Regulations on the Supervision and Administration of Medical Devices

Chapter I General Provisions

Article 1 These Regulations are formulated for the purpose of ensuring the safety and effectiveness of medical devices, safeguarding human health and life safety, and promoting the development of the medical device industry.

Article 2 These Regulations shall apply to the research and development, production, management and use of medical devices within the territory of the People's Republic of China as well as their supervision and administration.

Article 3 The drug regulatory department under the State Council shall be responsible for the supervision and administration of medical devices throughout the country.

The relevant departments of the State Council shall be responsible for the supervision and administration of medical devices within the scope of their respective functions and duties.

Article 4 The local people's government at or above the county level shall strengthen the leadership of the supervision and administration of medical devices within its administrative region, organize and coordinate the supervision and administration of medical devices within its administrative region as well as the emergency response work, strengthen the capacity building of the supervision and administration of medical devices, and provide guarantee for the safety work of medical devices.

The departments responsible for drug supervision and administration under the local people's governments at or above the county level shall be responsible for the supervision and administration of medical devices within their respective administrative regions. The relevant departments of the local people's governments at or above the county level shall be responsible for the supervision and administration of medical devices within their respective functions and duties.

Article 5 The supervision and administration of medical devices shall follow the principles of risk management, whole-process control, scientific supervision and social co-governance.

Article 6 The State shall carry out classified management of medical devices according to the degree of risk.

The first category is low risk degree, the implementation of routine management can ensure its safety and effectiveness of medical devices.

The second category is the medical devices with moderate risks, which need to be strictly controlled and managed to ensure their safety and effectiveness.

The third category is the medical devices with high risks, which need to take special measures to strictly control and manage to ensure their safety and effectiveness.

In evaluating the risk degree of medical devices, factors such as the intended purpose, structural characteristics and application methods of medical devices should be considered.

The drug regulatory department under the State Council shall be responsible for formulating the classification rules and catalogue of medical devices, and shall timely analyze and evaluate the risk changes of medical devices and make adjustments to the classification rules and catalogue based on the production, marketing and use of medical devices. When formulating and adjusting the classification rules and catalogue, the opinions of medical device registrants, record holders, production and business enterprises, user units and industrial organizations shall be fully solicit, and the international medical device classification practice shall be referred to. The classification rules and catalogue of medical devices shall be published to the public.

Article 7 Medical device products shall meet the mandatory national standards for medical devices; If there is no compulsory national standard, the medical device industry standard shall be complied with.

Article 8 The State formulates plans and policies for the medical device industry, brings the innovation of medical devices into the focus of development, gives priority to the evaluation and approval of innovative medical devices, supports the clinical promotion and use of innovative medical devices, and promotes the high-quality development of the medical device industry. The drug regulatory department under the State Council shall cooperate with the relevant departments under the State Council to implement the national medical device industry planning and guidance policies.

Article 9 The State shall improve the innovation system of medical devices, support the basic research and applied research of medical devices, promote the popularization and application of new technologies of medical devices, and provide support in scientific and technological project approval, financing, credit, bidding and procurement, medical insurance and other aspects. Support enterprises to set up or jointly set up research and development institutions, encourage enterprises to cooperate with institutions of higher learning, scientific research institutes and medical institutions to carry out research and innovation of medical devices, strengthen protection of intellectual property rights of medical devices, and improve the ability of independent innovation of medical devices.

Article 10 The State shall strengthen the construction of informatization in the supervision and management of medical devices, improve the level of online government services, and provide convenience for the administrative licensing and filing of medical devices.

Article 11 Medical device industry organizations shall strengthen industry self-discipline, promote the construction of credit system, urge enterprises to carry out production and operation activities according to law, and guide enterprises to be honest and trustworthy.

Article 12 Units and individuals that have made outstanding contributions to the research and innovation of medical devices shall be commended and rewarded in accordance with the relevant provisions of the State.

Chapter II Registration and Filing of Medical Device Products

Article 13 Category I medical devices shall be subject to the management of product registration, while category II and category III medical devices shall be subject to the management of product registration.

Registrants and recorders of medical devices shall strengthen the quality management of the whole life cycle of medical devices, and shall be legally responsible for the safety and effectiveness of medical devices during the whole process of research, production, operation and use.

Article 14 The following materials shall be submitted for the record of Class I medical device products and for the registration of Class II and Class III medical device products:

(1) Product risk analysis data;

(2) Technical requirements of the product;

(3) Product inspection report;

(4) Clinical evaluation data;

(5) Product specifications and sample labels;

(6) Documents of quality management system related to product development and production;

Other materials needed to prove the safety and effectiveness of the products.

The product inspection report shall meet the requirements of the drug regulatory department under the State Council, and may be the self-inspection report of the medical device registration applicant and the record holder, or the inspection report entrusted to a qualified medical device inspection institution to be issued.

Those who meet the circumstances of exemption from clinical evaluation prescribed in Article 24 of these Regulations may be exempted from submitting clinical evaluation data.

The medical device registration applicant and the record holder shall ensure that the materials submitted are legal, true, accurate, complete and traceable.

Article 15 For recordkeeping of Category I medical devices, the recorder shall submit the recordkeeping materials to the department in charge of drug supervision and administration of the people's government of the city divided into districts where it is located.

For an overseas record holder exporting Category I medical devices within the territory of China, the domestic enterprise legal person designated by the foreign record holder shall submit the record filing materials and the certification documents of the competent authority of the country (region) of the record holder's home country approving the marketing of such medical devices to the drug regulatory department under the State Council. For an innovative medical device that has not been listed abroad, the competent authority of the country (region) where the archivist resides may not submit the certificate approving the marketing of such medical device.

The archival filing shall be completed upon submission of archival filing materials conforming to the provisions of these Regulations to the department responsible for drug supervision and administration. The department in charge of drug supervision and administration shall, within 5 working days from the date of receiving the archival data, publicize relevant archival information to the public through the online government affairs service platform of the drug regulatory department under the State Council.

Where any item specified in the archival documents changes, it shall be changed to the original archival department for archival purposes.

Article 16 To apply for the registration of Class II medical device products, the registration applicant shall submit the registration application materials to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where it is located. To apply for the registration of Class III medical device products, the registration applicant shall submit the registration application materials to the drug regulatory department under the State Council.

Where an overseas registration applicant exports Category II or III medical devices within the territory of China, the domestic enterprise legal person designated by the applicant shall submit to the drug regulatory department under the State Council the registration application materials and the certification documents of the competent authority of the country (region) where the registration applicant is located approving the marketing of the medical devices. An innovative medical device that has not been listed abroad may not submit the certificate approving the marketing of such medical device by the competent authority of the country (region) where the registration applicant is located.

The drug regulatory department under the State Council shall stipulate the procedures and requirements for the registration examination of medical devices, and strengthen supervision and guidance over the registration examination of the drug regulatory departments of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government.

Article 17 The drug regulatory department accepting the application for registration shall examine the safety and effectiveness of the medical devices and the ability of the registration applicant to guarantee the safety and effective quality management of the medical devices.

The drug regulatory department accepting the application for registration shall, within 3 working days from the date of accepting the application for registration, hand over the materials of the application for registration to the technical evaluation institution. The technical evaluation agency shall, after completing the technical evaluation, submit the evaluation opinions to the drug regulatory department accepting the application for registration as the basis for approval.

Where the drug regulatory department accepting the application for registration deems it necessary to inspect the quality management system when organizing the technical evaluation of medical devices, it shall organize and carry out the inspection of the quality management system.

Article 18 The drug regulatory department that accepts the application for registration shall make a decision within 20 working days from the date of receiving the evaluation opinions. To those who meet the requirements, registration shall be granted and a medical device registration certificate shall be issued; Those who do not meet the requirements shall not be registered and shall give reasons in writing.

The drug regulatory department accepting the application for registration shall, within 5 working days from the date of approving the registration of medical devices, publish the registration information to the society through the online government affairs service platform of the drug regulatory department under the State Council.

Article 19 The drug regulatory department accepting the application for registration may make conditional approval decisions for urgently needed medical devices used for the treatment of rare diseases, diseases seriously endangering life and diseases with no effective treatment means, and for responding to public health events, and shall specify relevant matters in the registration certificate of medical devices.

Appear particularly important public health emergencies or other serious threat to public health emergencies, health administrative department under the State Council according to the need of the prevention and control of events suggest use of emergency medical apparatus and instruments, after agreed by the pharmaceutical supervisory and administrative department under the State Council organization argument can be used in a certain range within the time limit and emergency.

Article 20 The registrant and record holder of a medical device shall perform the following obligations:

(1) Establish a quality management system suitable for the products and maintain its effective operation;

(II) Formulate post-listing research and risk control plans and ensure their effective implementation;

(3) To carry out monitoring and reevaluation of adverse events according to law;

(4) Establish and implement product traceability and recall systems;

(5) Other obligations stipulated by the pharmaceutical supervisory and administrative department under the State Council.

The domestic enterprise legal person designated by the overseas medical device registrant or record holder shall assist the registrant or record holder to fulfill the obligations prescribed in the preceding paragraph.

Article 21 Where there are substantial changes in the design, raw materials, production process, scope of application and method of use of Class II and Class III medical devices that have been registered, which may affect the safety and effectiveness of the medical devices, the registrant shall apply to the original registration department for the registration alteration procedures; Any other changes shall be put on record or reported in accordance with the provisions of the drug regulatory department under the State Council.

Article 22 The term of validity of the medical device registration certificate is 5 years. Where it is necessary to renew the registration upon expiration of the term of validity, an application for renewal of registration shall be filed with the original registration department 6 months prior to the expiration of the term of validity.

Except for the circumstances as provided for in paragraph 3 of this Article, the drug regulatory department that has received the application for renewal of registration shall make a decision to grant renewal before the expiration of the validity period of the medical device registration certificate. If no decision is made within the time limit, the extension shall be deemed to be granted.

Registration shall not be renewed under any of the following circumstances:

(1) Failure to apply for renewal of registration within the prescribed time limit;

(2) The compulsory standards for medical devices have been revised, and the medical devices applying for renewed registration cannot meet the new requirements;

(3) For medical devices with conditional approval, it fails to complete the items specified in the registration certificate of medical devices within the prescribed time limit.

Article 23 of the newly developed has not been listed in the catalog of medical apparatus and instruments, the applicant may, in accordance with the regulations related to the regulation of the third class medical equipment product registration directly apply for product registration, can also according to the classification rules determine the product category and applied to the pharmaceutical supervisory and administrative department under the State Council for type confirmed in accordance with the provisions of these regulations apply to product registration or for a product for the record.

If a medical device product of Category III is directly applied for registration, the drug regulatory department under the State Council shall determine the category according to the degree of risk, and timely include the medical device approved for registration into the classified catalogue. If the category of the application is confirmed, the drug regulatory department under the State Council shall, within 20 working days from the date of accepting the application, determine the category of the medical device and inform the applicant.

Article 24 Clinical evaluation shall be conducted in the registration and filing of medical device products; However, if one of the following conditions is met, clinical evaluation may be exempted:

(1) A medical device of the same type that has been marketed with clear working mechanism, finalized design, mature production technology, and has been clinically used for many years without records of serious adverse events, and does not change its routine use;

(2) Other medical devices that can be proved to be safe and effective through non-clinical evaluation.

The drug regulatory department under the State Council shall formulate guidelines for clinical evaluation of medical devices.

Article 25 Clinical evaluation of medical devices may be conducted to prove the safety and effectiveness of medical devices by carrying out clinical trials or by analyzing and evaluating the clinical literature and clinical data of the same type of medical devices according to the product characteristics, clinical risks and existing clinical data.

According to the provisions of the drug regulatory department under the State Council, when conducting clinical evaluation of medical devices, if the existing clinical literature and clinical data are insufficient to confirm the safety and effectiveness of the products, clinical trials shall be carried out.

Article 26 A clinical trial of medical devices shall be conducted in a clinical test institution with appropriate conditions in accordance with the requirements of the quality control standards for clinical trial of medical devices, and shall be filed with the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where the sponsor of the clinical trial is located. The drug regulatory department that accepts the filing of clinical trial shall notify the drug regulatory department and the competent health department at the same level where the clinical trial institution is located.

Institutions for clinical trial of medical devices shall implement archival management. The requirements that a medical device clinical test institution shall have, the measures for archival administration and the standards for the quality control of clinical trials shall be formulated and promulgated by the drug regulatory department under the State Council jointly with the competent health department under the State Council.

The state supports medical institutions in carrying out clinical trials, includes evaluation of clinical trial conditions and capabilities in the hierarchical evaluation of medical institutions, and encourages medical institutions to carry out clinical trials of innovative medical devices.

Article 27 Where a clinical trial of Category III medical devices has a high risk to human beings, it shall be approved by the pharmaceutical supervisory and administrative department under the State Council. The pharmaceutical supervisory and administrative department under the State Council for examination and approval of clinical trials of medical devices shall be assumed to clinical trials of equipment, professional conditions, the degree of risk for medical devices and clinical trial implementation plan, clinical benefit and risk analysis report and other comprehensive analysis, and 60 working days from the date of acceptance of application, make a decision and notify the sponsor clinical trials.Failure to notify within the time limit shall be deemed as consent. Where a clinical trial is approved, a notification shall be made to the drug regulatory department and the competent health department of the people's government of the province, autonomous region or municipality directly under the Central Government where the clinical trial institution is located.

The catalogue of the third category of medical devices with high risk to human beings from clinical trials shall be formulated, adjusted and promulgated by the drug regulatory department under the State Council.

Article 28 When conducting a clinical trial of a medical device, ethical review shall be conducted in accordance with the provisions, and detailed information such as the purpose, use and possible risks of the test shall be informed to the subjects, and written informed consent shall be obtained from the subjects; If the subject is a person without civil capacity or a person with limited civil capacity, he/she shall obtain the written informed consent of his/her guardian according to law.

In conducting a clinical trial, no fees related to the clinical trial shall be charged from the subjects in any form.

Article 29 for ongoing clinical trials for the treatment of severe life-threatening and there is no effective treatment of diseases of medical apparatus and instruments, the medical observation may bring benefit to patients, after ethical review, informed consent, can the institutions of medical instrument clinical trial in free for other patients with the same illness, its safety data can be used for medical device registration.

Chapter iii production of medical devices

Article 30 A person engaged in the production of medical devices shall meet the following requirements:

(1) Having production sites, environmental conditions, production equipment and specialized technical personnel suitable for the medical devices to be produced;

(2) It shall have an organization or full-time inspection personnel and inspection equipment capable of conducting quality inspection of the medical devices produced;

(3) It shall have a management system to ensure the quality of medical devices;

(4) Having the after-sale service capability suitable for the medical devices produced;

(5) Comply with the requirements specified in the product development and production process documents.

Article 31 Anyone engaged in the production of Category I medical devices shall file a record with the department in charge of drug supervision and administration of the people's government of the city divided into districts where it is located, and the record shall be completed upon submission of the relevant materials meeting the conditions prescribed in Article 30 of these Regulations.

Where the medical device record holder produces category I medical devices by himself, he may, when making the product record according to the provisions of Article 15 of these Regulations, submit the relevant materials meeting the requirements of Article 30 of these Regulations together, that is, complete the production record.

Article 32 Anyone engaged in the production of Category II or III medical devices shall apply to the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government where it is located for the production license and submit the relevant materials that meet the conditions prescribed in Article 30 of these Regulations as well as the registration certificate of the medical devices it produces.

The drug regulatory department accepting the application for production license shall examine the application materials, check the application materials in accordance with the requirements of the quality control standards for the production of medical devices formulated by the drug regulatory department under the State Council, and make a decision within 20 working days as of the date of receiving the application. To those who meet the prescribed conditions, a license shall be granted and a medical device production license shall be issued; In case of failure to meet the prescribed conditions, no permission shall be granted and reasons shall be given in writing.

The medical device production license is valid for 5 years. Where the term of validity needs to be extended upon expiration, the extension procedures shall be handled in accordance with the relevant laws on administrative licensing.

Article 33 The quality management standards for the production of medical devices shall clearly stipulate matters affecting the safety and effectiveness of medical devices, such as the design and development of medical devices, production equipment conditions, raw material procurement, production process control, product release, organizational setup and staffing of enterprises, etc.

Article 34 A medical device registrant or record holder may produce medical devices by itself, or may entrust an enterprise that complies with the provisions of these Regulations and meets corresponding conditions to produce medical devices.

Where the production of medical devices is commissioned, the registrant and record holder of medical devices shall be responsible for the quality of the commissioned medical devices, strengthen the management of the production behavior of the commissioned production enterprise, and ensure that the production is conducted in accordance with the legal requirements. The registrant and record holder of a medical device shall sign an entrustment agreement with the entrusted manufacturing enterprise to clarify the rights, obligations and responsibilities of both parties. The entrusted manufacturing enterprise shall organize production in accordance with laws and regulations, quality management norms for the production of medical devices, compulsory standards, product technical requirements and entrustment agreement, be responsible for the production acts and accept the supervision of the entrusting party.

Implantable medical devices with high risks shall not be commissioned for production. The specific catalogue shall be formulated, adjusted and promulgated by the drug regulatory department under the State Council.

Article 35 The registrant, record holder and entrusted manufacturing enterprise of medical devices shall, in accordance with the quality management standards for the production of medical devices, establish and improve the quality management system suitable for the medical devices they produce and ensure its effective operation; Organize production in strict accordance with the technical requirements of registered or recorded products, and ensure that the medical devices left the factory meet the mandatory standards and the technical requirements of registered or recorded products.

Registrants, record holders and entrusted manufacturers of medical devices shall regularly conduct self-examination of the operation of the quality management system, and submit self-examination reports in accordance with the provisions of the drug regulatory department under the State Council.

Article 36 Where the production conditions of medical devices change and no longer meet the requirements of the quality management system of medical devices, the registrant, the record holder or the entrusted manufacturing enterprise of medical devices shall immediately take corrective measures; If it may affect the safety and effectiveness of medical devices, it shall stop the production activities immediately and report to the original production license or production record department.

Article 37 Common names shall be used for medical devices. The generic names shall conform to the naming rules for medical devices formulated by the drug regulatory department under the State Council.

Article 38 The State shall, according to the category of medical devices, implement a unique identification system for medical devices step by step so as to achieve traceability of

medical devices. The specific measures shall be formulated by the drug regulatory department under the State Council jointly with the relevant departments under the State Council.

Article 39 Medical devices shall have instructions and labels. The contents of the instructions and labels shall be consistent with the relevant contents registered or put on record to ensure authenticity and accuracy.

The manual and label of medical devices shall indicate the following matters:

(1) General names, models and specifications;

(2) Names, addresses and contact information of the registrants, record holders and entrusted manufacturers of medical devices;

(3) the date of production, the date of use or the date of expiration;

(4) Product performance, main structure and scope of application;

(5) Taboos, points for attention and other contents that need warning or reminder;

(6) Instructions or drawings for installation and use;

(7) maintenance and maintenance methods, special transportation and storage conditions and methods;

(8) Other contents that shall be indicated in the technical requirements of the product.

Medical devices of category two and category three shall also be marked with the registration certificate number of medical devices.

Medical devices used by consumers themselves should also have special instructions for safe use.

Chapter IV Operation and Use of Medical Devices

Article 40 Any medical device business shall have a business site and storage conditions appropriate to the business scale and business scope, and a quality control system and a quality control organization or personnel appropriate to the medical device business.

Article 41 Where a business enterprise engages in the business of medical devices of Category II, it shall file a record with the department in charge of drug supervision and administration of the people's government of the city divided into districts where it is located and submit the relevant materials that meet the requirements set forth in Article 40 of these Regulations.

According to the provisions of the pharmaceutical supervisory and administrative department under the State Council, category II medical devices whose product safety and effectiveness are not affected by the circulation process may be exempted from business filing.

Article 42 Where the trading enterprise engages in the trading of Class III medical devices, it shall apply for the business license to the department in charge of drug supervision and administration of the people's government of the city divided into districts where it is located and submit the relevant materials that meet the requirements stipulated in Article 40 of these Regulations.

The department in charge of drug supervision and administration that accepts the application for business license shall examine the application materials, organize verification when necessary, and make a decision within 20 working days as of the date of accepting the application. To those who meet the prescribed conditions, a license shall be granted and a medical device business license shall be issued; In case of failure to meet the prescribed conditions, no permission shall be granted and reasons shall be given in writing.

The term of validity of the medical device operating license is 5 years. Where the term of validity needs to be extended upon expiration, the extension procedures shall be handled in accordance with the relevant laws on administrative licensing.

Article 43 A medical device registrant or record holder does not need to apply for a medical device business license or record to operate the medical devices registered or recorded, but it shall comply with the business conditions stipulated in these Regulations.

Article 44 Anyone engaged in the sale of medical devices shall, in accordance with laws and regulations and the requirements of the quality control standards for the sale of medical devices formulated by the drug regulatory department under the State Council, establish and improve the quality control system suitable for the sale of medical devices and ensure its effective operation.

Article 45 Medical device trading enterprises and users shall purchase medical devices from medical device registrants, record holders and production and marketing enterprises with legal qualifications. When purchasing a medical device, the qualification of the supplier and the qualification certificate of the medical device shall be checked, and a system of purchasing inspection records shall be established. Business enterprises engaged in the wholesale business of Category II and Category III medical devices and the retail business of Category III medical devices shall also establish a sales record system.

Records include:

(1) Names, models, specifications and quantities of medical devices;

(2) The production batch number, use period or expiration date and sale date of the medical devices;

(3) Names of the registrant, the record holder and the entrusted manufacturing enterprise of medical devices;

(4) the name, address and contact information of the supplier or buyer;

(5) Numbers of relevant license documents, etc.

The purchase inspection records and sales records shall be true, accurate, complete and traceable, and shall be kept within the time limit prescribed by the drug regulatory department under the State Council. The State encourages the use of advanced technical means to keep records.

Article 46 A medical device registrant, a medical device record holder or a medical device trading enterprise shall be engaged in the online sale of medical devices. An operator engaged in network sales of medical devices shall inform the department in charge of drug supervision and administration of the people's government of the city divided into districts where it is located about the relevant information of network sales of medical devices, with the exception of the business of category I medical devices and category II medical devices as stipulated in paragraph 2 of Article 41 of these Regulations.

An operator of an e-commerce platform providing services for the online trading of medical devices shall register the operator of a medical device with its real name, examine its business license and filing status as well as the registration and filing status of the medical device products it operates, and administer its business behaviors. If an operator of an e-commerce platform discovers that an operator of a networked medical device has violated the provisions of these Regulations, it shall stop in time and immediately report to the drug supervision and administration department of the people's government of the city divided into districts where the operator is located. If serious illegal acts are found, it shall immediately stop providing online trading platform services.

Article 47 The transportation and storage of medical devices shall conform to the requirements of the specifications and labels of medical devices; Where there are special requirements for temperature, humidity and other environmental conditions, corresponding measures shall be taken to ensure the safety and effectiveness of medical devices.

Article 48 A medical device user shall have storage places and conditions suitable to the type and quantity of the medical devices in use. The medical device users shall strengthen the technical training for the staff, and use the medical devices according to the requirements of the product specifications and technical operation specifications.

Unit configuration of large medical equipment, medical apparatus and instruments shall be conform to the competent department of health under the State Council of the large medical equipment allocation planning, and its function orientation, clinical service requirements, with corresponding technical conditions, supporting facilities and have corresponding qualifications and ability of professional and technical personnel, and approved by the competent department

of health under the people's government at or above the provincial level, large medical equipment allocation licence.

Measures for the administration of the allocation of large medical equipment shall be formulated jointly by the competent health department under the State Council and other relevant departments under the State Council. The list of large medical equipment shall be submitted by the department in charge of health under the State Council in consultation with the relevant departments under the State Council and shall be implemented after being submitted to the State Council for approval.

Article 49 The medical device users shall dispose of the re-used medical devices in accordance with the regulations on disinfection and control formulated by the competent health department under the State Council.

Disposable medical devices shall not be reused, and those that have been used shall be destroyed and recorded in accordance with relevant provisions of the State. The list of disposable medical devices shall be formulated, adjusted and promulgated by the pharmaceutical supervisory and administrative department under the State Council jointly with the health department under the State Council. The medical devices listed in the list of disposable use shall have sufficient evidential reasons for not being able to be reused. Medical devices that can be reused to ensure safety and effectiveness shall not be included in the catalogue of disposable medical devices. For medical devices that can be guaranteed safe and effective by repeated use after improvement in design, production process, disinfection and sterilization technology, etc., the list of disposable medical devices shall be adjusted to allow repeated use.

Article 50 unit using medical devices to be regular inspection, testing, calibration, maintenance, maintenance of medical apparatus and instruments, shall be conducted in accordance with the requirements of the product manual inspection, testing, calibration, maintenance, maintenance and record, timely analysis, evaluation, ensure the medical equipment in good condition, ensure quality of use; For large medical devices with a long service life, a file shall be set up for each device to record its use, maintenance, transfer and actual use time, etc. The record keeping period shall not be less than 5 years after the expiration of the prescribed service period of the medical device.

Article 51 The medical device users shall properly keep the original data of the purchased medical devices of Category III, and ensure that the information is traceable.

Where large medical devices and implanted and interventional medical devices are used, the name, key technical parameters and other information of the medical devices as well as the necessary information closely related to the quality and safety of use shall be recorded in the medical records and other relevant records.

Article 52 Where any medical device used is found to have potential safety hazards, the medical device user shall immediately stop using the device and notify the registrant or the record holder of the medical device or any other institution responsible for product quality to

carry out overhaul. Medical instruments that still cannot meet the safety standards for use after overhaul shall not be allowed to continue to be used.

Article 53 For in vitro diagnostic reagents with products of the same variety not yet on the market in China, qualified medical institutions may, according to the clinical needs of their own units, develop them by themselves and use them in their own units under the guidance of medical practitioners. Specific control measures shall be formulated by the pharmaceutical supervisory and administrative department under the State Council jointly with the department in charge of health under the State Council.

Article 54 The departments responsible for drug supervision and administration and the competent health departments shall, according to their respective duties, supervise and administer the quality of medical devices and the use behavior of medical devices in the use link respectively.

Article 55 Medical device trading enterprises and users shall not operate or use medical devices that have not been registered or put on record according to law, have no qualified certification documents, or have expired, invalid or eliminated.

Article 56 When transferring in-use medical devices between medical device users, the transferor shall ensure the safety and effectiveness of the transferred medical devices, and shall not transfer any medical devices that are expired, invalid, obsolete or fail to pass the inspection.

Article 57 Imported medical devices shall be medical devices that have been registered or put on record in accordance with the provisions of Chapter II of this Regulation.

Imported medical devices shall have instructions and labels in Chinese. The instructions and labels shall comply with the provisions of the Regulations and the requirements of relevant mandatory standards, and the instructions shall indicate the place of origin of the medical devices and the name, address and contact information of the domestic enterprise legal person designated by the foreign registrant or record holder of the medical devices. Where there is no instruction manual or label in Chinese or the instruction manual or label does not conform to the provisions of this Article, it shall not be imported.

Where medical institutions urgently need to import a small amount of Category II or III medical devices for clinical purposes, they may import such devices with the approval of the drug regulatory department under the State Council or the people's governments of provinces, autonomous regions or municipalities directly under the Central Government authorized by the State Council. Imported medical devices shall be used for specific medical purposes in designated medical institutions.

It is forbidden to import expired, invalid, obsolete and other medical devices that have been used.

Article 58 Entry-exit inspection and quarantine institutions shall conduct inspection on imported medical devices according to law; Those failing to pass the inspection shall not be imported.

The drug regulatory department under the State Council shall timely notify the state entry-exit inspection and quarantine department of the registration and archival filing of imported medical devices. The entry-exit inspection and quarantine institution of the place where the import port is located shall timely inform the department in charge of drug supervision and administration of the people's government of the city divided into districts where the port is located of the clearance of imported medical devices.

Article 59 An enterprise exporting medical devices shall ensure that its exported medical devices meet the requirements of the importing country (region).

Article 60 The contents of an advertisement for a medical device shall be true and legal, and shall be subject to the instructions of the medical device registered or put on record by the department in charge of drug supervision and administration, and shall not contain any false, exaggerated or misleading contents.

Before publishing the advertisement of medical devices, the advertisement examination organs appointed by the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall examine the advertisement contents and obtain the approval document number of the advertisement of medical devices. No release without censorship.

The drug regulatory department of the people's government at or above the provincial level shall order the suspension of the production, import, marketing and use of medical devices, and shall not publish advertisements concerning the medical devices during the suspension period.

The examination measures for advertisements of medical devices shall be formulated by the market supervision and administration department of the State Council.

Chapter V Treatment of Adverse Events and Recall of Medical Devices

Article 61 The State establishes a medical device adverse event monitoring system to collect, analyze, evaluate and control adverse medical device events in a timely manner.

Article sixty-two of the registrant of medical equipment, for the record shall be set up medical device adverse event monitoring system, with its products that meet the needs of adverse events monitoring institutions and personnel, active adverse events monitoring of their products, and in accordance with the provisions stipulated by the pharmaceutical supervisory and administrative department under the State Council, report to the medical device adverse event monitoring technology organization investigation, analysis, evaluation, risk control, and so on and so forth.

The production and trading enterprises and users of medical devices shall assist the registrants and record holders of medical devices to carry out adverse event monitoring of the medical devices they produce, trade or use. Where adverse events or suspicious adverse events of medical devices are discovered, a report shall be made to the technical institution for monitoring adverse events of medical devices in accordance with the provisions of the drug regulatory department under the State Council.

Other units and individuals shall have the right to report adverse events or suspicious adverse events of medical devices to the departments responsible for drug supervision and administration or the technical institutions for monitoring adverse events of medical devices.

Article 63 The drug regulatory department under the State Council shall strengthen the construction of the monitoring information network for adverse medical device events.

The medical device adverse event monitoring technical institution shall strengthen the information monitoring of medical device adverse event, and actively collect the information of adverse event; If any adverse event is discovered or reported, it shall be verified in time, investigated, analyzed and evaluated when necessary, and shall be reported to the department in charge of drug supervision and administration and the department in charge of health and put forward suggestions for handling it.

The medical device adverse event monitoring technical institution shall publish the contact information so as to facilitate the medical device registrants, record holders, production and operation enterprises and users to report medical device adverse events.

Article 64 The department responsible for drug supervision and administration shall, based on the evaluation results of adverse events of medical devices, promptly take control measures such as issuing warning information and ordering suspension of production, import, distribution and use.

The drug regulatory department of the people's government at or above the provincial level shall, together with the competent health department at the corresponding level and relevant departments, organize the timely investigation and handling of adverse events of medical devices that cause sudden or mass serious injury or death, and organize the strengthening of monitoring of similar medical devices.

The department in charge of drug supervision and administration shall timely inform the competent health department at the same level of the monitoring of adverse events of the medical device users.

Article 65 Medical device registrants, record holders, production and trading enterprises and users shall cooperate with the medical device adverse event investigation carried out by medical device adverse event monitoring technical institutions, drug supervision and administration departments and competent health departments.

Article 66 Under any of the following circumstances, the registrant or record holder of a medical device shall take the initiative to carry out the reevaluation of a listed medical device:

(1) changes in understanding of the safety and effectiveness of medical devices in the light of the development of scientific research;

(2) The results of monitoring and evaluation of adverse events of medical devices indicate that there may be defects in medical devices;

(3) Other circumstances stipulated by the pharmaceutical supervisory and administrative department under the State Council.

The registrant and record holder of a medical device shall, based on the reevaluation result, take corresponding control measures to improve the listed medical device, and change the registration or record according to the provisions. Where the reevaluation results show that the listed medical device cannot guarantee safety and effectiveness, the registrant or record holder of the medical device shall actively apply for cancellation of the registration certificate of the medical device or cancel the record; Where a medical device registrant or record holder fails to apply for the cancellation of the medical device registration certificate or the cancellation of the record, the department in charge of drug supervision and administration shall cancel the medical device registration certificate or the record.

The drug regulatory departments of the people's governments at or above the provincial level shall re-evaluate the listed medical devices based on the monitoring and evaluation of adverse events of medical devices. Where the reevaluation results show that the listed medical device cannot guarantee safety and effectiveness, the medical device registration certificate shall be cancelled or the record of the medical device shall be cancelled.

The department responsible for drug supervision and administration shall promptly publish to the public the cancellation of the registration certificate of medical devices and the cancellation of the record. No medical device whose registration certificate of medical device has been cancelled or whose record has been cancelled shall continue to be produced, imported, operated or used.

Article sixty-seven medical equipment registrant, for the record people found that the production of medical equipment do not conform to the compulsory standards, the product technical requirements for registration or registration, or other defects, it shall immediately stop production, notify the relevant enterprises, the use of units and consumers to stop operation and use, recall has been on sale of medical apparatus and instruments, remedial, destruction, record relevant information, release information, and will be treated as medical device recall and circumstance to responsible for the pharmaceutical supervisory and administrative department and the competent department of health report.

Where the entrusted manufacturing or trading enterprises of medical devices discover that the medical devices produced or operated exist in the circumstances prescribed in the preceding paragraph, they shall immediately stop the production and trading, notify the registrant and the

record holder of the medical devices, and record the circumstances of the suspension of production and trading and notification. The medical device registrant or record holder shall immediately recall the medical device that the medical device registrant or record holder considers to be the medical device that needs to be recalled according to the provisions of the preceding paragraph.

If a medical device registrant, record holder, entrusted manufacturer or distributor fails to recall or stop production or distribution in accordance with the provisions of this Article, the drug regulatory department in charge may order the registrant or distributor to recall or stop production or distribution.

Chapter VI Supervision and Inspection

Article 68 The State establishes a system of professional and professional inspectors to strengthen the supervision and inspection of medical devices.

Article 69 Departments responsible for drug supervision and administration shall strengthen supervision and inspection of the research and development, production and marketing of medical devices as well as the quality of medical devices in the link of use, and focus on the following matters:

(1) Whether the production is organized in accordance with the technical requirements of the product that have been registered or put on record;

(2) Whether the quality management system is maintained in effective operation;

(3) whether the production and operation conditions continuously meet the legal requirements.

When necessary, the department in charge of drug supervision and administration may conduct extended inspection over other relevant units and individuals that provide products or services for the research, production, marketing and use of medical devices.

Article 70 The departments responsible for drug supervision and administration shall have the following functions and powers during supervision and inspection:

(1) Entering the site for inspection and sampling;

(2) to consult, duplicate, seal up or detain relevant contracts, bills, account books and other relevant materials;

(3) Sealing up and detaining the medical devices that do not meet the legal requirements, the spare parts and raw materials illegally used, as well as the tools and equipment used in the illegal production and marketing of medical devices;

(4) Sealing up places engaged in the production and business activities of medical devices in violation of the provisions of these Regulations.

When conducting supervision and inspection, they shall show their law enforcement certificates and keep the business secrets of the units under inspection.

The units and individuals concerned shall cooperate with the supervision and inspection, provide relevant documents and materials, and may not conceal, refuse or obstruct it.

Article 71 Departments in charge of health shall strengthen supervision and inspection over the use of medical devices in medical institutions. When carrying out supervision and examination, they may enter medical institutions to consult and copy relevant archives, records and other relevant materials.

Article 72 If there are hidden risks of product quality and safety in the process of production and marketing of medical devices and no timely measures are taken to eliminate them, the department in charge of drug supervision and administration may take such measures as warning, responsibility interview, ordering rectification within a time limit, etc.

With respect to medical devices that cause harm to human beings or have evidence proving that they may endanger human health, the department in charge of drug supervision and administration may take emergency control measures ordering the suspension of production, import, distribution and use, and issue safety warning information.

Article 73 Departments responsible for drug supervision and administration shall strengthen the spot check and inspection of medical devices produced, traded or used by medical device registrants, record holders, production and trading enterprises and users. No inspection fee or any other fee shall be charged for random inspection and inspection, and the expenses required shall be brought into the budget of the government at the corresponding level. The drug regulatory department of the people's government at or above the provincial level shall timely issue the quality announcement of medical devices on the basis of the conclusion of random inspection.

Departments in charge of health shall supervise and evaluate the use of large medical equipment; In case of illegal use or excessive examination and treatment related to large medical equipment, it shall be corrected immediately and dealt with according to law.

Article 74 If the department responsible for drug supervision and administration fails to timely discover the systemic safety risks of medical devices and fails to timely eliminate the hidden safety risks of medical devices within the supervision and administration area, the people's government at the same level or the department responsible for drug supervision and administration of the people's government at a higher level shall make an interview with its main responsible persons.

Where the local people's government fails to perform its duty of safety of medical devices and fails to eliminate in a timely manner the major regional hidden danger of safety of medical

devices, the people's government at a higher level or the drug supervision and administration department of the people's government at a higher level shall make an interview with its main person-in-charge.

The interviewed departments and local people's governments shall immediately take measures to rectify the supervision and administration of medical devices.

Article 75 The qualification verification of medical device testing institutions shall be uniformly administered in accordance with the relevant provisions of the State. The inspection institutions confirmed by the certification and accreditation supervisory and administrative department of the State Council together with the pharmaceutical supervisory and administrative department of the State Council may carry out the inspection of medical devices.

Where the department in charge of drug supervision and administration needs to conduct inspection on medical devices in the course of law enforcement, it shall entrust a qualified medical device inspection institution to conduct inspection and pay the relevant expenses.

If the party concerned disagrees with the inspection conclusion, it may, within 7 working days from the date of receipt of the inspection conclusion, submit an application for re-inspection to the department conducting sampling inspection or the department in charge of drug supervision and administration at the next higher level, and the department accepting the re-inspection application shall randomly designate the re-inspection agencies in the list of re-inspection agencies for re-inspection. The medical device inspection institution that undertakes the re-inspection shall make a re-inspection conclusion within the time limit prescribed by the drug regulatory department under the State Council.The reinspection conclusion shall be the final inspection conclusion. The re-inspection organization and the preliminary inspection organization may not be the same organization. If there is only one qualified inspection institution for the relevant inspection items, the department or personnel in charge shall be changed during the re-inspection. The list of re-inspection institutions shall be published by the drug regulatory department under the State Council.

Article seventy-six for possible hazardous substances or unauthorised changes to the medical device design, raw materials and the safety of medical apparatus and instruments, production process and according to the regulations of the medical equipment national standards, industry standards of inspection items and test methods can't inspection, medical device testing institutions can use approved by the pharmaceutical supervisory and administrative department under the State Council added inspection items and inspection methods; The test conclusions drawn by the use of supplementary test items and test methods may be taken as the basis for the department responsible for drug supervision and administration to determine the quality of medical devices.

Article 77 The market supervision and administration departments shall, in accordance with the provisions of the relevant laws and administrative regulations on the administration of advertisements, supervise and inspect the advertisements of medical devices, and investigate and deal with illegal acts.

Article 78 The department in charge of drug supervision and administration shall, through the online government affairs service platform of the drug supervision and administration department under the State Council, promptly publish daily supervision and administration information such as medical device licensing, filing, random inspection and testing, and investigation and punishment of illegal acts, according to law. However, they shall not divulge the business secrets of the parties concerned.

Departments responsible for drug supervision and administration shall establish credit files of medical device registrants, record holders, production and business enterprises and users, increase the frequency of supervision and inspection for those with bad credit records, and strengthen punishment for trust-breaking according to law.

Article 79 The departments responsible for drug supervision and administration and other departments shall publish their contact information and accept consultation, complaints and informants. The departments responsible for drug supervision and administration and other departments shall promptly reply to any consultation related to the supervision and administration of medical devices as received; Upon receipt of complaints and reports, they shall promptly verify, handle and reply to them. Records shall be kept of the consultation, complaint and report, as well as the answers, verification and handling thereof.

If the informant concerning the research, production, marketing and use of medical devices is verified through investigation, the department in charge of drug supervision and administration shall reward the informant. The departments concerned shall keep secret the informant.

Article 80 The drug regulatory department under the State Council shall publicly solicit opinions when formulating, adjusting and revising the list as provided for in these Regulations and the standards related to the supervision and administration of medical devices. The opinions of experts, registrants, record holders, production and operation enterprises, users, consumers, trade associations and relevant organizations were heard in the form of hearing and demonstration meeting.

Chapter VII Legal Liability

Article 81 Under any of the following circumstances, the department in charge of drug supervision and administration shall confiscate the illegal gains, medical devices and instruments used in illegal production and marketing, and tools, equipment, raw materials and other articles used in illegal production and marketing. Where the value of medical devices illegally produced and operated is less than 10,000 yuan, a fine of not less than 50,000 yuan but not more than 150,000 yuan shall be imposed; If the value of the goods is more than 10,000 yuan, a fine between 15 times and 30 times the value of the goods shall also be imposed;If the circumstances are serious, order to suspend production or business operation, 10 years not to accept the unit and put forward relevant licensing applications, medical devices for illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained 30% above 3 times the following amerce, life-long ban its engaged in medical equipment production and business operation activities:

(1) Class II and Class III medical devices that are produced or sold without a medical device registration certificate;

(2) Engaging in the production of Category II and III medical devices without permission;

(3) Engaging in business activities of Category III medical devices without permission.

If the circumstances and circumstances in the first paragraph of the preceding paragraph are serious, the original license-issuing department shall revoke the medical device production license or medical device business license.

Article 82 Whoever allocates and uses large medical equipment without permission shall be ordered by the competent health department of the people's government at or above the county level to stop the use, give a warning and confiscate his illegal gains; If the illegal gains are less than 10,000 yuan, a fine of not less than 50,000 yuan but not more than 100,000 yuan shall be imposed;If the illegal income is more than 10,000 yuan, a fine of not less than 10 times but not more than 30 times the illegal income shall be imposed concurrently;If the circumstances are serious, don't accept those responsible for five years as well as the unit is put forward for large medical equipment allocation permission, for illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained 30% above 3 times the following amerce, given sanctions in accordance with the law.

Article eighty-three when applying for administrative licensing medical devices to provide false information or take other tricks, no administrative license, has made the administrative licensing, by administrative licensing decision department revocation of administrative license, confiscate the illegal income and the illegal use of medical equipment in production and management, 10 years not to accept the relevant responsible persons and the medical device license application submitted unit; Where the value of medical devices used in illegal production and operation is less than 10,000 yuan, a fine of between 50,000 yuan and 150,000 yuan shall also be imposed;If the value of the goods is more than 10,000 yuan, a fine between 15 times and 30 times the value of the goods shall also be imposed;If the circumstances are serious, order to suspend production or business operation for illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained 30% above 3 times the following amerce, life-long ban its engaged in medical equipment production and operation activities.

In case of forging, altering, trading, leasing or lending licenses for medical devices, the original license-issuing department shall confiscate or revoke the illegal income; If the illegal gains are less than 10,000 yuan, a fine of not less than 50,000 yuan but not more than 100,000 yuan shall be imposed; If the illegal income is more than 10,000 yuan, a fine of not less than 10 times but not more than 20 times the illegal income shall be imposed concurrently;If the act constitutes a violation of the administration of public security, the public security organ shall impose penalties for the administration of public security according to law.

Article 84 Under any of the following circumstances, the department in charge of drug supervision and administration shall announce to the public the name of the unit and the product, and order it to make corrections within a time limit; If it fails to make corrections within the time limit, the illegal income and the medical devices illegally produced and sold shall be confiscated; Where the value of the medical devices illegally produced and operated is less than 10,000 yuan, a fine of not less than 10,000 yuan but not more than 50,000 yuan shall also be imposed; If the value of the goods is more than 10,000 yuan, a fine of 5 times to 20 times the value of the goods shall be imposed concurrently;If the circumstances are serious, the legal representative, main person-in-charge, directly responsible person-in-charge and other responsible persons of the illegal entity shall be confiscated of the income obtained from the entity during the period of the illegal act, be fined more than 30% and less than twice the income obtained, and be prohibited from engaging in the production and business activities of medical devices for five years:

(1) The production or marketing of Category I medical devices without record;

(2) Engaging in the production of Category I medical devices without archival filing;

(3) The business of Category II medical devices shall be put on record but fails to do so;

(4) The materials already on record do not meet the requirements.

Article 85 Where false materials are provided during archiVAL filing, the department in charge of pharmaceutical supervision and administration shall make public the archiVAL filing unit and the name of the product, confiscate the illegal income and the medical devices illegally produced and sold. Where the value of medical devices illegally produced and operated is less than 10,000 yuan, a fine of not less than 20,000 yuan but not more than 50,000 yuan shall also be imposed;If the value of the goods is more than 10,000 yuan, a fine of 5 times to 20 times the value of the goods shall be imposed concurrently;If the circumstances are serious, order to suspend production or business operation for illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained 30% above 3 times the following amerce, banned its 10 years engaged in medical equipment production and operation activities.

Article 86 Under any of the following circumstances, the department in charge of drug supervision and administration shall order a correction and confiscate the medical devices used in illegal production and marketing; Where the value of medical devices used in illegal production and operation is less than 10,000 yuan, a fine of not less than 20,000 yuan but not more than 50,000 yuan shall also be imposed; If the value of the goods is more than 10,000 yuan, a fine of 5 times to 20 times the value of the goods shall be imposed concurrently;If the circumstances are serious, order to suspend production or business operation, until revoked by the original license issuing department registration certificate of medical equipment, medical equipment production license, medical equipment business licenses, the illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained

30% above 3 times the following amerce, banned its 10 years engaged in medical equipment production and business operation activities:

(1) The production, marketing or use of medical devices that do not meet mandatory standards or do not meet the technical requirements for products registered or filed;

(2) Failure to organize production in accordance with the technical requirements for products that have been registered or put on record, or failure to establish a quality management system and maintain effective operation in accordance with the provisions of these Regulations, which affects the safety and effectiveness of products;

(3) Operating or using medical devices without qualified certificates, expired, invalid or obsolete, or using medical devices that have not been legally registered;

(4) Refusing to stop the production, import or sale of medical devices after being ordered to do so by the department in charge of drug supervision and administration, or refusing to stop the production, import or sale of medical devices after being ordered to stop or suspend the production, import or sale by the department in charge of drug supervision and administration;

(5) Entrust the production of medical devices to an enterprise that does not meet the conditions prescribed in these Regulations, or fail to administer the production acts of the entrusted manufacturer;

(6) the import of expired, invalid, obsolete and other medical devices that have been used.

Article eighty-seven of the medical equipment management enterprise, the use of units to fulfil the obligations such as the incoming inspection of these regulations, have sufficient evidence to prove that they don't know the management, use of medical apparatus and instruments for the regulations in the first paragraph of the first paragraph of article eighty-one, article eighty-four in the first paragraph, and the third paragraph of article eighty-six, paragraph 1 of the situation of medical apparatus and instruments, and can truthfully explain the source of replenish onr's stock, confiscate its management, use of do not conform to the legal requirements of medical apparatus and instruments, can be exempted from administrative penalty.

Article 88 In any of the following circumstances, the department in charge of drug supervision and administration shall order a correction and impose a fine of not less than 10,000 yuan but not more than 50,000 yuan; If he refuses to make corrections, he shall be imposed a fine of not less than 50,000 yuan but not more than 100,000 yuan;If the circumstances are serious, order to suspend production or business operation, until revoked by the original license issuing department of medical equipment production license, medical equipment business licenses, the illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained by more than 30%, 2 times the following amerce, banned its engaged in medical equipment production and business operation activities within five years:

(1) The production conditions change, no longer meet the requirements of the quality management system of medical devices, fail to rectify, stop production and report in accordance with the provisions of these Regulations;

(2) Medical devices whose production or business specifications and labels do not conform to the provisions of these Regulations;

(3) Failing to transport or store medical devices in accordance with the specifications and labels of medical devices;

(4) Transfer of in-use medical devices that are expired, invalid, eliminated or fail to pass the inspection.

Article 89 Under any of the following circumstances, the department in charge of drug supervision and administration and the department in charge of health shall, according to their respective functions and duties, order a correction and give a warning; If he refuses to make corrections, he shall be imposed a fine of not less than 10,000 yuan but not more than 100,000 yuan; If the circumstances are serious, the violator shall be ordered to stop production and business until the original license-issuing department revoke the medical device registration certificate, medical device production license and medical device business license, and the legal representative, main person-in-charge, directly responsible person-in-charge and other responsible personnel of the violator shall be fined not less than 10,000 yuan but not more than 30,000 yuan:

(1) Fail to submit the self-inspection report of the quality management system as required;

(2) Purchasing medical devices from a supplier who is not legally qualified;

(3) Failing to establish and implement a medical device purchase inspection record system according to the provisions of these Regulations;

(4) Business enterprises engaged in the wholesale business of Category II and Category III medical devices and the retail business of Category III medical devices fail to establish and implement a sales record system in accordance with the provisions of these Regulations;

(5) medical equipment registrant, for the record, the production and operation enterprises, use the unit is not in accordance with these regulations in medical device adverse event monitoring, did not report adverse events in accordance with the requirements, or responsible for the medical device adverse event monitoring technology institutions, pharmaceutical supervisory and administrative department, adverse events survey conducted by the competent department of health shall not cooperate;

(6) The registrant and record holder of medical devices fail to formulate post-listing research and risk control plans and ensure their effective implementation in accordance with relevant provisions;

(7) The registrant or record holder of the medical device fails to establish and implement the product traceability system in accordance with the provisions;

(8) The registrants, record holders or trading enterprises of medical devices fail to notify the department in charge of drug supervision and administration in accordance with relevant provisions when they engage in online sales of medical devices;

(9) For the medical devices that need regular inspection, inspection, calibration, maintenance and maintenance, the user unit of the medical devices fails to inspect, test, calibrate, maintain and record the medical devices according to the requirements of the product specifications, and timely conducts analysis and evaluation to ensure that the medical devices are in good condition;

(10) The medical device user fails to properly preserve the original materials of the medical devices of Category III purchased.

Article 90 Under any of the following circumstances, the department in charge of health under the people's government at or above the county level shall order it to make corrections and give it a warning; If he refuses to make corrections, he shall be imposed a fine of not less than 50,000 yuan but not more than 100,000 yuan; If the circumstances are serious, a fine of less than 100000 yuan of above 300000 yuan, shall be ordered to suspend the relevant medical devices using activity, until revoked by the original license issuing department practice license, in accordance with the law shall be ordered to relevant responsible suspended under 6 months above 1 year's practice activities, until revoked by the original license issuing department relevant personnel, practice certificate of the legal representative of the illegal units, principal, directly responsible person in charge and other responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained 30% above 3 times the following amerce, given sanctions in accordance with the law:

(1) With regard to the reused medical devices, the user unit of the medical devices fails to dispose of them in accordance with the provisions on disinfection and management;

(2) The medical device user unit reuses the disposable medical devices or fails to destroy the used disposable medical devices according to provisions;

(3) The medical device user unit fails to record the information of large medical devices and implanted and interventional medical devices in the medical records and other relevant records in accordance with the provisions;

(4) The medical device user fails to stop the use of the medical devices immediately after discovering that the medical devices used have hidden safety hazards, or notifies the user for overhaul, or continues to use the medical devices that fail to meet the safety standards for use after overhaul;

(5) The use of large medical equipment by the medical device users fails to guarantee the quality and safety of medical treatment.

Article 91 Those who import medical devices in violation of the relevant laws and administrative regulations on import and export commodity inspection shall be dealt with by the entry-exit inspection and quarantine authorities according to law.

Article ninety-two provide service for medical device network trade e-commerce platform operators in violation of the provisions of these regulations, did not fulfil to real-name registration of the net medical equipment operators, review, licensing, registration for the record, stop and report illegal behavior, stop the Internet trading platform services such as the obligation of management, by the responsible for the pharmaceutical supervisory and administrative departments in accordance with the electronic commerce of the People's Republic of China law rules to give punishment.

Article 93 Where a clinical trial is carried out without filing in a clinical test institution for medical devices, the department in charge of drug supervision and administration shall order it to stop the clinical trial and make corrections; In case of refusal to make corrections, the clinical trial data shall not be used for product registration or filing, shall be imposed a fine of not less than 50,000 yuan but not more than 100,000 yuan, and shall be published to the public;Thereby causing serious consequences, 5 year ban on its relevant professional medical device clinical trials, and be fined between RMB 300000 yuan and 100000 yuan, by the competent department of health for illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained 30% above 3 times the following amerce, given sanctions in accordance with the law.

Where a clinical trial applicant carries out a clinical trial without filing for the record, the department in charge of drug supervision and administration shall order the applicant to stop the clinical trial, impose a fine of not less than 50,000 yuan but not more than 100,000 yuan on the applicant, and make an announcement to the public; If serious consequences are caused, a fine of not less than 100,000 yuan but not more than 300,000 yuan shall be imposed.The clinical trial data shall not be used for product registration and filing, and medical device registration applications submitted by relevant responsible persons and units shall not be accepted within 5 years.

Where an applicant of a clinical trial carries out a clinical trial of Category III medical devices with a high risk to human beings without approval, the department in charge of drug supervision and administration shall order the applicant of a clinical trial to stop the clinical trial immediately, impose a fine of not less than RMB 100,000 yuan but not more than RMB 300,000 yuan on him, and make an announcement to the public; If serious consequences are caused, a fine of not less than 300,000 yuan but not more than 1 million yuan shall be imposed.The clinical trial data shall not be used for product registration, 10 years not to accept the relevant responsible persons and units of medical apparatus and instruments for clinical trials and registration, the illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and be fined income obtained 30% above 3 times the following.

Article 94 Where a medical device clinical test institution conducts a clinical test of medical devices without complying with the standards for the quality control of clinical test, the department in charge of drug supervision and administration shall order it to make corrections or immediately stop the clinical test, and impose a fine of not less than 50,000 yuan but not more than 100,000 yuan; Thereby causing serious consequences, 5 year ban on its relevant professional medical device clinical trials, by the competent department of health for illegal unit, legal representative, principal responsible person in charge and other directly responsible, confiscate the illegal behavior occurs during the income obtained from the unit, and the income obtained 30% above 3 times the following amerce, given sanctions in accordance with the law.

Article 95 Where a medical device clinical test institution issues a false report, the department in charge of drug supervision and administration shall impose a fine of not less than 100,000 yuan but not more than 300,000 yuan; The illegal gains, if any, shall be confiscated;It will be banned from conducting clinical trials of related professional medical devices within 10 years;The department in charge of health shall confiscate the legal representative, the principal person-in-charge, the directlyresponsible person-in-charge and other responsible persons of the unit in violation of the law, confiscate the income obtained from the unit during the period of the violation of the law, impose a fine of more than 30% and less than three times the income obtained, and impose sanctions according to law.

Article 96 Where a medical device inspection institution issues a false inspection report, the inspection qualification shall be revoked by the competent department that granted the qualification, the application for qualification verification submitted by the relevant responsible person or unit shall not be accepted within 10 years, and a fine of not less than RMB 100,000 yuan but not more than RMB 300,000 yuan shall be imposed; The illegal gains, if any, shall be confiscated; The legal representative, the principal person-in-charge, the directlyresponsible person-in-charge and other responsible persons of the law-breaking entity shall be confiscated of the income obtained from the entity during the period when the law-breaking entity is committed, and shall be fined not less than 30% but not more than three times the income obtained, and shall be punished according to law;Those who are dismissed shall be prohibited from engaging in the examination of medical devices within 10 years.

Article 97 Whoever violates the provisions of these Regulations on the administration of the advertisement of medical devices shall be punished in accordance with the provisions of the Advertisement Law of the People's Republic of China.

Article 98 Where a domestic enterprise legal person designated by an overseas medical device registrant or record holder fails to fulfill relevant obligations in accordance with the provisions of these Regulations, the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government shall order it to make corrections, give it a warning and impose a fine of not less than 50,000 yuan but not more than 100,000 yuan. If the circumstances are serious, they shall be fined between RMB 100,000 yuan and RMB 500,000 yuan, and shall be prohibited from engaging in the production and business of medical devices within 5 years by their legal representative, principal person-in-charge, directly responsible person-in-charge and other responsible personnel.

Where an overseas registrant or record holder of medical devices refuses to implement the administrative punishment decision made according to these Regulations, the import of such medical devices shall be prohibited within 10 years.

Article 99 Where a research and development, production and marketing unit of medical devices or a testing institution, in violation of the provisions of these Regulations, employs personnel who are prohibited from engaging in the production and marketing activities and testing work of medical devices, the department in charge of drug supervision and administration shall order correction and give a warning; Those who refuse to make corrections shall be ordered to suspend production or business operations until their license is revoked.

Article 100 Where a medical device technical evaluation institution or a medical device adverse event monitoring technical institution fails to perform its duties in accordance with the provisions of these Regulations, resulting in a major error in the evaluation and monitoring work, the drug regulatory department in charge shall order it to make corrections, circulate a notice of criticism and give a warning; Where serious consequences have been caused, the legal representative, the principal person-in-charge, the directly responsible person-in-charge and other responsible persons of the law-breaking unit shall be given sanctions according to law.

Article 101 Any functionary of the department in charge of drug supervision and administration or other relevant departments who, in violation of the provisions of these Regulations, abuses his power, neglects his duty or engages in malpractices for personal gain shall be punished according to law.

Article 102 Whoever violates the provisions of these Regulations and constitutes a crime shall be investigated for criminal responsibility according to law; If it causes personal, property or other damage, it shall be liable for compensation according to law.

Chapter VIII Supplementary Provisions

Article 103 Definition of the following terms used in these Regulations:

Medical instruments refer to instruments, equipment, instruments, in vitro diagnostic reagents, calibrators, materials and other similar or related articles directly or indirectly used in the human body, including the necessary computer software; Its effect is primarily obtained by physical means rather than pharmacological, immunological or metabolic means, or it is involved in these means but only plays a supporting role; Its objectives are:

(1) diagnosis, prevention, monitoring, treatment or remission of a disease;

(2) diagnosis, monitoring, treatment, remission or functional compensation of injury;

(3) examination, substitution, regulation or support of physiological structures or processes;

(4) life support or maintenance;

(5) control of pregnancy;

(6) to provide information for medical or diagnostic purposes through examination of samples from the human body.

A medical device registrant or record holder refers to an enterprise or research and development institution that has obtained a medical device registration certificate or gone through record-keeping for medical devices.

Medical device users refer to institutions that use medical devices to provide medical and other technical services to others, including medical institutions, family planning technical service institutions, blood stations, single-collection plasma stations, and institutions for adapting rehabilitation AIDS.

Large medical equipment refers to the large medical equipment with complicated technology, large capital input, high operating cost, great influence on medical expenses and included in the catalogue management.

Article 104 fees may be charged for the registration of medical device products. Specific fee items and standards shall be formulated separately by the finance and price departments under the State Council in accordance with the relevant provisions of the State.

Article 105 Measures for the control of medical devices and devices developed by medical and health institutions in response to public health emergencies shall be formulated jointly by the drug regulatory department under the State Council and the department in charge of health under the State Council.

The storage, allocation and supply of non-profit contraceptive medical devices shall comply with the administrative measures formulated by the competent health department under the State Council jointly with the drug regulatory department under the State Council.

The technical guiding principles for TCM medical devices shall be formulated jointly by the pharmaceutical regulatory department under the State Council and the administrative department of TCM under the State Council.

Article 106 The supervision and administration of the use of military medical instruments shall be carried out in accordance with these Regulations and the relevant provisions of the armed forces.

Article 107 These Regulations shall enter into force as of June 1, 2021.