Order of the State Council of the People's Republic of China

No. 739

The Regulations on the Supervision and Administration of Medical Devices, which were revised and approved at the 119th executive meeting of the State Council on December 21, 2020, are hereby announced and shall come into force on June 1, 2021.

Premier: Li Keqiang
February 9, 2021

Regulations on the Supervision and Administration of Medical Devices

(Order No. 276 of the State Council of the People's Republic of China was released on January 4, 2000. Order No. 276 was revised and approved at the 39th Executive Meeting of the State Council on February 12, 2014. It was revised according to the Decision of the State Council on Amending the Regulations on the Supervision and Administration of Medical Devices on May 4, 2017. It was revised and approved at the 119th executive meeting of the State Council on December 21, 2020)

Chapter I General Regulation

Article 1 In order to ensure the safety and effectiveness of medical devices, protect human health and life safety, and improvement the development of the medical device industry, these regulations are released.

Article 2 These regulations shall apply to all activities of research and study, development, production, operation, use and supervision of medical devices domestic of the People's Republic of China.

Article 3 The State Council's Drug Administration Department is responsible for the supervision and administration of medical devices nationwide.

The relevant departments of the State Council are responsible for the supervision and management of medical devices within their respective responsibilities.

Article 4 The local government at or above the county level shall strengthen the leadership of the medical device supervision and management work in its administrative area, organize and coordinate the medical device supervision and management work and emergency response within the administrative area, and strengthen the build of medical device supervision and management capabilities. Provide guarantee for the safety of medical equipment.

The departments responsible for drug supervision and management of local people's governments at or above the county level are responsible for the supervision and management of medical devices in their respective administrative regions. The relevant departments of the local people's governments at or above the county level are responsible for the supervision and management of medical devices within their respective responsibilities.

Article 5 Medical device supervision and management shall follow the principles of risk management, full-process control, scientific supervision, and social co-governance.

Article 6 The state implements classified management of medical devices according to the degree of risk.

Class I Device is low-risk medical devices that implements routine management which can ensure their safety and effectiveness.

Class II Device is moderate risk medical devices that requires strict control and management to ensure their safety and effectiveness.

Class III Device is higher risk medical devices that requires special measures to strictly control and manage them to ensure their safety and effectiveness.

To evaluate the risk level of a medical device, factors such as the intended use, structural characteristics, and use method of the medical device should be considered.

The State Council's drug regulatory department is responsible for formulating the classification rules and classification catalogs of medical devices, and according to the production, operation and use of medical devices, timely analysis and evaluation of the risk changes of medical devices, and

adjustments to the classification rules and classification level. To define and adjust classification rules and classification level, the opinions of medical device registrants, recorders, production and operation enterprises, user units, and industry organizations should be fully listened to, and the practice of international medical device classification should be referred to. The classification rules and classification level of medical devices shall be published to the public.

Article 7 Medical device products shall comply with the mandatory national standards for medical devices; if there are no mandatory national standards, they shall comply with the mandatory industry standards for medical devices.

Article 8 The state sets up plans and policies for the medical device industry, incorporates medical device innovation into the development focus, prioritizes the review 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 of the State Council shall cooperate with the relevant departments of the State Council to implement the national medical device industry planning and guiding policies.

Article 9 The state shall improve the medical device innovation system, support the basic research and application research of medical devices, promote the promotion and application of new medical device technologies, and provide support in scientific and technological projects, financing, credit, bidding and procurement, and medical insurance. Support enterprises to establish or jointly establish research and development institutions, encourage enterprises to cooperate with universities, scientific research institutes, medical institutions, etc. to carry out research and innovation of medical devices, strengthen intellectual property protection of medical devices, and improve independent innovation capabilities of medical devices.

Article 10 The state strengthens the informatization of medical device supervision and management, improves the level of online government services, and facilitates the administrative licensing and filing of medical devices.

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

Article 12 Medical Device company and individuals that have made outstanding contributions to the research and innovation of medical devices

shall be commended and rewarded in accordance with relevant national regulations.

Chapter II Medical device product registration and filing

Article 13 Product filing management is implemented for Class I medical devices, and product registration management is implemented for Class II and Class III medical devices.

Medical device applicant and record holders shall strengthen the quality management of the entire life cycle of medical devices and shall be responsible for the safety and effectiveness of medical devices in the entire process of development, production, operation, and use according to law.

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

(1) Product risk analysis data,

(2) Product technical requirements,

(3) Product inspection report,

(4) Clinical evaluation data,

(5) Product IFU and label samples,

(6) Quality management system documents related to product research and development, production.

(7) Other materials needed to prove that the product is safe and effective.

The product inspection report shall meet the requirements of the drug regulatory department of the State Council. It may be a self-inspection report of the medical device by registration applicant or filing person, or an inspection report issued by a qualified medical device inspection agency.

Those which meet the requirements of Article 24 of to be exempt from clinical evaluation may be exempt to submit clinical evaluation materials.

Medical device registration applicants and recorders shall ensure that the materials submitted are legal, true, accurate, completely and traceable.

Article 15 For the filing of Class I medical device products, the filing personnel shall submit the filing materials to the department in charge of drug supervision and management of the municipal people's government with districts.

For overseas recorders that export Class I medical devices to People Republic of China, the domestic company or legal personnel designated by the oversea medical device company shall submit the record materials and certification documents of the competent authority of the country (region) where the recorder is located to approve the sale of the medical device to the State Council's drug regulatory authority. Innovative medical devices that have not been listed overseas may not be required to submit a certification document that the competent authority of the country (region) where the recorder is located allows the medical device to be marketed.

The filing personnel shall complete the filing after submitting the filing materials in compliance with these regulations to the department in charge of drug supervision and administration. The department in charge of drug supervision and administration shall, within 5 working days from the date of receipt of the filing materials, announce the filing-related information to the public through the online government service platform of the drug supervision and administration department of the State Council.

If there are changes in the matters stated in the filing materials, the filing shall be changed to the original filing department.

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 authority of the State Council.

For overseas registration applicants who export Class II and Class III medical devices to the People of Republic China, the domestic company or legal personnel designated by oversea medical device company shall submit the registration application materials to the drug regulatory authority of the State Council and sale permit approved by the competent authority of the country (region) where the registration applicant is located. Innovative medical devices that have not been listed overseas may not be required to submit sale permit approved by the competent authority of the country (region) where the registration applicant is located.

The drug regulatory authority under the State Council shall make provisions on the procedures and requirements for medical device registration review, and strengthen the supervision and guidance of the drug regulatory authority of the people's government of provinces, autonomous regions, and municipalities directly under the Central Government.

Article 17 The drug regulatory authority who accepts the registration application shall review the safety and effectiveness of the medical device, as well as the registration applicant's ability to ensure the safety and effective quality management of the medical device.

The drug regulatory authority who accepts the registration application shall forward the registration application materials to the technical review agency within 3 working days from the date of acceptance of the registration application. The technical review agency shall submit the review comments to the drug regulatory authority that accepts the registration application as the basis for review and approval after completing the technical review.

When the drug regulatory authority who accepts the registration, if considers it necessary to verify the quality management system when organizing the technical review of the medical device, it shall organize the quality management system verification.

Article 18 The drug regulatory authority who accepts the registration application shall decide within 20 working days from the date of receipt of the review opinion. For those that meet the conditions, the registration shall be approved, and a medical device registration certificate shall be issued; for those that do not meet the conditions, the registration shall not be granted, and the reasons will be given in writing.

The drug regulatory authority that accepts the registration application shall, within 5 working days from the date of approval of the registration of the medical device, announce the registration-related information to the public through the online government service platform of the drug regulatory authority of the State Council.

Article 19 For medical devices that are used to treat rare diseases, severely life-threatening diseases without effective treatment, and respond to public health incidents and other urgently needed medical devices, the drug regulatory authority that accepts the registration application may make a conditional approval decision. Relevant matters are stated in the medical device registration certificate.

In the event of a particularly major public health emergency or other emergencies that seriously threaten public health, the health authority of the

State Council shall make recommendations for emergency use of medical devices according to the needs of prevention and control of the incident. After the approval by the drug regulatory authority of the State Council, the Emergency use within the scope and time limit.

Article 20 The registrant applicant and the filing recorder of medical devices personnel shall perform the following obligations:

(1) Establish a quality management system suitable for the product and maintain effective operation,

(2) Set up post-market research and risk management and control plans and ensure their effective implementation,

(3) Conduct monitoring and re-evaluation of adverse events in accordance with the law,

(4) Establish and implement a product traceability and recall system,

(5) Other obligations stipulated by the drug regulatory department of the State Council.

The domestic company or legal personnel designated by the overseas medical device registrant and filing personnel shall assist the registrant and filing party in fulfilling the obligations stipulated in the preceding paragraph.

Article 21 For the registered medical device products of class II and class III, the design, raw materials, production process, scope of application, method of use, etc. have undergone substantial changes, which may affect the safety and effectiveness of the medical device, registration personnel should apply to the original registration department to go through the formalities for registration modification; if other changes occur, they should be filed or reported in accordance with the regulations of the drug regulatory department under the State Council.

Article 22 The effective period of the medical device registration certificate is 5 years. If the registration needs to be renewed after the expiration of the validity period, an application for renewal of the registration shall be submitted to the original registration department 6 months before the expiration of the validity period.

Except for the circumstances specified in the third paragraph of this article, the drug regulatory authority that receives an application for renewal shall make a decision to approve the renewal before the expiration of the

medical device registration certificate. If no decision is made within the time limit, it shall be deemed that the renewal is approved.

In any of the following circumstances, registration shall not be renewed:

(1) Failure to file an application for renewal of registration within the specific time limit,

(2) The mandatory standards for medical devices have been revised, and the medical devices applying for renewal of registration cannot meet the new requirements,

(3) For medical devices approved with conditions, the items specified in the medical device registration certificate have not been completed within the prescribed time limit.

Article 23 For newly developed medical devices that have not yet been included in the classification catalog, the applicant may directly apply for product registration in accordance with the regulations on class III of medical device product registration, or may determine the product category based on the classification rules and apply to the State Council After the drug regulatory authority applies for category confirmation, it applies for product registration or product filing in accordance with the provisions of these regulations.

For directly applying for the registration of Class III medical device products, the drug regulatory department of the State Council shall determine the category according to the degree of risk, and timely include the registered medical devices into the classification catalog. If the application category is confirmed, the drug regulatory department of the State Council shall determine the category of the medical device and notify the applicant within 20 working days from the date of acceptance of the application.

Article 24 The medical device product registration and filing shall be subject to clinical evaluation; however, if one of the following conditions is met, clinical evaluation may be exempted:

(1) The working mechanism is clear, the design is finalized, the production process is mature, the medical devices of the same variety that have been marketed have been used in clinical practice for many years, and there is no record of serious adverse events, and the conventional use is not changed;

(2) Other non-clinical evaluations can prove that the medical device is safe and effective.

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

Article 25 The clinical evaluation of medical devices can be completed according to the product characteristics, clinical risks, existing clinical data, etc., through clinical trials, or through analysis and evaluation of the clinical literature and clinical data of the same variety of medical devices to prove the medical treatment. The equipment is safe and effective.

In accordance with the provisions of the State Council's drug regulatory authority, when conducting clinical evaluation of medical devices, if the existing clinical literature and clinical data are insufficient to confirm the product safety and effectiveness of medical devices, clinical trials should be carried out.

Article 26 The clinical trials of medical devices shall be conducted in clinical trial institutions with corresponding conditions in accordance with the requirements of the quality management standards for medical device clinical trials, and shall be reported to the people's government of the province, autonomous region, and municipality where the clinical trial sponsor is located. Department record. The drug supervision and administration department that accepts clinical trial filing shall notify the drug supervision and administration department and the health authority at the same level where the clinical trial institution is located.

Medical device clinical trial institutions shall implement record management. The conditions that a medical device clinical trial institution should have, as well as the filing management measures and clinical trial quality management specifications, shall be formulated and announced by the drug regulatory authority of the State Council in conjunction with the health authority of the State Council.

The state supports medical institutions to carry out clinical trials, incorporates the evaluation of clinical trial conditions and capabilities into the level review of medical institutions, and encourages medical institutions to carry out clinical trials of innovative medical devices.

Article 27 If the clinical trials of Class III medical devices have a higher risk to the human body, it shall be approved by the drug regulatory department of the State Council. When examining and approving clinical trials, the drug regulatory authority of the State Council shall conduct a comprehensive analysis of the device and professionals of the institution that intends to undertake clinical trials of medical devices, the risk level of the medical devices, clinical trial implementation plans, and comparative analysis reports of clinical benefits and risks , And make a decision and notify the

clinical trial sponsor within 60 working days from the date of acceptance of the application. Failure to notify within the time limit shall be deemed as consent. If a clinical trial is approved, it should be notified to the drug regulatory department and the health authority of the people's government of the province, autonomous region, or municipality where the clinical trial institution is located.

Class III medical devices with higher risks to humans in clinical trials shall be formulated, adjusted and published by the drug regulatory authority under the State Council.

Article 28 To conduct clinical trials of medical devices, ethical reviews shall be conducted in accordance with the regulations, the subjects shall be informed of the details of the purpose, use and possible risks of the trial, and written informed consent of the subjects shall be obtained; A person with civil capacity or a person with limited civil capacity shall obtain the written informed consent of his guardian in accordance with the law.

In conducting clinical trials, no fees related to clinical trials shall be collected from subjects in any form.

Article 29 For medical devices that are undergoing clinical trials for the treatment of severely life-threatening diseases that have no effective treatment methods, medical observations may benefit patients. After ethical review and informed consent, medical devices can be used for medical treatment. The device clinical trial institution is free for other patients with the same condition, and its safety data can be used for medical device registration applications.

Chapter III Medical Device Production

Article 30 To engage in medical device production activities, the following conditions shall be met:

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

(2) Having institutions or full-time inspectors and inspection equipment that can conduct quality inspections on the medical devices produced,

(3) It has a management system to ensure the quality of medical devices,

(4) Having the after-sales service capabilities that are compatible with the medical devices produced,

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

Article 31 Those engaged in the production of Class I medical devices shall file with the department responsible for drug supervision and management of the municipal people's government at the districted level, and complete the filing after submitting relevant materials that meet the conditions specified in Article 30 of these regulations.

If a medical device recorder produces Class I medical devices on his own, he may submit relevant materials that meet the conditions specified in Article 30 of these Regulations at the time of product filing in accordance with Article 15 of these Regulations to complete the production record.

Article 32 Those who are working on the production of Class II and Class III medical devices shall apply to the drug regulatory department of the local province, autonomous region, or municipality directly under the Central Government for a production license and submit relevant materials that meet the conditions specified in Article 30 of these Regulations. And the registration certificate of the medical device produced.

The drug regulatory authority that accepts the application for production license shall review the application materials, conduct verification in accordance with the requirements of the medical device production quality management regulations formulated by the drug regulatory authority of the State Council, and make a decision within 20 working days from the date of accepting the application. For those that meet the prescribed conditions, a medical device production license is granted; for those that do not meet the prescribed conditions, the license is not granted, and the reasons are stated in writing.

The medical device production license is valid for 5 years. If the validity period expires and needs to be renewed, the renewal procedures shall be handled in accordance with the relevant administrative license laws.

Article 33 The medical device production quality management norms shall address matters that affect 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, and enterprise organization and staffing Clearly defined.

Article 34 Medical device registrants and record holders may produce medical devices by themselves, or they may entrust enterprises that meet the requirements of these regulations and have corresponding conditions to produce medical devices.

In the case of entrusted production of medical devices, the medical device registrant and recorder shall be responsible for the quality of the entrusted production of medical devices, and strengthen the management of the production activities of the entrusted production enterprises to ensure that they are produced in accordance with statutory requirements. The medical device registrant and recorder shall sign a commission 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, medical device production quality management norms, mandatory standards, product technical requirements and entrusted agreements, be responsible for the production activities, and accept the supervision of the entrusting party.

Implantable medical devices with high risks shall not be outsource of manufacture, and the specific catalogue shall be regulated, adjusted and published by the drug regulatory department of the State Council.

Article 35 Medical device registrants, recorders, and OEM manufacturers shall establish and improve a quality management system compatible with the medical devices produced and ensure their effective operation in accordance with the medical device production quality management regulations; strictly follow the registered or record The technical requirements of the products are organized to ensure that the medical devices that leave the factory meet the mandatory standards and the technical requirements of registered or filed products.

Medical device registrants, record holders, and OEM manufacturers shall regularly conduct self-inspection on the operation of the quality management system and submit self-inspection reports in accordance with the regulations of the drug regulatory authority under the State Council.

Article 36 If the production conditions of medical devices change and no longer meet the requirements of the medical device quality management system, the medical device registrant, recorder, and entrusted manufacturer shall immediately take corrective actions; if it may affect the safety and effectiveness of the medical device, The production activities shall be stopped immediately and a report shall be made to the original production license or production filing department.

Article 37 Medical devices shall use general names. The general name shall comply with the medical device naming rules regulated by the drug regulatory authority under the State Council.

Article 38 The State shall implement a unique identification system for medical devices step by step according to the category of medical device

products to identify the traceability of medical devices. The specific measures shall be regulated by the drug regulatory department of the State Council in conjunction with relevant departments of the State Council.

Article 39 Medical devices shall have Instructions for Use and labels. The contents of the IFU and labels shall be consistent with the relevant contents registered or filed to ensure authenticity and accuracy.

The IFU and labels of medical devices shall indicate the following items:

(1) general name, model and specifications,

(2) The name, address and contact information of the medical device registrant, recorder, and entrusted manufacturing enterprise,

(3) Date of production, period of use or expiration date,

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

(5) Constrain, precautions and other content that needs warning or reminding,

(6) Installation and use instructions or figures,

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

(8) Other content that should be indicated in the product technical requirements.

Class II and III of medical devices should also be marked with the number of the medical device registration certificate.

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

Chapter IV Operation and use of Medical Device

Article 40 To have business activities in medical device, there shall be business permit and storage conditions with the business scope, as well as a quality management system and quality management agency or quality management personnel.

Article 41 For those who are doing business of Class II medical devices, the business enterprise shall file with the department responsible for drug supervision and administration of the people's government at the districted

city level and submit relevant materials that meet the conditions specified in Article 40 of these Regulations.

According to the regulations of the State Council's drug regulatory department, the Class II medical devices product safety and effectiveness are not affected by the circulation process can be exempted from business registration.

Article 42 For those have business of Class III medical devices, the business enterprise shall apply for business license from the department of the people's government at the districted city level in charge of drug supervision and administration and submit relevant materials that meet the conditions specified in Article 40 of these Regulations.

The department responsible for drug supervision and administration that accepts the application for business license shall review the application materials, organize verification if necessary, and make a decision within 20 working days from the date of acceptance of the application. For those that meet the prescribed conditions, the medical device business license shall be granted; for those that do not meet the prescribed conditions, the license shall not be granted and the reasons will be stated in writing.

The medical device business license is valid for 5 years. If the validity period expires and needs to be renewed, the renewal procedures shall be handled in accordance with the relevant administrative license laws.

Article 43 Registrants and recorders of medical devices who operate their registered and filed medical devices do not need to apply for a medical device business license or record, but they shall meet the operating conditions specified in these Regulations.

Article 44 To have business in the operation of medical devices, one shall establish and improve a quality management system suitable for the medical devices operated in accordance with the laws and regulations and the requirements of the medical device operation quality management standards formulated by the drug regulatory department of the State Council and ensure its effective operation.

Article 45 Medical device business company and user units shall purchase medical devices from legal qualified medical device registrants, record holders, and production and business companies. When purchasing medical devices, the supplier's qualifications and medical device qualification certificates shall be checked, and a record system for purchasing inspection records shall be established. Operating enterprises engaged in the wholesale

business of Class II and Class III medical devices and the retail business of Class III medical devices shall also establish a sales record system.

Record items include:

(1) The name, model, specification, and quantity of the medical device,

(2) The production batch number, use period or expiration date, and sales date of the medical device,

(3) The names of the medical device registrant, recorder, and entrusted manufacturing enterprise,

(4) The name, address and contact information of the supplier or purchaser,

(5) Numbers of relevant license certificates, etc.

Purchase inspection records and sales records shall be true, accurate, complete, and traceable, and shall be kept in accordance with the time limit prescribed by the drug regulatory authority under the State Council. The state encourages the use of advanced technical means for recording.

Article 46 Those have online sales of medical devices shall be medical device registrants, record holders or medical device business companies. Operators have online sales of medical devices shall inform the relevant information about online sales of medical devices to the department responsible for drug supervision and management of the people's government at the municipal level where the districts are located, and operate Class I medical devices and Article 41 of these Regulations. Except for the second-class medical devices specified in paragraph 2.

Operators of e-commerce platforms that provide services for online transactions of medical devices shall perform real-name registration of operators of online medical devices, review their business licenses, filing conditions, and the registration and filing of medical device products they operate, and manage their business operations. If an e-commerce platform operator discovers that the networked medical device operator has violated the provisions of these Regulations, it shall stop and immediately report to the medical device operator's location of the districted municipal people's government responsible for drug supervision and management; if serious violations are found, The provision of online trading platform services should be stopped immediately.

Article 47 Transportation and storage of medical devices shall comply with the requirements of medical device instructions and labeling; if there are special requirements for environmental conditions such as temperature and humidity, corresponding measures shall be taken to ensure the safety and effectiveness of medical devices.

Article 48 A medical device user unit shall have storage places and conditions suitable for the variety and quantity of medical devices in use. The medical device user unit shall strengthen the technical training of the staff and use the medical device in accordance with the requirements of the product manual and technical operation specifications.

The deployment of large dimension medical equipment by the medical device user unit shall comply with the large dimension medical equipment configuration plan regulated by the health authority of the State Council, meet its functional positioning and clinical service needs, and have corresponding technical conditions, supporting facilities, and professional technology with corresponding qualifications and capabilities. Personnel, and have been approved by the health authorities of the people's government at or above the provincial level to obtain a large-scale medical equipment configuration permit.

The measures for the management of large dimension medical equipment configuration shall be formulated by the competent health department of the State Council in conjunction with relevant departments of the State Council. The list of large dimension medical equipment is proposed by the competent health department of the State Council in consultation with relevant departments of the State Council and will be implemented after being approved by the State Council.

Article 49: Reusable medical devices shall be disposed in accordance with the regulations on disinfection and management formulated by the competent health department of the State Council.

Disposable medical devices shall not be reused, and the used ones shall be destroyed and recorded in accordance with relevant national regulations. The list of single-use medical devices shall be regulated, adjusted, and published by the drug regulatory department of the State Council in conjunction with the competent health department of the State Council. The list of disposable medical devices should have sufficient evidence that they cannot be reused. Medical devices that can be reused to ensure safety and effectiveness are not included in the list of disposable medical devices. For medical devices whose design, production process, disinfection, and sterilization technology, etc. are improved after repeated use can be

guaranteed to be safe and effective, a disposable medical device catalog should be adjusted to allow repeated use.

Article 50 For medical devices that require regular inspection, inspection, calibration, maintenance, and maintenance, medical device users shall conduct inspection, inspection, calibration, maintenance, and maintenance in accordance with the requirements of the product manual and record them, and conduct timely analysis and evaluation. Ensure that medical devices are in good condition and guarantee the quality of use; for large-scale medical devices with a long service life, use files should be established one by one to record their use, maintenance, transfer, actual use time and other matters. The record retention period shall not be less than 5 years after the expiration of the prescribed use period of the medical device.

Article 51 The medical device user unit shall properly preserve the original materials of the Class III medical device purchased and ensure that the information is traceable.

When large dimension medical devices and implantable and interventional medical devices are used, information such as the name of the medical device, key technical parameters, and necessary information closely related to the quality and safety of use shall be recorded in relevant records such as medical records.

Article 52 If the medical device used is found to have potential safety hazards, the medical device user unit shall immediately stop using it, and notify the medical device registrant, recorder or other organization responsible for product quality to perform maintenance; after the maintenance, the safety of use cannot be achieved Standard medical equipment must not be used anymore.

Article 53 For in-vitro diagnostic reagents that do not have the same product on the market in China, qualified medical institutions can develop them on their own according to the clinical needs of their own units, and use them in their own units under the guidance of medical practitioners. The specific management measures shall be formulated by the drug regulatory department of the State Council in conjunction with the health authority of the State Council.

Article 54 The department responsible for drug supervision and management and the health authority shall, in accordance with their respective duties, supervise and manage the quality of medical devices and the behavior of medical devices in use.

Article 55 Medical device business enterprises and user units shall not operate or use medical devices that have not been registered or filed in

accordance with the law, have no qualified certification documents, and have expired, expired, or eliminated.

Article 56 In the transfer of medical devices in use between medical device users, the transferor shall ensure that the transferred medical devices are safe and effective, and shall not transfer expired, invalid, obsolete, or unqualified medical devices.

Article 57 Imported medical devices shall be medical devices that have been registered or filed in accordance with the provisions of Chapter II of these Regulations.

Imported medical devices should have Chinese IFU and Chinese labels. The IFU and labels shall comply with the requirements of these regulations and relevant mandatory standards, and the IFU shall state the origin of the medical device and the name, address and contact information of the domestic enterprise legal person designated by the overseas medical device registrant and filing party. No Chinese IFU, Chinese label, or Chinese IFU or Chinese label that does not comply with the provisions of this article shall not be imported.

If a medical institution urgently needs to import a small amount of Class II and Class III medical devices for clinical reasons, they may import them with the approval of the drug regulatory department of the State Council or the people's governments of provinces, autonomous regions, and municipalities authorized by the State Council. Imported medical devices should be used for specific medical purposes in designated medical institutions.

It is forbidden to import expired, out of date, and obsoleted medical devices that have been used.

Article 58 Entry-Exit Inspection and Quarantine Agency shall conduct inspections on imported medical devices in accordance with the law; those that fail the inspection shall not be imported.

The drug regulatory department of the State Council shall promptly notify the national entry-exit inspection and quarantine department of the registration and filing of imported medical devices. The entry-exit inspection and quarantine agency where the import port is located shall promptly report the customs clearance of imported medical devices to the department in charge of the drug supervision and management of the municipal people's government with districts.

Article 59 Companies exporting medical devices shall ensure that the medical devices they export meet the requirements of the importing country (region).

Article 60 The content of medical device advertisements shall be true and legal and shall be subject to the medical device instructions registered or filed by the department responsible for drug supervision and administration, and shall not contain false, exaggerated, or misleading contents.

When publishing medical device advertisements, the advertisement review agency designated by the people's government of the province, autonomous region, or municipality directly under the Central Government shall review the content of the advertisement and obtain the approval number of the medical device advertisement; it shall not be published without review.

The drug supervision and administration department of the people's government at or above the provincial level shall order the suspension of production, import, operation and use of medical devices, and during the suspension period, advertisements involving such medical devices shall not be published.

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

Chapter V Medical Device Adverse Event and Recall Process

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

Article 62 Medical device registrants and recorders shall establish a medical device adverse event monitoring system, be equipped with adverse event monitoring institutions and personnel suitable for their products, actively carry out adverse event monitoring for their products, and comply with the drug regulatory authority of the State Council. According to the regulations, report investigation, analysis, evaluation, product risk control, etc. to the technical agency for monitoring of medical device adverse events.

Medical device manufacturers and users should assist medical device registrants and record holders in monitoring the adverse events of the medical devices they produce, operate or use; discover medical device adverse events or suspicious adverse events in accordance with the regulations of the State Council’s drug regulatory authority, To report to the technical agency for medical device adverse event monitoring.

Other units and individuals who discover medical device adverse events or suspicious adverse events have the right to report to the department in charge of drug supervision and management or medical device adverse event monitoring technical institutions.

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

Medical device adverse event monitoring technical institutions should strengthen the monitoring of medical device adverse event information, and actively collect information on adverse events; if adverse events are discovered or received, they should be verified in a timely manner, and investigation, analysis, and evaluation should be carried out when necessary, and they should report to the responsible drug Supervising and managing departments and health authorities report and put forward suggestions for handling.

Medical device adverse event monitoring technical institutions shall publish contact information to facilitate medical device registrants, record holders, production and operation enterprises, users, etc. to report medical device adverse events.

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

The drug supervision and administration department of the people's government at or above the provincial level shall, in conjunction with the health authorities and relevant departments at the same level, organize timely investigation and treatment of medical device adverse events that cause sudden, mass injuries or deaths, and organize strengthened monitoring of similar medical devices.

The department in charge of drug supervision and management shall promptly notify the health authority at the same level of the adverse event monitoring of the medical device user unit.

Article 65 Medical device registrants, record holders, production and operation enterprises, and users shall cooperate with medical device adverse event monitoring technical institutions, drug supervision and management departments, and health authorities in the investigation of medical device adverse events.

Article 66 In any of the following circumstances, the medical device registrant and recorder shall take the initiative to carry out the re-evaluation of the medical device that has been marketed:

(1) According to the development of scientific research, there is a change in the understanding of the safety and effectiveness of medical devices,

(2) The monitoring and evaluation results of the adverse event of the medical device indicate that the medical device may have defects,

(3) Other circumstances stipulated by the drug regulatory department of the State Council.

The medical device registrant and recorder shall, based on the results of the re-evaluation, take corresponding control measures to improve the medical devices already on the market, and make registration changes or record changes in accordance with regulations. If the result of the re-evaluation shows that the safety and effectiveness of the medical device on the market cannot be guaranteed, the medical device registrant and recorder shall take the initiative to apply for cancellation of the medical device registration certificate or cancellation of the record; the medical device registrant or recorder has not applied for the cancellation of the medical device registration certificate or cancellation In case of filing, the medical device registration certificate shall be cancelled or the filing shall be cancelled by the department responsible for drug supervision and administration.

The drug supervision and administration department of the people's government at or above the provincial level shall conduct re-evaluation of medical devices that have been marketed based on the monitoring and evaluation of medical device adverse events. If the result of the re-evaluation shows that the safety and effectiveness of the medical device on the market cannot be guaranteed, the medical device registration certificate shall be cancelled, or the filing shall be cancelled.

The department responsible for drug supervision and administration shall promptly announce the cancellation of the medical device registration certificate and the cancellation of the record to the public. Medical devices whose registration certificates for medical devices have been cancelled or whose filings have been cancelled shall not continue to be produced, imported, operated, or used.

Article 67 If the medical device registrant or filing person discovers that the medical device produced does not meet the mandatory standards, the technical requirements of the registered or filed product, or has other defects, it shall immediately stop production and notify the relevant operating

enterprise and user unit Stop business and use with consumers, recall medical devices that have been on the market, take measures such as remediation and destruction, record relevant conditions, release relevant information, and report the recall and handling of medical devices to the department responsible for drug supervision and management and the health authority report.

If the entrusted production or operation enterprise of medical devices discovers that the production or operation of the medical device is in the circumstances specified in the preceding paragraph, it shall immediately stop the production and operation, notify the medical device registrant and filing person, and record the suspension of production, operation and notification. The medical device registrant and recorder believe that the medical device that needs to be recalled in accordance with the provisions of the preceding paragraph shall be recalled immediately.

If the medical device registrant, recorder, entrusted manufacturing enterprise, or operating enterprise fails to implement the recall or stop production or operation in accordance with the provisions of this article, the department responsible for drug supervision and administration may order the recall or stop production or operation.

Chapter VI Supervision

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

Article 69 The department responsible for drug supervision and administration shall strengthen the supervision and inspection of the quality of medical devices in the development, production, business activities and use of medical devices, and conduct key supervision and inspection on the following matters:

(1) Whether the production is organized in accordance with the registered or filed technical requirements of the product,

(2) Whether the quality management system maintains effective operation,

(3) Whether the production and operation conditions continue to meet the legal requirements.

When necessary, the department responsible for drug supervision and administration may conduct extended inspections of other relevant units and

individuals that provide products or services for medical device development, production, operation, and use.

Article 70 The department in charge of drug supervision and administration shall have the following powers in supervision and inspection:

(1) Entering the site to conduct inspections and take samples,

(2) Consult, copy, seal up, and detain relevant contracts, bills, account books and other relevant materials,

(3) Sealing up and seizing medical devices that do not meet statutory requirements, illegally used spare parts, raw materials, and tools and equipment used for illegally producing and operating medical devices,

(4) Seal up places that violate the provisions of these regulations and engage in the production and operation of medical devices.

In conducting supervision and inspection, law enforcement certificates shall be presented to keep the business secrets of the entity under inspection.

Relevant units and individuals shall cooperate in supervision and inspection, provide relevant documents and materials, and shall not conceal, refuse, or obstruct.

Article 71 The competent health department shall strengthen supervision and inspection of the use of medical devices by medical institutions. When conducting supervision and inspection, you can enter a medical institution to consult and copy relevant files, records, and other relevant materials.

Article 72 Where there are hidden product quality and safety hazards in the production and operation of medical devices, and if no timely measures are taken to eliminate them, the department responsible for drug supervision and administration may take measures such as warnings, responsibility interviews, and orders for rectification within a time limit.

For medical devices that cause harm to the human body or have evidence to prove that they may harm human health, the department responsible for drug supervision and administration may take emergency control measures that order the suspension of production, import, operation, and use, and issue safety warning information.

Article 73 The department responsible for drug supervision and management shall strengthen the random inspection and inspection of medical devices produced, operated, and used by medical device registrants,

record holders, production and operation enterprises and users. Random inspections shall not charge inspection fees and any other expenses, and the required expenses shall be included in the budget of the government at the same level. The drug supervision and administration department of the people's government at or above the provincial level shall issue a medical device quality announcement in a timely manner based on the conclusions of random inspections.

The competent health department shall supervise and evaluate the use of large-scale medical equipment; if it discovers illegal use and excessive inspection and over-treatment related to large-scale medical equipment, it shall immediately correct it and deal with it in accordance with the law.

Article 74 If the department responsible for drug supervision and management fails to discover the systemic risks of medical device safety in time, and fails to eliminate the hidden dangers of medical device safety in the supervision and management area in time, the people's government at the same level or the department responsible for drug supervision and management of the people's government at a higher level shall deal with The main person in charge conducts an interview.

Where the local people's government fails to perform its medical device safety responsibilities and fails to eliminate major regional medical device safety hazards in a timely manner, the higher-level people's government or the drug supervision and management department of the higher-level people's government shall hold an interview with its main person in charge.

The department and local people's government interviewed shall take immediate measures to rectify and reform the supervision and management of medical devices.

Article 75 The qualification certification of medical device inspection institutions shall be managed in a unified manner in accordance with relevant national regulations. Only the inspection agency recognized by the certification and accreditation supervision and administration department of the State Council in conjunction with the drug supervision and administration department of the State Council can carry out inspections on medical devices.

If the department in charge of drug supervision and administration needs to inspect medical devices in law enforcement work, it shall entrust a qualified medical device inspection agency to conduct the inspection and pay the relevant expenses.

If the parties have objections to the inspection conclusions, they may submit an application for re-inspection to the department that conducts

sampling inspections or the higher-level department responsible for drug supervision and administration within 7 working days from the date of receipt of the inspection conclusion, and the department that accepts the re-inspection application The re-inspection agency is randomly selected in the list of re-inspection agencies to conduct re-inspection. The medical device inspection agency undertaking the re-inspection work shall make a re-inspection conclusion within the time specified by the drug regulatory authority under the State Council. The re-inspection conclusion is the final inspection conclusion. The re-inspection institution and the initial inspection institution shall not be the same institution; if there is only one qualified inspection institution for the relevant inspection items, the undertaking department or personnel shall be changed during the re-inspection. The list of re-inspection agencies shall be announced by the drug regulatory authority under the State Council.

Article 76 For medical devices that may contain harmful substances or change the design, raw materials and production processes of medical devices without authorization and have hidden safety hazards, medical devices cannot be inspected in accordance with the inspection items and inspection methods specified in the national standards and industry standards for medical devices. The inspection agency may use the supplementary inspection items and inspection methods approved by the drug regulatory department of the State Council to conduct inspections; the inspection conclusions drawn from the supplementary inspection items and inspection methods can be used as the basis for the quality of medical devices recognized by the drug regulatory authority.

Article 77 The market supervision and management department shall supervise and inspect medical device advertisements in accordance with the relevant advertising management laws and administrative regulations and investigate and deal with illegal acts.

Article 78: The department in charge of drug supervision and administration shall, through the online government service platform of the drug supervision and administration department of the State Council, promptly publish the daily supervision and management information of medical device licensing, filing, random inspection, investigation and punishment of illegal activities in accordance with the law. However, the commercial secrets of the parties shall not be disclosed.

The department in charge of drug supervision and management establishes the credit files of medical device registrants, recorders, production and operation enterprises, and users, increases the frequency of supervision and inspection for those with bad credit records, and strengthens punishment for untrustworthiness in accordance with the law.

Article 79 The department in charge of drug supervision and administration and other departments shall publish the contact information of the unit, and accept consultation, complaint, and report. The department in charge of drug supervision and management and other departments shall respond in time when receiving inquiries related to the supervision and management of medical devices; upon receiving complaints and reports, they shall verify, handle, and respond in a timely manner. The situation of consultation, complaint, report and its response, verification and handling shall be recorded and kept.

If a report on medical device development, production, operation, and use is true after investigation, the department in charge of drug supervision and administration and other departments shall reward the reporter. Relevant departments shall keep the reporter confidential.

Article 80 The drug regulatory department of the State Council formulates, adjusts, and revises the catalogs and regulations related to the supervision and management of medical devices, and shall solicit opinions publicly; take the form of hearings and demonstration meetings to listen to experts and medical device registrants, The opinions of the filing person, production and operation enterprises, user units, consumers, industry associations and related organizations.

Chapter VII Legal Liability

Article 81 In any of the following circumstances, the department responsible for drug supervision and administration shall confiscate illegal income, illegal production and operation of medical devices, and tools, equipment, raw materials and other items used in illegal production and operation; illegal production and operation of medical devices If the value of the goods is less than 10,000 yuan, a fine of more than 50,000 yuan and less than 150,000 yuan shall be imposed; if the value of the goods is more than 10,000 yuan, a fine of 15 times to 30 times the value of the goods shall be imposed; if the circumstances are serious, production and business shall be suspended , Within 10 years, the relevant responsible persons and units will not accept medical device license applications, and the legal representatives, main responsible persons, directly responsible persons in charge and other responsible personnel of the illegal units will be confiscated from the unit's income during the occurrence of the illegal acts. , And impose a fine of more than 30% of income but not more than 3 times, and prohibit them from engaging in medical device production and operation activities for life:

(1) Production and operation of Class II and Class III medical devices that have not obtained the medical device registration certificate,

(2) Have the production of Class II and Class III medical devices without permission,

(3) Have Class III medical device business activities without permission.

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

Article 82 Anyone who installs and uses large dimension medical equipment without permission shall be ordered to stop the use by the health authority of the people's government at or above the county level, given a warning, and confiscated the illegal income; if the illegal income is less than 10,000 yuan, a penalty of more than 50,000 yuan shall be imposed. A fine of less than 100,000 yuan; if the illegal income is more than 10,000 yuan, a fine of 10 times to 30 times the illegal income shall be imposed; if the circumstances are serious, applications for large dimension medical equipment configuration licenses submitted by the relevant responsible persons and units will not be accepted within 5 years. The legal representative, the main person in charge, the directly responsible person in charge and other responsible persons of the unit shall confiscate the income received from the unit during the period of the illegal act, and impose a fine of 30% or more but less than 3 times the income, and shall be punished according to law.

Article 83 Where false information is provided or other deceptive methods are used when applying for an administrative license for medical devices, the administrative license shall not be granted. If the administrative license has been obtained, the administrative license shall be revoked by the department that made the administrative license decision, and the illegal income and illegal production shall be confiscated. For medical devices used in business, applications for medical device licenses submitted by relevant responsible persons and units will not be accepted within 10 years; medical devices used in illegal production and operation with a value of less than 10,000 yuan shall be fined between 50,000 yuan and 150,000 yuan; If the value of the goods is more than 10,000 yuan, a fine of 15 times to 30 times the value of the goods shall be imposed; if the circumstances are serious, the production and business shall be suspended, and the legal representative, the main person in charge, the directly responsible person in charge and other responsibilities of the illegal unit Personnel, confiscate the income received from the unit during the period of the illegal act, and impose a fine of more than 30% of the income but not more than 3 times, and prohibit them from engaging in the production and operation of medical devices for life.

Anyone who forges, alters, sells, rents, or lends relevant medical device licenses shall be confiscated or revoked by the original license-issuing department, and the illegal gains shall be confiscated; if the illegal gains are less than 10,000 yuan, a fine of 50,000 yuan up to 100,000 yuan shall be imposed. ; If the illegal income is more than 10,000 yuan, a fine of 10 times to 20 times of the illegal income shall be imposed; if a violation of public security management is constituted, the public security organ shall impose public security management penalties in accordance with the law.

Article 84 In any of the following circumstances, the department responsible for drug supervision and administration shall announce the name of the unit and product to the public and order it to make corrections within a time limit; if the correction is not made within the time limit, the illegal income and medical devices produced and operated illegally shall be confiscated; illegal production and operation If the value of the medical device is less than 10,000 yuan, a fine of 10,000 yuan or more and less than 50,000 yuan shall be imposed; if the value of the medical device is more than 10,000 yuan, a fine of 5 times or more and 20 times the value of the value shall be imposed; if the circumstances are serious, The legal representative, main person in charge, directly responsible person in charge and other responsible personnel of the illegal unit shall confiscate the income from the unit during the period of the illegal act, and impose a fine of more than 30% and less than 2 times of the income. Prohibited within 5 years It is engaged in the production and operation of medical devices:

(1) Production and operation of Class I medical devices that have not been filed,

(2) Engaging in the production of Class I medical devices without filing,

(3) The operation of Class II medical devices shall be filed but not filed,

(4) The documents that have been filed do not meet the requirements.

Article 85 Where false information is provided during filing, the department responsible for drug supervision and management shall announce the name of the filing unit and product to the public, and confiscate illegal income and illegally produced and operated medical devices; the value of illegally produced and operated medical devices is less than 1 If the value of the goods is more than 10,000 yuan, a fine of more than 20,000 yuan and less than 50,000 yuan shall be imposed; if the value of the goods is more than 10,000 yuan, a fine of more than 5 times and less than 20 times the value of the goods shall be imposed; if the circumstances are serious, production and business shall be suspended; The legal representative, the main person in charge, the directly responsible person in charge and other responsible

persons shall confiscate the income received from the unit during the period of the illegal act, and shall impose a fine of more than 30% of the income but not more than 3 times of the income, and prohibit them from engaging in medical equipment for 10 years Production and business activities.

Article 86 In any of the following circumstances, the department responsible for drug supervision and administration shall order corrections and confiscate the medical devices used in illegal production and operation; if the value of the medical devices used in illegal production and operation is less than 10,000 yuan, they shall be punished 2 A fine of not less than 10,000 yuan but not more than 50,000 yuan; if the value of the goods is more than 10,000 yuan, a fine of more than 5 times and less than 20 times the value of the goods shall be imposed; if the circumstances are serious, the production and business shall be suspended until the medical device registration certificate is revoked by the original issuing department , Medical device production license, medical device business license, the legal representative, main person in charge, directly responsible person in charge and other responsible personnel of the illegal unit shall confiscate the income obtained from the unit during the period of the illegal act and the premises Receive a fine of more than 30% of income but less than 3 times, and prohibit them from engaging in medical device production and operation activities for 10 years:

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

(2) Failing to organize production in accordance with the technical requirements of the registered or filed product, or failing 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 the product;

(3) Operating or using medical devices that do not have conformity certification documents, expired, invalidated, or eliminated, or use medical devices that have not been registered according to law,

(4) The department in charge of drug supervision and administration still refuses to recall after it is ordered by the department in charge of drug supervision and administration, or the production, import, and operation of medical devices are still refused to stop after the department in charge of drug supervision and administration orders to stop or suspend production, import, or operation;

(5) Entrusting an enterprise that does not meet the requirements of these regulations to produce medical devices, or failing to manage the production activities of the entrusted manufacturing company,

(6) Import expired, out of date, and obsoleted medical devices that have been used.

Article 87 Medical device business enterprises and user units have fulfilled the obligations of purchase inspection and other requirements stipulated in these Regulations, and have sufficient evidence to prove that they do not know the medical devices they operate and use are in the first paragraph of Article 81 of the Regulations. If the medical devices under the conditions specified in paragraph 1 of Article 84, paragraph 1 of Article 86, and paragraph 3 of Article 86 can truthfully state the source of their purchases, the medical devices operated and used by them that do not meet the statutory requirements shall be confiscated Devices can be exempted from administrative penalties.

Article 88 In any of the following circumstances, the responsible department drug supervision and administration shall order corrections and impose a fine of 10,000 yuan to 50,000 yuan; if it refuses to make corrections, a fine of 50,000 yuan but less than 100,000 yuan shall be imposed; circumstances In serious cases, it shall be ordered to suspend production and business until the original license-issuing department revokes the medical device production license and medical device business license. The legal representative, main person in charge, directly responsible person in charge and other responsible persons of the illegal unit shall be confiscated During the period of the act, the income received from the unit, and a fine of more than 30% of the income received but not more than 2 times, is prohibited from engaging in medical device production and operation activities within 5 years:

(1) Changes in production conditions, no longer meeting the requirements of the medical device quality management system, failure to rectify, stop production, and report in accordance with the provisions of these regulations,

(2) Medical devices whose production and operation manuals and labels do not meet the requirements of these regulations,

(3) Failing to transport and store medical devices in accordance with the instructions and labeling requirements of the medical devices,

(4) Transfer of medical devices in use that are expired, invalid, eliminated, or unqualified.

Article 89 In any of the following circumstances, the responsible department of drug supervision and administration and the competent health department shall order corrections and give warnings according to their respective duties; if they refuse to make corrections, a fine of 10,000 yuan to 100,000 yuan shall be imposed; the circumstances are serious If the company is involved, it shall be ordered to suspend production and business until the original issuing department revokes the medical device registration certificate, medical device production license, and medical device business license. The legal representative, main person in charge, directly responsible person in charge and other responsibilities of the illegal entity personnel shall be fined not less than 10,000 yuan but not more than 30,000 yuan:

(1) Failing to submit the quality management system self-inspection report as required,

(2) Purchase medical devices from suppliers who do not have legal qualifications,

(3) Medical device operating enterprises and user units fail to establish and implement the medical device purchase inspection record system in accordance with the provisions of these Regulations,

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

(5) Medical device registrants, record holders, manufacturing and operating enterprises, and user units fail to carry out medical device adverse event monitoring in accordance with the provisions of these Regulations, fail to report adverse events in accordance with requirements, or monitor technical institutions for medical device adverse events and are responsible for drug supervision and management Failing to cooperate in the investigation of adverse events carried out by the relevant departments and health authorities;

(6) Medical device registrants and recorders fail to formulate post-marketing research and risk control plans in accordance with regulations and ensure their effective implementation,

(7) The medical device registrant and recorder fail to establish and implement a product traceability system in accordance with the regulations,

(8) Medical device registrants, recorders, and operating companies engaged in online sales of medical devices fail to notify the department

responsible for drug supervision and administration in accordance with regulations,

(9) For medical devices that require regular inspection, inspection, calibration, maintenance, and maintenance, the medical device user fails to perform inspection, inspection, calibration, maintenance, and maintenance in accordance with the requirements of the product manual and records to analyze and evaluate in time to ensure medical treatment the equipment is in good condition;

(10) The medical device user fails to properly keep the original materials of Class III medical device purchased.

Article 90 In any of the following circumstances, the competent health department of the people's government at or above the county level shall order correction and give a warning; if it refuses to make corrections, a fine of 50,000 yuan but less than 100,000 yuan shall be imposed; if the circumstances are serious, 100,000 yuan shall be imposed For fines above 300,000 yuan or less, the relevant medical device use activities shall be suspended until the original license issuing department revokes the practice license, and the relevant responsible personnel shall be ordered to suspend practice activities for more than 6 months and less than 1 year until the original license issuing department revokes the relevant activities. Personnel practice certificate, the legal representative, main responsible person, directly responsible person in charge and other responsible personnel of the illegal unit shall confiscate the income received from the unit during the period of the illegal act, and impose a fine of 30% or more and less than 3 times the income. , To be punished according to law:

(1) For re-used medical devices, the medical device user unit fails to deal with it in accordance with the regulations on disinfection and management,

(2) The medical device user unit reuses single-use medical devices, or fails to destroy used single-use medical devices in accordance with regulations,

(3) The medical device user fails to record the information of large-scale medical devices and implantable and interventional medical devices in relevant records such as medical records in accordance with regulations,

(4) The medical device user unit discovers that the medical device used has a potential safety hazard and fails to immediately stop using it, notify it for maintenance, or continue to use the medical device that fails to meet the safety standards after the maintenance;

(5) Medical device users use large-scale medical equipment in violation of regulations and cannot guarantee medical quality and safety.

Article 91 Imported medical devices in violation of relevant laws and administrative regulations on import and export commodity inspection shall be dealt with by the entry-exit inspection and quarantine agency in accordance with the law.

Article 92 Operators of e-commerce platforms that provide services for medical device online transactions violate the provisions of these Regulations by failing to perform real-name registration of networked medical device operators, review licensing, registration, and filing conditions, stop and report illegal acts, and stop Those who provide management obligations such as online trading platform services shall be punished by the department responsible for drug supervision and management in accordance with the provisions of the "E-commerce Law of the People's Republic of China"**.**

Article 93 If a clinical trial is carried out without the filing of a medical device clinical trial institution, the department in charge of drug supervision and administration shall order it to stop the clinical trial and make corrections; if it refuses to make corrections, the clinical trial data shall not be used for product registration, filing, and processing A fine of between RMB 50,000 and RMB 100,000 shall be announced to the public; if serious consequences are caused, it shall be forbidden to carry out clinical trials of related professional medical devices within 5 years, and a fine of RMB 100,000 but not more than RMB 300,000 shall be imposed. The legal representative, the main person in charge, the directly responsible person in charge and other responsible persons of the unit shall confiscate the income received from the unit during the period of the illegal act, and impose a fine of 30% or more but less than 3 times the income, and shall be punished according to law.

If a clinical trial sponsor has carried out a clinical trial without filing, the department in charge of drug supervision and management shall order the suspension of the clinical trial, impose a fine of 50,000 yuan up to 100,000 yuan on the clinical trial sponsor, and make an announcement to the public; if serious consequences are caused, Impose a fine of 100,000 yuan up to 300,000 yuan. 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 will not be accepted within 5 years.

If a clinical trial sponsor conducts a third-class medical device clinical trial with a higher risk to the human body without approval, the department in charge of drug supervision and management shall order the immediate termination of the clinical trial and impose a penalty of 100,000 yuan to 300,000 yuan on the clinical trial sponsor The following fines shall be announced to the public; if

serious consequences are caused, a fine of 300,000 yuan up to 1 million yuan shall be imposed. The clinical trial data shall not be used for product registration, and the medical device clinical trial and registration applications submitted by relevant responsible persons and units will not be accepted within 10 years. The legal representative, main responsible person, directly responsible person in charge and other responsible persons of the illegal unit will not be accepted. , Confiscate the income received from the unit during the period of the illegal act, and impose a fine of 30% or more and less than 3 times the income.

Article 94 If a medical device clinical trial institution conducts a medical device clinical trial that fails to comply with the clinical trial quality management specifications, the department responsible for drug supervision and management shall order correction or immediately stop the clinical trial, and impose a fine of 50,000 yuan up to 100,000 yuan; If serious consequences are caused, the relevant professional medical device clinical trials are prohibited within 5 years. The health authority shall confiscate the legal representative, the main person in charge, the directly responsible person in charge and other responsible persons of the illegal unit during the period of the illegal act. The income earned by the unit and a fine of more than 30% and less than three times of the income received shall be punished in accordance with the law.

Article 95 If a medical device clinical trial institution issues a false report, the department in charge of drug supervision and administration shall impose a fine of 100,000 yuan up to 300,000 yuan; if there are illegal gains, the illegal gains shall be confiscated; the relevant professional medical treatment shall be prohibited within 10 years Device clinical trials; the health authority shall confiscate the legal representative, the main person in charge, the directly responsible person in charge and other responsible persons of the illegal unit, and confiscate the income received from the unit during the period of the illegal act, and more than 30% of the income obtained from the premises Fines below 3 times shall be punished according to law.

Article 96 If a medical device inspection agency issues a false inspection report, the competent authority that granted it will revoke the inspection qualification, and will not accept the qualification accreditation application submitted by the relevant responsible person and the unit within 10 years, and impose a charge of 100,000 yuan or more and 300,000 yuan. The following fines; where there is illegal income, the illegal income shall be confiscated; the legal representative, the main responsible person, the directly responsible person in charge and other responsible personnel of the illegal unit shall confiscate the income obtained from the unit during the period of the illegal act and dispose of the income obtained A fine of more than 30% of income but less than 3 times shall be punished in accordance with the law; those who

are expelled shall be prohibited from engaging in medical device inspection for 10 years.

Article 97 Violation of the regulations on the management of medical device advertising shall be punished in accordance with the provisions of the Advertising Law of the People’s Republic of China.

Article 98 Where a domestic enterprise legal person designated by an overseas medical device registrant or filing person fails to perform 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 correction, give a warning, and impose a 5 A fine of not less than 10,000 yuan but not more than 100,000; if the circumstances are serious, a fine of 100,000 yuan but not more than 500,000 yuan shall be imposed, and the legal representative, main responsible person, directly responsible person in charge and other responsible persons are prohibited from engaging in the production and operation of medical devices within 5 years activity.

If the overseas medical device registrant and recorder refuse to implement the administrative penalty decision made in accordance with these regulations, the import of medical devices shall be prohibited for 10 years.

Article 99 If medical device research and development, production, and operation units and inspection institutions violate these regulations and use personnel who are prohibited from engaging in medical device production and operation activities or inspections, the department responsible for drug supervision and administration shall order corrections and give warnings; If it is corrected, it shall be ordered to suspend production and business until the license is revoked.

Article 100 If the medical device technical review institution and the medical device adverse event monitoring technical institution fail to perform their duties in accordance with the provisions of these Regulations, causing major errors in the review and monitoring work, the department in charge of drug supervision and administration shall order corrections and report criticisms. A warning shall be given; if serious consequences are caused, the legal representative, the main responsible person, the directly responsible person in charge and other responsible persons of the illegal unit shall be punished in accordance with the law.

Article 101 If the staff of the department responsible for drug supervision and management or other relevant departments violates the provisions of these Regulations, abuses their power, neglects their duties, or engages in

malpractices for personal gain, they shall be punished in accordance with the law.

Article 102 Anyone who violates the provisions of these Regulations and constitutes a crime shall be investigated for criminal responsibility according to law; those who cause personal, property or other damage shall be liable for compensation according to law.

Chapter VIII Appendix

Article 103 The meaning of the following terms in these Regulations:

Medical devices refer to instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials, and other similar or related items used directly or indirectly on the human body, including the required computer software; their utility is mainly obtained through physical methods, etc. It is not obtained through pharmacology, immunology, or metabolism, or although these methods are involved but only play a supporting role; its purpose is:

(1) Diagnosis, prevention, monitoring, treatment, or alleviation of diseases,

(2) Diagnosis, monitoring, treatment, mitigation, or functional compensation of injury,

(3) Inspection, substitution, adjustment or support of physiological structure or physiological process,

(4) Life support or maintenance,

(5) Pregnancy control,

(6) Provide information for medical or diagnostic purposes by examining samples from the human body.

The medical device registrant and recorder refer to the enterprise or research institution that has obtained the medical device registration certificate or handled the record of medical device.

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,

apheresis plasma stations, rehabilitation assistive device adaptation institutions, etc.

Large dimension medical equipment refers to large dimension medical equipment with complex technology, large capital investment, high operating cost, large impact on medical expenses and included in catalog management.

Article 104 Fees may be charged for the registration of medical device products. The specific charging items and standards shall be respectively formulated by the finance and price authorities of the State Council in accordance with relevant state regulations.

Article 105 The administrative measures for medical devices developed by medical and health institutions in response to public health emergencies shall be formulated by the drug regulatory department of the State Council in conjunction with the competent health department of the State Council.

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

The technical guidelines for medical devices in traditional Chinese medicine shall be formulated by the drug regulatory department of the State Council in conjunction with the traditional Chinese medicine regulatory department of the State Council.

Article 106 The supervision and management of the use of military medical devices shall be implemented in accordance with these Regulations and the relevant provisions of the military.

Article 107 These regulations shall come into force on June 1, 2021.