

Article 77 The filing certificate number of Class I medical devices shall be arranged as follows:

x1XBxxxx2xxxx3

In which:

x1: short name of location of filing department

"Guo" is for the imported Class I medical devices;

The short names of provinces, autonomous regions and municipalities of filing department together with the short names of districted city level administrative region are for domestic Class I medical devices (in case there is no districted city level administrative region, only short names of provinces, autonomous regions and municipalities are for domestic Class I medical devices);

xxxx2: the year of the filing;

xxxx3: serial number of the filing.

Article 78 The registration and filing of the IVD Reagent which is managed as medical devices shall be governed by the *Management Measures of In Vitro Diagnostics D Reagent Registration*.

Article 79 The emergency approval process of medical devices and special process for approval of innovative medical devices shall be otherwise formulated by China Food and Drug Administration.

Comment [YT7171]: "械备"译法不确定, 核实, 译者注。

Article 80 China Food and Drug Administration can entrust food and drug regulatory authorities of provinces, autonomous regions and municipalities or technical institutions, relevant social organizations to conduct specific work related to medical device registration if necessary.

Article 81 The charging items and charging standard of medical device registration shall comply with the stipulations of the finance and price department of the State Council.

Article 82 The Measures will be put into force as of October 1, 2014. *Provisions for Medical Device Registration* (Order No.16 of China Food and Drug Administration) dated August 9, 2004 shall be annulled immediately.