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 or filing a record in accordance with the provisions of these Measures.

Article 3

Medical device registration means the process of systematic evaluation on research and results of the safety and effectiveness of the medical devices to be sold and used in accordance with the legal procedures by food and drug administration department to decide whether the application can be approved.

Medical device filing refers to food and drug administration department files record materials of class I products submitted by the applicant for future reference.

Article 4

Medical device registration approval and filing permission shall follow the principle of justice, fairness, publicity.

Article 5

Implement filing management for Class I medical devices, and registration management for Class II, Class III medical devices.

Class I domestic medical devices will be filed a record by food and drug administration departments of the districted cities.

Class II domestic medical devices are subject to examination by the food and drug supervision and management departments of the local provinces, autonomous regions, municipalities directly under the central government, and medical device registration certificates will be issued after approval by such authorities.

Class III domestic medical devices are subject to examination by the CFDA (China Food and drug administration department), and medical device registration certificates will be issued after approval by CFDA.

Class I imported medical devices need to be filed a record in CFDA.

Class II, class III imported medical devices are subject to examination by the CFDA, and medical device registration certificates will be issued after approval by CFDA.

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Medical devices from Taiwan, Hong Kong and Macao shall be registered or filed a record by reference to the measures for the registration of import medical devices.

Article 6

The applicants for registration or filing a record shall sell the related products in the market by their own names and be liable for legal responsibilities.

Article 7

Food and drug administration departments shall publish information related to medical device registration or filing in time legally. The applicant can inquire the approval rate of progress and results, the public can inquire approval results.

Article 8

The state encourages medical devices research and innovation and implements special approval procedure for innovative medical device, promotes the application of medical devices new technology and medical devices industry development.

Chapter 2 Essential Requirements

Article 9

The applicants for registration or filing a record shall establish quality management system related to product research and manufacture, maintain it work effectively at the mean time.

If entrust other manufacturers to manufacture samples for domestic medical devices which can be approved through special approval procedure, the entrusted manufacturer’s qualification should cover related scope; Samples which cannot be approved through special approval procedure should not be entrusted to manufacture.

Article 10

The person handling the matters related to application for medical device registration (filing) shall have the corresponding professional knowledge and be familiar with the laws, rules, regulations and technical requirements on the administration of medical device registration (filing).

Article 11

The applicant for registration or filing shall follow essential requirements of safety and effectiveness of medical devices, guarantee normalization in the development process and all the data should be authentic, intact and traceable.

Article 12

The submitted materials for registration or fling should be in Chinese. Provide original text if the submitted materials are translation version according to foreign language. Approval certificate issued by the data owner shall be provided when the quoted document has not been published. Applicants should take full responsibility for the authenticity of the submitted materials.

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Article 13

When apply for the registration (filing) of a foreign medical device in China, the foreign sales license for medical devices in original state or region is needed.

If the foreign product is not supervised as a medical device in original state or region, the applicant shall provide related certificate documents, including the foreign sales license in original state or region.

Article 14

Regarding application for the registration (filing) of foreign medical devices, the foreign manufacturer via its representative office in China or a designated organization located within the territory of China to act as the foreign manufacturer's agent to apply for the registration (filing).

Agent within the territory of China for the foreign applicant shall bear the following responsibility:

1. Contact with the corresponding food and drug administration department and the foreign applicant (or proposer).
2. Convey the regulations and technical requirements to the foreign applicant (or proposer) accurately and precisely
3. Collect adverse events of the post-marketing medical device and feed back to the foreign applicant (or proposer), and report it to the corresponding food and drug administration department.
4. Recall the post-marketing medical device which has quality matters and report it to the corresponding food and drug administration department.
5. Other responsibility related to product quality and after-sale service.

Chapter 3 Product Technical Requirements and Registration Test

Article 15

The applicant shall compile product technical requirements for medical devices. Product technical requirements for class Ⅰ products shall be submitted to related food and drug administration department. Product technical requirements for class II, class III medical devices will be checked and approved by food and drug administration department during the registration.

Product technical requirements mainly contain performance indexes and test methods for finished products. The performance indexes refer to indexes which can give objective assessment of the functionality, security and quality control.

Medical devices applied for sales in Chinese market should conform to the approved product technical requirements.

Article 16

Implement registration test when register class II, class III medical devices. Medical device test organizations shall test the samples according to product technical requirements.

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Samples for registration test should be manufactured according to related requirement of medical device quality management system. Only those with a qualified registration test can carry out clinical trials or apply for registration.

For filing class Ⅰ products, the applicant can submit product self-report.

Article 17

When applying for registration test, the applicant shall submit technical materials, samples for inspection and product technical requirements to medical device test organizations.

Article 18

Medical device test organizations should have medical device inspection qualification within the test range, and pre-assess product technical requirements, the pre-assess opinion will be issued along with registration test report to the applicant.

Medical devices have been beyond the test range of the test organizations, the related registration examination and approval department will designate a qualified test organization to test the medical devices.

Article 19

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.

Chapter 4 Clinical Trials Evaluation

Article 20

Clinical trials evaluation is a process to assure the products can meet the use requirements or application scope via clinical document literature, clinical empirical data, clinical trials, etc.

Article 21

Clinical trials materials refer to documents formed during clinical trials evaluation by applicant.

Clinical trials materials shall include clinical trials protocol and clinical trials report if clinical trials need to be carried out.

Article 22

Clinical trials are needed to be carried out when registering class II, class III medical devices but not when filing a record for class I medical devices. Clinical trials can be exempted when conform to one of the following circumstances.

1) With clear working mechanism, finalization design, mature manufacturing technique, or similar products which have been on the market have no serious adverse events when used in clinical for several years and the general-purpose has not been changed.
2) The safety and effectiveness of medical device can be ensured via other data rather than clinical trials.

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3) The safety and effectiveness of medical device can be ensured by analysis and evaluation the data achieved in the clinical trials or clinical use of the same type medical device.

Catalogue for medical device whose clinical trials can be exempted is made, adjusted and issued by the food and drug administration department under the state council.

Applicants can analyze and assess data achieved from clinical trials or clinical use, illustration and related proving documents can be given during registration if the data can prove medical devices safety and effectiveness.

Article 23

Clinical trials should comply with the requirement of the quality management criterion for medical device clinical trials and be launched in the qualified clinical test units，samples for clinical trials shall be manufactured according to related requirement of quality management system.

Article 24

Class III medical device clinical trials with higher risk to human body shall be approved by the food and drug administration department of the state council. The catalogue of class III medical device clinical trials with higher risk to human body is made, adjusted and issued by the food and drug administration department of the state council.

Article 25

Clinical trials approval is determined by CFDA, CFDA will assess clinical trials risk degree, clinical trials protocol, contrastive analysis of clinical benefits and risk, etc. to determine clinical trials approval.

Article 26

Applicant shall submit application materials according to related requirements to CFDA for applying for clinical trials approval.

Article 27

CFDA will deliver application materials to medical device technical assessment organization within 3 working days after accepting application for clinical trials approval.

Medical device technical assessment organization will complete technical assessment within 40 working days. CFDA will make determination within 20 working days after technical assessment and issue medical device clinical trials approval if clinical trials are permitted or give a written reason for refusing approval.

Article 28

During the technical assessment of application documents for medical device registration, the food and drug administration department authority shall issue the applicant a notice for the supplementation of documents once and for all. The applicant shall fully supplement the necessary documents once and for all within a year in accordance with the requirements of the notice. The technical assessment institute shall finish the technical assessment within 60 working days after

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receiving the supplement documents. The period of documents supplement shall not be included in the time limit specified in this Article.

The technical assessment institute can terminate the examination and propose approval failure if the applicant fails to submit supplementary documents within the specified time limit without justified reason, CFDA will make decision of approval failure after check.

Article 29

CFDA will repeal achieved clinical trials approval if the following circumstances happen:

1. Application materials of clinical trials is mendacious;
2. There has been proofs to certificate original clinical trials is problematic in ethicality and scientificity;
3. Other circumstances.

Article 30

Clinical trials should be carried out within 3 years after receiving clinical trials approval, otherwise the clinical trials approval document will be abolished automatically and you should apply for the clinical trials approval again if you want to carry out clinical trials.

Product Registration

Article 31

Applicant shall submit application materials to related food and drug administration department when applying for medical device registration.

Article 32

After a food and drug administration department authority receives an application, this authority shall do formal examination after receiving the application, and dispose of the application respectively according to the following circumstances:

(1) The application will be accepted only if application items are within the limits of the functions and power of the authority, the application materials are all in readiness and conform to formal examination.

(2) If the application documents have mistakes that can be corrected on the spot, the food and drug administration department 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, food and drug administration department authority shall issue a notice for the supplementation or correction of documents to the applicant within 5 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 and drug administration department authority fails to inform the applicant of the contents that need supplementation or correction within the time limit;

(4) Food and drug administration department authority shall inform the applicant for application

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refuse in time if the application items are beyond the limits of the function and power of the authority.

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

Article 33

The food and drug administration department authority which accept the registration application shall transfer the application documents to the technical assessment institute within 3 working days.

Technical assessment institute shall finish technical assessment for class II medical devices within 60 working days, and that for class III medical devices within 90 working days.

Time required in inviting external experts, unity assessment with drug assessment agency for medicine combination medical devices will not be calculated in the technical assessment period, technical assessment agency shall inform the needed time to the applicant.

Article 34

Technical assessment institute of the food and drug administration department authority can check and read related original document if necessary during technical assessment and can also organize examination the quality management system related to product research and manufacture.

Examination of quality management system for domestic class II, class III medical devices will be implemented by food and drug departments of the local provinces, autonomous regions, municipalities directly. CFDA will inform the local provinces, autonomous regions, municipalities directly food and drug departments to check the quality management system and participate in the check if necessary. The local provinces, autonomous regions, municipalities directly food and drug departments shall finish quality management system examination within 30 working days according to related requirements.

If CFDA feels the need to check the quality management system when launch the technical evaluation for imported class II, class III medical devices, it should organize the technical institutions for inspecting the quality management system to check the quality management system.

Time required in checking the quality management system will not be calculated in technical evaluation period.

Article 35

During the technical examination of application documents for medical device registration, the food and drug administration department authority shall issue the applicant a notice for the supplementation of documents once and for all. The applicant shall fully supplement the necessary documents once and for all within a year in accordance with the requirements of the notice. The technical examination institute shall finish the technical examination within 60 working days after receiving the supplement documents. Time of documents supplement shall not be calculated in

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technical examination period.

The applicant can give a written opinion and supporting materials to the corresponding technical assessment agency if dissent with supplementation materials.

If applicants do not submit supplementation materials within the given period, technical assessment agency will terminate technical assessment and propose suggestion of refusing registration, and food and drug administration department will give the refused determination after checking.

Article 36

The food and drug administration department which accept the application should make the decision within 20 working days after finishing the technical evaluation. Permit the applicant to register if the product meets the requirements of the safety and effectiveness, and issue the registration certificate of medical devices within 10 working days; For those do not comply with the requirements, reject the registration and give a written explanation and inform the applicant of the right to reexamine or apply for administrative reconsideration or propose administrative litigation.

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

Article 37

Medical device registration items include approval items and recording items. Approval items include product name, model, specification, structure and composite, applicable scope, technical requirements, manufacture address of imported medical device, etc.; Recording items include name and address of the applicant, name and address of the agent, manufacture address of domestic medical device, etc..

Article 38

For medical device in urgent need of rare disease treatment and dealing with public health emergencies, food and drug administration department can request the applicant to finish related task after post-marketing, furthermore, state the requirement on the medical device registration certificate.

Article 39

The food and drug administration department shall reject the registration and give an explanation to the applicant if the received application conforms to the following circumstances:

1. If research carried by applicant and or its results cannot certify the safety and effectiveness of medical devices to be sold in the market.
2. If the application material is mendacious.
3. If the content of the application material is in disorder or inconsistent.
4. If the content of the application material does not conform to the applied items.
5. Other circumstances cannot be registered.

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Article 40

If the application has been accepted, the applicant shall give an explanation to the food and drug administration department which accept the application before administrative approval and withdraw the registration application.

Article 41

If there are proofs to certify that the application materials of the received registration application are mendacious, food and drug administration department shall terminate examination. Continue to examine or decide not to register based on the result of the check.

Article 42

The applicant can propose the food and drug administration department to reexamine within 20 working days from receiving the refusing registration decision if dissent with the it. The reexamination content is limited to the original items and application materials.

Article 43

Food and drug administration department shall decide whether to do the reexamination within 30 working days dating from receiving the reexamination application and give a written notice to the applicant. Food and drug administration department will not accept the reexamination application proposed by the applicant again if maintains the original decision.

Article 44

Food and drug administration department will refuse reexamination application if the applicant was dissent with the decision and has applied for administrative reconsideration or administrative litigation.

Article 45

Where a Medical Device Registration Certificate is lost, the medical device applicant shall make a public announcement about the loss on the media designated by the original license-issuing authority immediately and apply to the original license-issuing authority for a reissue after one month of the public announcement, the original license-issuing authority shall issue a new Medical Device Registration Certificate within 20 working days.

Article 46

The food and drug administration department shall inform the applicant and interested party the right of hearing application according to laws, regulations and other regulations made by CFDA as the registration application is directly related to major interest relationship between the applicant and others. The food and drug administration department shall publicize to the society and hold a hearing if the medical device registration application is thought to be involved in major approval items of public interest.

Article 47

The applicant can register the medical devices which are new and have not listed in the catalogue according to the class III registration regulation, and can also determine product categories in

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accordance with classification principles and apply to CFDA for category identification, and then do the registration or record procedures based on this regulation.

CFDA should identify the category of the medical device which is directly registered as class III product according to the degree of risk. If censored and registered as class II domestic medical devices, CFDA will transfer the submitted materials to food and drug administration department of provinces, autonomous regions and municipalities in locus of the applicants to determine whether approve and issue the registration certificate or not. If censored and registered as class I domestic medical devices, CFDA will transfer the submitted materials to food and drug administration department of cities with districts in locus of the applicants to file a record.

Article 48

Patent disputes occurred in the examination process or after approval shall be handled according to related laws and regulations.

Chapter 6 Registration Alteration

Article 49

If the content on the registration certificate and its attachment of the registered class II, class III medical devices has been changed, the applicant shall apply to the original license-issuing authority for registration change and submit application materials according to related requirement.

If one or more of the items such as product name, model, specification, structure and composite, applicable scope, technical requirements, manufacture address of imported medical device, etc. have been changed, the applicant shall apply for approval alteration to original department.

If the changed items are name and address of the applicant, name and address of the agent, applicant shall apply for recording items alteration to related food and drug administration department; If manufacture address for domestic medical devices has been changed, applicant shall apply for manufacture approve alteration prior to recording approval alteration.

Article 50

The food and drug administration department shall approve the alteration within 10 working days if the materials for registration alteration for recording items conform to requirements and issue medical device registration alteration documents. If the materials for recording items alteration are incomplete or do not conform to the regulation of formal examination, the food and drug administration department shall issue the applicant a notice for the supplementation of documents once and for all.

Article 51

Technical examination institute shall focus on the changed part for assessment towards approval items change, and evaluate whether the changed products are safe or effective.

Food and drug administration department shall organize technical assessment within the limited period according to regulations on chapter 5 after accepting the approval items alteration application.

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Article 52

The registration alteration approval and the original medical device registration certificate are united to be used and the valid period is in accordance with that of the original registration certificate. The applicant shall amend technical requirement, instruction manuals, labels based on the changed items in the approval voluntarily.

Article 53

If the procedure for examination and approval of application for registered items change is not included in this article, it applies to related regulations in chapter 5.

Chapter 7 Extending Registration

Article 54

The holder of the certificate shall apply for extending the validity term of registration 6 months before the certificate expires if the certificate expires come near. Apply to the related food and drug administration department for extending registration and submit application materials according to the corresponding requirements.

Food and drug administration department shall make decision of extending approval before the certificate expires if do not has the circumstances in article 55 in this provision. If the determination is not made beyond the certificate expires, the certificate is deemed to be approved extending.

Article 55

Refuse extending registration if conform to the following circumstances:

1. The applicant does not propose registration within the limited period.

2. The compulsory standard for medical device has been amended, and the medical device cannot meet the new requirement.

3. For medical device in urgent need of rare disease treatment and dealing with public health emergencies, the applicant does not finish the items stated on the medical device certificate which proposed by the registration approval department.

Article 56

The procedure for examination and approval of application for extending registration is not included in this article, it applies to related regulations in chapter 5.

Chapter 8 Product Filing

Article 57

File a record for class Ⅰ products prior to products manufacture.

Article 58

The applicant shall submit the materials for filing a record according to the corresponding requirements in article 9 of Regulations for the Supervision and Administration of Medical

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Devices.

Food and drug administration department will file a record on the spot if the materials conform to requirements or make a notice for the supplementation or correction of documents to the applicant to inform the applicant of all the contents that need to be supplemented or corrected once and for all if the application documents are incomplete or do not meet the regulated formal; applicant can file a record after the supplement.

Food and drug administration department shall make filing certificate according to related requirement for class [illegible] filing products, furthermore, information stated on [illegible] will be published on its website.

Article 59

If the content in the filing information sheet or product technical requirements have been changed, the record proposer shall submit the illustration of the changed contents and related certificate documents to apply to original issuing authority for information alteration application. The food and drug administration department will file a record for those whose record materials conform to the formal requirement and the related information will be updated on the website.

Article 60

If medical devices classification was adjusted, the record proposer shall apply to the food and drug administration department for canceling the filing proactively; if medical devices classification was adjusted to class II or class III medical devices, apply for registration according to regulations in this provision.

Chapter 9 Supervision and Administration

Article 61

CFDA is responsible for supervision and administration of medical devices nationwide, supervise and guide registration and filing task in local food and drug administration department.

Article 62

Food and drug administration departments of the local provinces, autonomous regions, municipalities directly under the central government is responsible for supervision and administration of medical devices registration and filing within its own area, organize supervision and examination, furthermore, report related information to CFDA in time.

Article 63

Food and drug administration departments of the local provinces, autonomous regions, municipalities directly under the central government will implement daily supervision and administration for registration and filing task of imported medical devices by agents according to its local regulations.

Article 64

Food and drug administration department of the municipalities consisting of districts shall carry out examination of filing task regularly and report related information to food and drug

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administration department of the local provinces, autonomous regions, municipalities directly under the central government.

Article 65

Food and drug administration department can repeal the registration certificate and publish to the public when the registered medical devices conform to circumstances of repealing according to laws or regulations or the applicant apply for repealing within the valid period of registration certificate.

Article 66

Medical device registration certificate will be effective if its classification was adjusted from high classification to low classification within its valid period. The applicant shall apply for extending registration or filing a record 6 months before the certificate expires on the basis of new classification if necessary.

Applicant shall refer to regulations in chapter 5 to apply for registration based on new classification if the classification was adjusted from low classification to high classification. CFDA shall make rules for medical device adjustment period in the notice of classification adjustment.

Article 67

Food and drug administration department of provinces level who break the rule during the registration approval will be ordered to make corrections within a time limit by CFDA. CFDA will directly announce to repeal registration certificate if it fails to make corrections.

Article 68

Food and drug administration department, the related technical institute and its staff shall keep secret of the submitted test data and technology.

Chapter 10 Legal Liability

Article 69

Achieve Medical device Registration Certificate via false materials or other deception means, penalize the related party according to article 64 in Regulations for the Supervision and Administration of Medical Devices.

Provide fake materials for filing, penalize the related party according to article 65 in Regulations for the Supervision and Administration of Medical Devices.

Article 70

If Medical device Registration Certificate is forged, changed, bought and sold, rented, lent, penalize the related party according to article 64 in Regulations for the Supervision and Administration of Medical Devices.

Article 71

Violate regulations in this provision by failing to apply for filing alteration for class I products or

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recording items registration alteration for class II, class III products, penalize the related party according circumstances of failing to file a record in Regulations for the Supervision and Administration of Medical Devices.

Article 72

Violate regulations in this provision by failing to apply for approval items alteration registration, penalize the related party according circumstances of failing to achieve a Medical device Registration Certificate in Regulations for the Supervision and Administration of Medical Devices.

Article 73

Food and drug administration departments at county level and above shall order applicants who fail to carry out clinical trials according to Regulations for the Supervision and Administration of Medical Devices and this provision to make corrections and can fine less than 30000 yuan; Clinical trials will be terminated immediately if the circumstance is serious, the clinical trials approval will be repealed.

Chapter 11 Supplementary Provisions

Article 74

Medical device registration or filing shall be divided based on technical principle, structure and composite, performance indexes and applicable scope, etc.

Article 75

Composite parts listed in the “structure and composition” item on the medical device registration certificate with the purpose for consumables changing, after-sale service, repairs, etc., they can sale solely if they are used in original products.

Article 76

Medical device registration certificate format shall be made by CFDA uniformly.

Registration numbers shall be arranged in the following form:
×1 械注×2××××3×4××5××××6. Where,

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

The letter “国” shall be adopted for Category III domestic medical devices, Category II, III foreign medical devices;

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;

×2 shall indicate registration form;

“准” is applicable to domestic medical devices;

“进” is applicable to foreign medical devices;

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“许” is applicable to medical devices from Taiwan, Hong Kong and Macao;

××××3 shall indicate the year of approval for the original registration;

×4 shall indicate the category of product administration;

××5 shall indicate the type code of product;

××××6 shall indicate serial number of the original registration.

For the extending registration, the numbers of ××××3 and ××××6 will remain unchanged. New registration numbers will be issued if the category of product administration has been changed.

Article 77

The filing certificate numbers for class Ⅰ products shall be arranged in the following form:

×1 械备××××2××××3 号. Where:

×1 shall mean the abbreviation of the place where authority which files a record for class Ⅰ products is located:

The letter “国” shall be adopted for class Ⅰ foreign medical devices;

The abbreviation of the province, autonomous region or municipality where authority which files a record is located plus the abbreviation of the local municipal level administrative area with districts shall be adopted for class 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 year when filing a record;

××××3 shall indicate serial number for filing a record.

Article 78

In vitro diagnostic reagents which are managed as medical devices shall do registration and filing according to Measures for the Administration of In-vitro Diagnosis Reagents Registration.

Article 79

Procedure for emergency approval and special approval will be made by CFDA separately.

Article 80

CFDA can entrust food and drug administration departments of the local provinces, autonomous regions, municipalities directly under the central government or technical organizations, related social organization to undertake related task for medical device registration.

Article 81

Charging items and charging standards for medical device registration can be implemented based on related regulations of financial departments and price competent departments in State Council.

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Article 82

This provision will come into force from 1st October 2014, Measures for the Administration of Medical Device Registration issued on 9th August 2004 will be abolished meanwhile.

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