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Draft of the Medical Device Management Law of the People's Republic of China (Solicitation for Comments)

Chapter One General Principles

Article One In order to strengthen the management of medical devices, ensure the safety and effectiveness of medical devices, promote the high-quality development of the medical device industry, and protect and promote public health, this law is formulated.

Article 2: This law applies to the research and development, production, operation, use, and supervision and management activities of medical devices within the territory of the People's Republic of China.

Article 3: The management of medical devices should be centered on the health of the people, establish a safety development concept, and adhere to the principles of risk management, comprehensive control, scientific supervision, and social co-governance, ensuring the safety, effectiveness, and accessibility of medical devices.

Article 4: The state will improve the innovation system for medical devices, strengthen basic and applied research, and increase efforts in tackling original leading-edge technologies and key core technologies. Encourage interdisciplinary research in fields such as life sciences, materials science, applied sciences, information science, and medical sciences, promote technological advancements in medical devices and their raw materials and components, and enhance the level of transformation and industrialization of scientific and technological achievements.

Strengthen the primary position of enterprises in technological innovation, support enterprises in establishing or jointly forming research and development institutions, and encourage collaboration between enterprises and higher education institutions, research institutes, and medical institutions to carry out the development and innovation of medical devices. Strengthen brand building, enhance intellectual property protection, and improve the independent innovation capability of enterprises. Encourage medical institutions to make full use of clinical resources and to develop and innovate medical devices in accordance with medical practices and clinical needs.

Article 5: The state formulates plans and policies for the medical device industry, incorporating the research and innovation of medical devices into key development areas, and providing support in aspects such as scientific project approval, financing, credit, bidding procurement, and medical insurance.

The country has established a medical device industry development fund to promote the innovative development of high-performance and high-quality medical devices. Encourage cooperation between fiscal funds and social capital to broaden the financing channels for medical device companies.

The country supports the development of disciplines in the medical device field and accelerates the training of interdisciplinary, skilled medical technology talents and management professionals.

Article 6: The state supports the development of medical devices guided by clinical value, utilizing new technologies, new processes, new methods, and new materials; it encourages innovation in the development of medical devices aimed at rare diseases and life-threatening conditions that currently lack effective treatment options, enhancing the capacity for product supply.

The country encourages the use of modern scientific technology and traditional Chinese medicine research methods to carry out innovative research on Chinese medicine medical devices.
The country promotes the coordinated development and governance of healthcare, medical insurance, and pharmaceuticals, improves policies on bidding and procurement, medical fees, and health insurance, and supports the clinical promotion and use of innovative medical devices.
Encourage medical institutions to prioritize the procurement and use of innovative medical devices.
Article 7: The country implements a system for the registrants and filers of medical devices. The registrant and record-keeper of medical devices are legally responsible for the safety and effectiveness of medical devices throughout the entire process of research, production, operation, and use.
Medical device registrants and filers should establish and effectively operate a quality management system for medical devices to ensure that the research, production, and business activities of medical devices continuously comply with legal requirements.
The legal representative and main responsible person of the medical device registrant or filer are fully responsible for the quality of the medical devices.
Article 8: Units and individuals engaged in the research, production, operation, and use of medical devices shall comply with laws, regulations, rules, standards, and norms, ensuring that the information throughout the entire process is true, accurate, complete, and traceable.
Article 9: The National Medical Products Administration 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 areas of responsibility.
The drug supervision and administration departments of local people's governments at or above the county level are responsible for the supervision and administration of medical devices within their administrative regions. Departments of local people's governments at or above the county level are responsible for the supervision and management of medical devices within their respective areas of responsibility.
Article 10: The local people's governments at or above the county level are responsible for the supervision and management of medical devices within their administrative regions. They shall lead, organize, and coordinate the supervision and management of medical devices in their respective areas, and establish and improve the supervision and management mechanism for medical devices.
Local people's governments at or above the county level should incorporate the supervision and management of medical devices into their national economic and social development plans. They should include funding for the supervision and management of medical devices in their government budgets, strengthen the capacity for the evaluation, inspection, monitoring, and law enforcement of medical devices,
The State Council's drug supervision and administration department has established an evaluation system for local medical device supervision and management work, strengthening the oversight and guidance of local medical device supervision and management efforts.
Article 11: The drug supervision and administration department shall, in accordance with the needs of scientific and technological progress and industrial development, establish or designate specialized technical institutions for medical devices following prescribed procedures, and shall undertake the necessary review, inspection, examination, and monitoring work for the supervision

and management of medical devices in accordance with the law.
Article 12: The state implements classified management of medical devices according to their risk levels.
The first category consists of medical devices with a low level of risk, for which routine management can ensure their safety and effectiveness.
The second category consists of medical devices with moderate risk, which require strict management controls to ensure their safety and effectiveness.
The third category consists of medical devices that carry a higher risk and require special measures for strict management to ensure their safety and effectiveness.
Article 13: The state shall establish and improve the medical device data management system, strengthen data statistics work, achieve data interoperability, business collaboration, resource sharing, and serve society.
The country is strengthening the information technology construction for the supervision and management of medical devices, improving the level of online government services and the effectiveness of supervision and management.
The State Council's drug supervision and management department has established unified regulations for the management of medical device supervision data, promoting the collection, exchange, openness, and sharing of medical device supervision data. The drug supervision and management departments of provincial, autonomous region, and directly governed municipal people's governments should implement the unified national standards to achieve the interconnection and sharing of medical device regulatory information.
Article 14: The state establishes and improves the unique identification system for medical devices.
The State Council's drug supervision and administration department has established rules for the unique identification coding of medical devices. In collaboration with the State Council's health and wellness authorities and the State Council's medical insurance administration, a cooperative working mechanism will be set up. The implementation of the unique identification system for medical devices will be
Article 15: The state supports scientific research and application in the regulation of medical devices, encourages the integration of regulatory science with higher education and industrial development, innovates regulatory tools, standards, and methods, and promotes the modernization of the medical device regulatory system and regulatory capabilities.
Article 16: The medical device industry association should strengthen self-discipline within the industry, establish and improve industry standards, promote the construction of industry integrity, fulfill social responsibilities, and guide and supervise enterprises in conducting research, production, operation, and usage activities in accordance with the law.
Encourage the medical device industry association to strengthen academic exchanges, promote demonstration projects, and advance technological innovation. Encourage qualified social professional technical institutions to provide relevant technical services for the research, production, operation, and use of medical devices.
Article 17: People's governments at all levels and their relevant departments, as well as medical device industry associations, should strengthen the promotion and education of medical device safety, and carry out the dissemination of knowledge regarding medical device safety laws and regulations.
News media should carry out public awareness campaigns on the laws and regulations regarding

the safety of medical devices and conduct public opinion supervision over illegal activities related to medical devices. Promotional reports on medical devices should be comprehensive, scientific, objective, and fair.
Article 18: Units and individuals that make outstanding contributions to the research, production, operation, use, and supervision of medical devices shall be recognized and rewarded in accordance with relevant national regulations.
Article 19: The state encourages international exchanges in technological innovation for medical devices, strengthens international cooperation in the regulation of medical devices, and promotes international coordination and trust in the regulation of medical devices.
Support medical device companies in exploring international markets. Encourage third-party organizations to establish and improve service guarantee systems for import and export legal consulting, testing, certification, and intellectual property, to promote the international development of industries.

Chapter Two: Standards and Classification of Medical Devices

Article 20: The formulation of standards for medical devices should aim to ensure public health and safety, and must be scientific, rigorous, standardized, and applicable.
Article 21: The technical requirements for ensuring human health and life safety shall be established as mandatory national standards for medical devices. The national standards for mandatory medical devices are made public and available for free consultation by the public.
For the technical requirements that meet basic general needs, align with mandatory national standards for medical devices, and play a leading role in the medical device industry, recommended national standards for medical devices can be established.
Medical device products should comply with mandatory national standards for medical devices. For medical devices without mandatory national standards, the adoption of recommended national standards for medical devices is encouraged.
Article 22: The drug supervision and administration department of the State Council, in conjunction with the State Council's standardization administrative department, shall establish a National Medical Device Standardization Committee, which will be uniformly responsible for the formulation and organization of the implementation of medical device standards, as well as the overall management of standardization technical organizations in various professional fields
Article 23: The formulation of national standards for medical devices shall be based on scientific and technological research results and social practice experiences, reference relevant international standards, conduct in-depth investigations and demonstrations, widely solicit opinions, ensure the scientific, normative, and timely nature of the standards, and improve the quality of the standards.
Article 24 encourages enterprises, research institutions, industry associations, and other relevant parties to actively participate in the formulation and revision of national standards for medical devices. It also encourages medical device companies to take the lead as the primary drafting unit in the drafting and verification of recommended national standards for medical devices.
Article 25: The drug supervision and administration department of the State Council actively participates in international standardization activities, engages in external cooperation and exchanges on standardization, takes part in the formulation of international standards, adopts

international standards in accordance with national conditions, and promotes the conversion and application of Chinese standards in relation to international standards. Encourage enterprises, social organizations, and research institutions to participate in international standardization activities.
For international standards that have not yet been converted into national standards for medical devices in our country, we encourage medical device registration applicants and filers to actively adopt and implement international standards that exceed the relevant mandatory national standards for medical devices, in accordance with the product situation.
Article 26: Before the implementation of the newly released mandatory national standards for medical devices, medical device registrants and filers may choose to comply with either the original mandatory national standards for medical devices or the new mandatory national standards for medical devices.
Article 27: The drug supervision and administration department of the State Council shall establish an evaluation mechanism for the implementation of medical device standards, regularly track and evaluate these standards, and promptly organize the revision of national standards for medical devices based on the evaluation results.
Article 28: Standard samples of medical devices are physical standards in the inspection and testing of medical devices, and their management should comply with the relevant regulations of the State Council's drug supervision and administration department.
Article 29: The drug supervision and administration department of the State Council shall formulate classification rules and a classification catalog for medical devices based on the level of risk associated with them. Additionally, it shall analyze and evaluate changes in the risk of medical devices in a timely manner based on their production, operation, and usage, and adjust the classification rules. When evaluating the risk level of medical devices, factors such as the intended purpose, structural characteristics, and usage methods of the medical devices should be taken into account.
When formulating and adjusting classification rules and directories, it is essential to fully consider the opinions of medical device registrants, recorders, manufacturers, users, industry organizations, and others, while also referencing international medical device classification practices. The classification rules and catalog of medical devices should be made public to society.
Article 30: The drug supervision and administration department provide classification and definition services for medical devices to applicants and filers of medical device registrations.
For newly developed medical devices that have not yet been included in the classification catalog, applicants may directly apply for product registration in accordance with the provisions of this law regarding the registration of Class III medical devices, or they may apply to the State Council's drug supervision and administration department for classification determination.
For direct applications for the registration of Class III medical devices, the State Council's drug supervision and administration department shall determine the category based on the level of risk.
For medical devices approved for registration, the State Council's drug supervision and administration department should promptly include them in the classification catalog.
The drug supervision and administration department should determine the category of the applied medical devices based on classification rules and promptly disclose the classification information.
If it meets the requirements for dynamic adjustment of the classification catalog, the State Council's drug supervision and administration department should timely adjust the classification

catalog.
Article 31: The State Council's drug supervision and administration department shall establish a technical committee for the classification of medical devices to provide technical support for the management of medical device classification.
Article 32: Medical devices shall use generic names. The generic name should comply with the naming rules for generic names of medical devices established by the State Council's drug supervision and administration department.
The generic names for medical insurance by the administrative department of the State Council and the customs import and export coding names should be coordinated with the generic names of medical devices.
Article 33: The instructions and labels for medical devices should cover the basic information regarding the safety and effectiveness of the product, and the content should be consistent with the relevant information that has been registered or filed.
Medical devices that can be used by consumers individually should have special instructions for safe use, which must be clearly indicated on the label or marked with a special identifier.
The instructions and labels for medical devices should comply with the management requirements for medical device instructions and labels established by the State Council's drug supervision and administration department, ensuring they are true, accurate, clear, and easily identifiable. The medical device registrant or filer can provide either a paper or electronic instruction manual based on the product's risk and usage characteristics.
The registrants and filers of medical devices should proactively disclose the content of the instructions approved or filed with the drug supervision and administration department to the public.

Chapter Three: Development of Medical Devices

Article 34: The development of medical devices should take into account the existing recognized level of technology, ensuring that all known and foreseeable risks, as well as unintended effects, are minimized and acceptable.
Article 35: The development of medical devices should be based on the clinical usage requirements of the product, its technical characteristics, and the anticipated and unanticipated hazards identified. Non-clinical research should be conducted to ensure stable product quality and to meet the requirements of the applicable scope and technical characteristics. The functional and safety indicators and methods determined during the non-clinical research of medical devices should be consistent with the intended use conditions and purposes of the product. The research samples should be representative and typical.
Non-clinical research on medical devices should comply with the non-clinical research management requirements set by the State Council's drug supervision and administration department.
Article 36: The registration of medical device products shall undergo clinical evaluation.
Conducting clinical evaluations of medical devices can be based on product characteristics, clinical risks, existing clinical data, and other factors. This can be achieved through clinical trials or by analyzing and evaluating clinical trial data, clinical experience data, clinical literature, including real-world data, of similar medical devices to demonstrate the safety and

According to the regulations of the State Council's drug supervision and management department, when conducting clinical evaluations of medical devices, if existing clinical literature and data are insufficient to confirm the safety and effectiveness of the medical device, clinical trials should be conducted.
The State Council's drug supervision and administration department should formulate guidelines for the clinical evaluation of medical devices.
Article 37: The following circumstances may exempt from clinical evaluation:
(1) Medical devices with a clear working mechanism, established design, mature production processes, that have been on the market for many years with no recorded serious adverse events, and do not change their conventional use;
(2) Other cases where the safety and effectiveness of the medical device can be demonstrated without the need for clinical evaluation.
Exempt from clinical evaluation. is formulated, adjusted, and published by the drug supervision and administration department of the State Council.

Article 38: Conducting clinical trials for medical devices must comply with the quality management standards for clinical trials.

Medical device clinical trial institutions are subject to record management.

The conditions that medical device clinical trial institutions must meet, as well as the filing management methods and clinical trial quality management standards, shall be formulated and published by the drug supervision and administration department of the State Council in conjunction with the health and wellness department of the State Council.

Article 39: Clinical trials for medical devices must be filed with the drug supervision and administration department of the people's government of the province, autonomous region, or municipality directly under the central government where the clinical trial sponsor is located. Clinical trials for Class III medical devices that pose a higher risk to human subjects must be approved by the State Council's drug supervision and administration department.

The catalog of Class III medical devices, which pose a higher risk to the human body in clinical trials, is formulated, adjusted, and published by the State Council's drug supervision and administration department.

The drug supervision and administration department of the State Council shall conduct a comprehensive analysis of the clinical trial implementation plan and other related documents when approving clinical trials, and make a decision within 30 working days, notifying the clinical trial applicant; if no notification is made within this period, it shall be deemed as approval.Those authorized to conduct clinical trials should notify the drug supervision administration and health authorities of the provincial, autonomous region, or municipal government where the clinical trial institution is located.

Article 40: The drug supervision and administration departments of provincial-level and higher people's governments are responsible for the supervision and management of clinical trials for medical devices, conducting supervision and inspection of clinical trial institutions and clinical trial

projects. The health authorities should strengthen the management of clinical trials for medical devices within their scope of responsibilities.

Article 41: The state supports medical institutions in conducting clinical trials, strengthens the capacity building of clinical trial institutions for medical devices, incorporates the evaluation of clinical trial conditions and capabilities into the grading assessment of medical institutions, and encourages medical institutions to carry out clinical trials for innovative medical devices.

Article 42: Conducting clinical trials for medical devices must be carried out in accordance with regulations for ethical review. Participants should be informed in detail about the purpose, use, and potential risks of the trial, and obtain their written informed consent. If the participant is a person without civil capacity or with limited civil capacity, written informed consent must be obtained

When conducting clinical trials to collect personal information, it should be processed in accordance with the provisions of the Personal Information Protection Law of the People's Republic of China. If a subject withdraws from a clinical trial or revokes consent for the processing of personal information, the relevant information may continue to be processed within the retention period of the basic documents of the clinical trial.

Clinical trials must not charge participants any fees related to the clinical trial in any form.

Article 43: In our country, for multi-center clinical trials, after the ethical review by the leading institution of the clinical trial, the ethics review committees of other participating institutions may confirm the ethical review opinions of the leading institution using a simplified procedure. Encourage local governments to strengthen the capacity building of regional ethical review and promote mutual recognition of regional ethical review results.

Encourage the conduct of international multicenter clinical trials for medical devices. Overseas clinical trials should be carried out in countries (regions) with clinical trial quality management and must comply with China's regulatory requirements for medical device clinical trials.Overseas trial data that is scientific, complete, and sufficient, and meets our country's registration requirements, can be used for medical device registration applications.

Article 44: Medical devices used for the diagnosis or treatment of severe life-threatening diseases for which there are no effective treatment options may be used free of charge for other patients with the same condition within the institution conducting clinical trials, provided that medical observation indicates potential benefits for patients, and after ethical review and informed consent. The safety data obtained can be used

Article 45: Class I medical devices are subject to product filing management, while Class II and Class III medical devices are subject to product registration management.

Article 46: The filing of Class I medical device products shall be submitted by the filer to the drug supervision and administration department of the municipal people's government at the district level where the filer is located. Overseas registrants exporting Class I medical devices into our country must designate a domestic legal entity that has obtained medical device production or business licenses as the domestic responsible party and submit the registration materials to the State Council's drug regulatory authority.

The State Council's drug supervision and administration department is responsible for establishing a national filing management platform. Once the filer submits the filing materials that comply with the provisions of this law to the corresponding drug supervision and administration department on the filing management platform, the filing is considered complete. The drug supervision and administration department should, within 5 working days from the date of receiving the filing materials, publish the relevant filing information to the public through the online government service platform of the State Council's drug supervision and administration department.

After the product is registered, the drug supervision and administration department will review the registration materials according to regulations. If the review finds that the registration materials do not meet the requirements, it will be handled in accordance with the relevant provisions of this law.

If there are changes to the matters specified in the filing documents, the original filing department should be notified of the changes.

If the registrant no longer produces or sells the registered products, they should proactively cancel the registration.

Article 47: When applying for the registration of Class II medical devices, the applicant shall submit the registration application materials to the drug supervision and administration department of the people's government of the province, autonomous region, or municipality directly under the central government where they are located. To apply for the registration of Class III medical devices, the applicant must submit the registration application materials to the State Council's drug supervision and administration department.

Foreign applicants for the registration of Class II and Class III medical devices to be exported to our country must designate a domestic legal entity that has obtained a medical device production or business license as the responsible party in the country and submit the registration application materials to the State Council's drug supervision and administration department.

The State Council's drug supervision and administration department should establish regulations for the registration review procedures and requirements for medical devices and strengthen the supervision and guidance of the registration review work conducted by the drug supervision and administration departments of provincial, autonomous region, and municipal governments.

Article 48: The registration of Class I medical device products shall submit product technical requirements, product inspection reports, product manuals, label samples, quality management system documents related to product development and production, as well as other materials necessary to prove the product's safety and effectiveness.

When applying for the registration of Class II and Class III medical devices, one must submit product risk analysis materials, product technical requirements, product inspection reports, clinical evaluation materials, product manuals and label samples, quality management system documents related to product development and production, as well as any other materials necessary to prove the product

In cases that meet the conditions for exemption from clinical evaluation as stipulated in Article 37 of this law, submission of clinical evaluation data may be waived.

The applicant or registrant of medical devices should ensure that the submitted materials are legal, authentic, accurate, complete, and traceable.

Article 49: The product inspection report shall comply with the requirements of the State Council's drug supervision and administration department. It may be a self-inspection report from the medical device registration applicant or record holder, or it may be an inspection report issued by a qualified medical device inspection institution.

Article 50: For applications for the registration of Class II and Class III medical devices, the drug supervision and administration department shall organize a technical review to examine the safety, effectiveness, and quality controllability of the medical devices.

The drug supervision and administration department that accepts the registration application shall transfer the registration application materials to the technical review agency within three working days from the date of acceptance of the registration application. Technical review institutions should submit their review opinions to the drug regulatory authority that accepted the registration application as the basis for approval after completing the technical review.

The drug supervision and administration department that accepts the registration application should organize a registration inspection if it deems it necessary to verify the quality management system and the clinical trial site during the technical review of medical devices.

Article 51: The drug supervision and administration department that accepts the registration application shall decide within 20 working days from the date of receiving the review comments. For those that meet the criteria, registration will be granted, and a medical device registration certificate will be issued; for those that do not meet the criteria, registration will be denied with a written explanation of the reasons.

The drug supervision and management department that accepts the registration application shall, within five working days from the date of approval for the registration of medical devices, publish the relevant registration information to the public through the online government service platform of the State Council's drug supervision and management department.

Article 52: Special review shall be conducted for innovative medical devices that possess core technology invention patents, have a product's main working principle or mechanism of action that is a domestic innovation, are at the forefront of international technology, and have significant clinical application value.

Medical devices used for the diagnosis or treatment of rare diseases, malignant tumors, diseases specific to the elderly, and common diseases, as well as medical devices specifically for children, or those that are urgently needed in clinical settings but have not yet been approved for registration or have a limited number of similar products in our country

Article 53: Emergency approval shall be implemented for medical devices that are necessary for responding to sudden public health emergencies and for which there are no similar products available on the market in our country, or although similar products are available, their supply cannot meet the needs for emergency response to such public health events.

In the event of a particularly significant public health emergency or other serious threats to public health, the health authorities and disease prevention and control departments of the State Council may propose the emergency use of medical devices based on the needs for prevention and control of the incident. After being organized and approved by the State Council's drug

Article 54: For medical devices used to treat rare diseases, life-threatening conditions for which there are currently no effective treatment methods, and for urgent medical devices needed to respond to public health emergencies, the drug supervision and management department that accepts the registration application may make a conditional approval decision and specify relevant matters in the medical device registration certificate.

Article 55: Medical device registrants and filers shall continuously conduct research on medical devices that have been marketed, in order to continuously improve the quality and safety levels.

For medical devices approved with conditions, the registrant of the medical device should take appropriate risk management measures and complete the relevant research as required within the specified time frame. If the registrant fails to complete the research as required or cannot prove that the benefits outweigh the risks, they should promptly apply for the cancellation of

Article 56: The validity period of the medical device registration certificate is 5 years. If the validity period is about to expire and a renewal of registration is required, an application for renewal should be submitted to the original registration department within the period of 12 months to 6 months before the expiration of the validity period. The following circumstances will result in the non-renewal of registration:

(1) Failure to submit a renewal application within the specified time frame;

(2) The issuance and implementation of new mandatory national standards for medical devices, where the medical device applying for renewal cannot meet the new requirements;

(3) Medical devices approved with conditions that have not completed the requirements stated in the medical device registration certificate within the specified time frame.

The drug supervision and administration department that receives the application for the renewal of registration should make a decision to grant the renewal before the expiration of the medical device registration certificate. If no decision is made by the deadline, it will be considered as approved for extension.

Article 57: Changes to registered Class II and Class III medical devices shall be managed categorically based on the level of risk and impact on the safety, effectiveness, and quality controllability of the medical devices.

The medical device registrant should comprehensively assess and verify the impact of changes on the medical device. If there are substantial changes in its design, raw materials, manufacturing process, scope of application, or usage methods that could affect the safety and effectiveness of the device, the registrant should apply to the original registration

Article 58: With the approval of the drug supervision and administration department, the medical device registrant may transfer the medical device registration certificate. The transferee should

possess the capabilities for quality management and risk prevention to ensure the safety, effectiveness, and controllability of medical devices, and fulfill the obligations of a medical device registrant.

Article 59: The drug supervision and administration department of the State Council shall reasonably allocate review resources based on national strategic needs, strengthen supervision and guidance over the review work of regional sub-centers and the drug supervision and administration departments of provincial, autonomous region, and municipal governments, establish and improve the review quality management system, and comprehensively enhance the review

The State Council's drug supervision and management department evaluates the review institutions and personnel capabilities of the drug supervision and management departments of provincial, autonomous region, and municipal governments, establishing a scientific assessment and evaluation mechanism. If the capabilities of the review institutions and personnel are insufficient, corrective measures such as suspending reviews may beIf it is found that the review and approval work does not meet the requirements, adjustments can be made to the approval authority of the drug supervision and administration departments of provincial, autonomous region, and municipal governments with the consent of the State Council.

The State Council's drug supervision and administration department should establish regulations for the registration review procedures and requirements of medical devices, improve the system for the review and approval of medical devices, establish and enhance mechanisms for communication, expert consultation, and optimize the review and approval process to increase efficiency.

The review conclusions and basis for the approval of medical devices for market launch should be made public in accordance with the law, allowing for social oversight.

Chapter Five: Medical Device Business

Article 72: Engaging in medical device business activities must comply with laws, regulations, and the quality management standards for medical device operations. A quality management system that is appropriate for the medical devices being operated should be established and improved to ensure that the entire process of medical device business continuously meets legal requirements. The legal representative and the main responsible person of a medical device operating enterprise are fully accountable for the medical device business activities of the company.
Medical device operating companies should equip themselves with key personnel such as quality managers and quality management staff that are appropriate to their scope of business and scale of operations. Responsibilities should be clearly defined, training should be strengthened, and necessary support should be provided to ensure they can fully perform their duties.
Article 73: The quality management specifications for the operation of medical devices should clearly stipulate the establishment and improvement of the quality management system for medical device operating enterprises, responsibilities and systems, organizations, personnel and training, facilities and equipment, procurement, receipt and acceptance, warehousing, storage and

inspection, sales, outbound and transportation, as well as after
Article 74: Engaging in the business of medical devices shall have business premises and storage conditions that are appropriate to the scale and scope of operations, as well as a quality management system and quality management organization or personnel that are suitable for the medical devices being operated.
Article 75: Engaging in the business of Class II medical devices shall be filed with the drug supervision and administration department of the municipal people's government at the district level, in accordance with the regulations of the State Council's drug supervision and administration department.
According to the regulations of the State Council's drug supervision and management department, Class II medical devices, whose safety and effectiveness are not affected by the circulation process, can be exempted from business filing.
Article 76: Those engaged in the operation of Class III medical devices shall apply for a business license from the drug supervision and administration department of the municipal people's government at the district level, in accordance with the regulations set by the State Council's drug supervision and administration department.
The drug supervision and management department that accepts the business license application should 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 who meet the specified conditions, a permit will be granted along with a medical device business license; for those who do not meet the requirements, the permit will not be granted, and a written explanation will be provided.
The medical device business license is valid for 5 years.If the validity period expires and continued operation is necessary, the relevant procedures for extension should be handled in accordance with the legal provisions of administrative licensing.If a medical device business has not received any administrative penalties above a warning from the drug supervision and administration department within the validity period, it may submit a self-inspection report that meets the requirements of the medical device quality management system to apply for the direct reissuance of a new certificate. If the drug supervision
Article 77: Medical device registrants and filers may sell their registered or filed medical devices themselves, or they may entrust qualified medical device operating enterprises to sell them. The registrant or record-keeper of medical devices may sell their registered or recorded medical devices at their residence or production address without needing to obtain a medical device business license or record. However, they must comply with the operating conditions stipulated by this law. If they store and sell medical devices at other locations, they
Article 78: Medical device operating enterprises shall purchase medical devices from legally qualified medical device registrants, recorders, manufacturers, and operating enterprises. When purchasing medical devices, it is necessary to verify the qualifications of the supplier and the certification documents of the medical devices, and to establish a system for maintaining purchase records.
Enterprises engaged in the wholesale business of Class II and Class III medical devices, as well as the retail business of Class III medical devices, shall also establish a sales record system.
Records of purchases and sales should be true, accurate, complete, and traceable, and must be kept for the period specified by the drug regulatory authorities of the State Council. The country

encourages the use of advanced technological means for recording.
Article 79: Medical device operating enterprises shall establish and implement systems for the transportation and storage of medical devices. The transportation and storage of medical devices must comply with the requirements specified in the medical device instructions and labels. For those with special requirements regarding temperature, humidity, and other environmental conditions, appropriate measures must be taken to ensure the safety and effectiveness of
Article 80: When the registrant, record-keeper, and operating enterprise of medical devices entrust other units with the transportation and storage of medical devices, they shall assess the quality assurance capability of the entrusted party for the transportation and storage of medical devices. They must also sign a commission agreement with the entrusted party, clearly defining the quality responsibilities during
Medical device operating enterprises that specialize in transportation and storage services should have equipment and facilities that are suitable for the transportation and storage conditions and scale of the products. They should also possess an information management platform and technical means that enable traceability throughout the entire quality management process of product operations.
Enterprises entrusted with the storage of medical devices are not allowed to delegate storage again.
Article 81: Those engaged in the online sale of medical devices must be the registrant, record-keeper, or operating enterprise of the medical devices.
Operators engaged in the online sales of medical devices should inform the drug supervision and administration department of the municipal people's government in their location about relevant information regarding their online sales of medical devices, except for those dealing with Class I medical devices and Class II medical devices that are exempt from filing. The online sale of medical devices should comply with the relevant regulations concerning the operation of medical devices as stipulated by this law. The specific management measures will be formulated by the State Council's drug supervision and administration department.
Operators engaged in the online sale of medical devices should prominently display their obtained medical device registration certificates, business licenses, or filing information on the homepage of their medical device sales activities. They should also continuously display the medical device registration certificate or filing information for the products on their sales pages. If there are changes to the relevant information, the public information should be updated promptly.
Article 82: Operators of e-commerce platforms providing services for the online trading of medical devices shall, in accordance with the regulations of the State Council's drug supervision and administration department, file with the drug supervision and administration department of the people's government of the province, autonomous region, or municipality directly under the central government where they are located. They must prominently
Article 83: Operators of medical device e-commerce platforms shall, in accordance with the law, conduct real-name registration for medical device online sales operators applying to enter the platform, review their medical device business licenses, filing status, and the registration and filing status of the medical devices they operate, ensuring compliance with legal requirements.
Operators of medical device e-commerce platforms should manage the online sales activities of medical devices occurring on their platforms. If they discover that any medical device sellers on the platform are violating the provisions of this law, they must promptly put a stop to such actions and

immediately report to the local municipal drug supervision department. In cases
Article 84: Operators of medical device e-commerce platforms shall record their compliance with the obligations stipulated by this law. Among them, the retention period for verification and registration records of medical device online sales operators on the platform shall be no less than 3 years from the date the operators exit the platform; for management records of medical device online sales activities that occur on the platform, the retention period shall be no less than 5Relevant records should be true, accurate, complete, and traceable, and records related to implanted medical devices should be permanently preserved.
Article 85: Operators of medical device online sales and operators of medical device e-commerce platforms shall comply with laws, regulations, and the requirements of the quality management standards for online sales of medical devices, ensuring that the online transaction process remains continuously compliant.
The government has established a monitoring platform for online transactions of medical devices, conducting monitoring and handling of online sales and transactions of medical devices. Any suspected illegal information identified during monitoring will be promptly forwarded to the relevant departments.
Article 86: The content of medical device advertisements must be truthful and lawful, and shall not contain false, exaggerated, or misleading information. It should be based on the instructions for use of medical devices that are registered or filed with the drug regulatory authority.
The advertisement for medical devices must be reviewed by the advertising review authority designated by the people's government of the province, autonomous region, or municipality directly under the central government where the medical device registrant, record-keeper, or domestic responsible person for imported medical devices is located, and obtain the approval number for the medical
The pharmaceutical supervision and administration departments of provincial-level and above people's governments shall order the suspension of the production, operation, import, and use of medical devices. During the suspension period, no advertisements related to the medical devices in question may be published.
The review methods for medical device advertisements are formulated by the market supervision and administration department of the State Council.

Chapter Six: Import and Export of Medical Devices

Article 87: Imported medical devices must be those that have been registered or filed in accordance with the provisions of this law.
Imported medical devices should have Chinese instruction manuals and Chinese labels. The instructions and labels must comply with the requirements of this law and relevant mandatory standards, and the instructions should specify the country of origin of the medical device as well as the name, address, and contact information of the responsible person designated by the overseas medical device registrant or filer within China. Without a Chinese instruction manual, Chinese labels, or if the instruction manual and labels do not comply with the provisions of this law, importation is not permitted.
Article 88: The domestic responsible party for imported medical devices shall fulfill the following obligations:

(1) Conduct post-market risk management for imported medical devices;
(2) Undertake monitoring and reporting of adverse events related to imported medical devices, and cooperate with drug supervision and management departments and medical device vigilance technical institutions in investigating and handling adverse events;
(3) Organize and implement the recall of imported medical devices within China;
(4) Assist the registrants and filers of imported medical devices in conducting post-market studies;
(5) Assist the registrants and filers of imported medical devices in establishing a quality management system that is appropriate for the products and maintaining its
The registrant and record-keeper of imported medical devices should provide necessary support to the domestic responsible party for imported medical devices in fulfilling the aforementioned obligations.
The domestic responsible party for imported medical devices shall bear joint liability with the registrant and record-keeper of the imported medical devices.
Article 89: For the import of medical devices, customs clearance procedures must be carried out with the medical device registration certificate or filing number and a written authorization issued by the domestic responsible party for the imported medical device. The responsible party for imported medical devices should confirm the basic information of the imported medical devices, including the product name, specifications and models, import quantity, and port of entry.
The customs commodity number should be aligned with the classification catalog of medical devices, and customs shall conduct inspections of imported medical devices in accordance with the law. Medical devices that fail inspection or have been used are not allowed to be imported, except for those that have been repaired overseas after importation or those that have been exported for repair and are being brought back into the country.
The State Council's drug supervision and administration department should promptly inform the General Administration of Customs about the registration and filing status of imported medical devices. Customs at the port of import should timely report the customs clearance data and related information of imported medical devices to the drug supervision and administration department of the municipal government at the district
The country is strengthening the information technology infrastructure for the customs clearance of imported medical devices, aimed at managing the customs clearance of imported medical devices.
Article 90: Medical institutions may import a small quantity of Class II and Class III medical devices due to urgent clinical needs or for the diagnosis and treatment of rare diseases, with the approval of the State Council's drug supervision and administration department or the provincial, autonomous region, or municipal government authorized by the State Council. Imported medical devices should be used for specific medical purposes within designated medical institutions.
Article 91: Those engaging in cross-border e-commerce retail import of medical devices must designate a legally established corporate entity within China as the domestic service provider and conduct business activities in strict accordance with national regulations. If the domestic service provider is not specified, the relevant medical devices will not be allowed to clear customs.
The catalog of medical devices allowed for retail import through cross-border e-commerce is formulated by the Ministry of Finance and the Ministry of Commerce of the State Council in conjunction with relevant departments. E-commerce platforms, websites, web pages, and internet applications must not provide information display, links, or other services for medical devices that

are not registered or filed within the country and are outside the catalog.
Article 92: If the drug supervision and administration department of the State Council legally suspends the import of medical devices, it shall promptly notify the General Administration of Customs. The customs should promptly take measures such as halting clearance.
Article 93: Enterprises exporting medical devices shall ensure that the medical devices they export comply with the requirements of the importing country (region).

Chapter Seven: Use of Medical Devices

Article 94: Medical device use units shall establish and implement a management system for the quality and usage behavior of medical devices, ensuring the reasonable and standardized use of medical devices to guarantee their safe usage.
The legal representative and the main responsible person of the medical device user unit are fully responsible for the quality of medical device use and the usage behavior within their unit.
Article 95: Medical device users that configure large medical equipment must comply with the large medical equipment configuration plan established by the health authorities of the State Council. This configuration should align with its functional positioning and clinical service needs, possess the corresponding technical conditions and supporting facilities, and have qualified and capable professional technical personnel. Additionally, it must be approved by the
The health authorities should supervise and assess the usage of large medical equipment; if any violations in the use of large medical devices are found, they should be corrected immediately and dealt with according to the law.
The management measures for the configuration of large medical equipment are formulated by the health and wellness authorities of the State Council in conjunction with relevant departments of the State Council. The catalog of large medical equipment is proposed by the health and wellness authority of the State Council to the relevant departments of the State Council and is implemented after approval by the State Council.
Article 96: Medical device users should procure medical devices from registered or filed entities and businesses that possess legitimate qualifications. When purchasing medical devices, one should verify the qualifications of the supplier and the certification documents of the medical devices and establish a system for recording procurement and acceptance. For the procurement of Class III medical devices, the medical device user unit should properly preserve the original documentation of the medical devices. Procurement, acceptance records, and related materials should be true, accurate, complete, and traceable, and must be kept for the period specified by the State Council's drug supervision and administration department.
Medical device usage units should designate a specific department or personnel to uniformly procure medical devices; other departments or personnel are not allowed to make independent purchases.
Article 97: Medical device users should have storage locations and conditions that are appropriate for the variety and quantity of medical devices in use. They should establish a storage management system and store the devices according to the storage conditions specified in the device instructions and labels, conducting regular inspections. For devices with special requirements regarding environmental conditions such as temperature and humidity, appropriate
If a medical device user unit entrusts storage, it should delegate to a specialized medical device

business that provides storage services and strengthen management to ensure quality and safety.
Article 98: Medical device users should adhere to the principles of safety, effectiveness, and economy, using medical devices that are appropriate for the patient's condition during diagnosis and treatment activities. They should enhance the technical training of staff and use medical devices reasonably according to clinical guidelines, product instructions, and technical operation specifications. If there is a need to inform patients

In special circumstances where there are no effective or better treatment options available, physicians may implement treatment using medical devices in ways not explicitly stated in the device's instructions, provided they have obtained the patient's clear informed consent and there is evidence from evidence-based medicine supporting such use. Medical device user units should establish management systems to monitor and evaluate the appropriateness of medical device usage, guiding clinical rational use.

Article 99: Medical device users must conduct inspections, tests, calibrations, maintenance, and servicing of medical devices that require regular checks in accordance with the product instructions. They should promptly analyze and assess the usage status of the medical devices to ensure safe use.

Medical device users should agree with suppliers on the provider of maintenance, upkeep, and repair services for the medical devices. The maintenance, upkeep, and repair services for medical devices can be provided by the registered or filed medical device registrant, the operating enterprise as agreed or can be carried out by the medical device user unit itself or entrusted to qualified and capable repair service organizations. If the medical device user unit conducts maintenance, upkeep, or repairs on its own or entrusts others to do so, the medical device registrant, record holder, and operating enterprise should provide necessary materials and information for maintenance, upkeep, and repairs, such as maintenance manuals, software backups, and repair passwords

Medical device users should keep records of the inspection, testing, calibration, maintenance, and repair of medical devices.

Article 100: If a medical device in use is found to have safety hazards, the medical device user unit shall immediately cease its use and notify the medical device registrant, record keeper, or other responsible quality assurance organizations for repairs; medical devices that still do not meet safety standards after repairs shall not be used further.

Article 101: Medical device user units shall establish usage records for each large medical device, documenting its usage, maintenance, transfer, actual usage time, and other relevant matters. The retention period for records must not be less than five years after the expiration of the specified usage period for medical devices.

Medical institutions using large medical devices, as well as implantable and interventional medical devices, should document the name of the medical device, its unique identifier, key technical parameters, and other necessary information closely related to the quality and safety of use in medical records and other relevant documentation.

Article 102: Single-use medical devices must not be reused; those that have been used should be destroyed and recorded in accordance with relevant national regulations.

Medical device users should handle reusable medical devices in accordance with the management and disinfection regulations established by the health authorities and disease prevention and control departments of the State Council.

Article 103: To meet the rare and special medical conditions of designated patients, when existing products on the market in our country are unable to satisfy clinical needs, eligible medical institutions may collaborate with medical device manufacturers that possess the necessary capabilities to jointly design and produce customized medical devices for designated patients. Medical institutions and manufacturers of customized medical devices should jointly file with the drug supervision and administration department of the provincial, autonomous region, or municipal government where the medical device manufacturer is located before producing and using customized medical devices.

Medical institutions should inform patients or their guardians about the reasons for using customized medical devices and the associated risks and obtain informed consent. Custom medical devices must not be entrusted for production.

The specific management measures will be formulated by the State Council's drug supervision administration in conjunction with the State Council's health and wellness authorities.

Article 104: For in vitro diagnostic reagents of the same variety that are not yet on the market domestically, qualified medical institutions may develop them independently based on their clinical needs and use them within their institution under the guidance of practicing physicians. The specific management measures will be formulated by the State Council's drug supervision administration in conjunction with the State Council's health and wellness authorities.

Article 105: When a medical device is transferred between medical device users, the transferor must ensure that the transferred medical device is safe and effective. It is prohibited to transfer expired, ineffective, obsolete, refurbished, or unqualified medical devices.

Article 106: The drug supervision and administration department and the health and wellness authority shall supervise and manage the quality of medical devices used and the behavior of medical device usage according to their respective responsibilities.

Chapter Eight: Vigilance and Recall of Medical Devices

Article 107: The state establishes a vigilance system for medical devices to monitor, identify, assess, and control adverse events related to medical devices, as well as other harmful incidents that have caused or may cause harm to human beings.

Adverse events related to medical devices are harmful incidents that occur during the normal use of quality-compliant medical devices, which lead to or may lead to harm to the human body. Other harmful events related to the use of medical devices include incidents caused by quality issues discovered during use, abnormal usage, interactions between medical devices, and other risks that lead to or may lead to bodily harm.

Article 108: Medical device registrants and filers shall conduct vigilance activities in accordance with the requirements of the medical device vigilance quality management standards, collecting, analyzing, and reporting vigilance information, conducting risk assessments, and strengthening risk management for products that are already on the market.

The using unit should establish a vigilance system for medical devices, clearly define the relevant departments and personnel, actively collect and report vigilance information, cooperate with registrants and filers to conduct risk assessments, and carry out vigilance activities in accordance with the law.

Medical device contract manufacturers and operating enterprises should collect and report alert information, assisting medical device registrants and filers in carrying out alert activities.
Other units and individuals who discover alert information can report it to the drug supervision and administration department or the medical device alert technical institution.
The registrants, filers, entrusted manufacturers, operating enterprises, and user units of medical devices should limit the personal information collected through medical device vigilance activities to the minimum necessary for vigilance purposes and must not excessively collect personal information. It is prohibited to illegally buy, sell, provide, or publicly collect personal information.
Medical device registrants, filers, entrusted manufacturers, operating enterprises, and user units should cooperate with the medical device vigilance activities conducted by vigilance technical institutions, drug supervision and administration departments, and health authorities.
Article 109: The State Council's drug supervision and administration department shall establish a medical device vigilance information network to collect vigilance information. Medical device vigilance technical institutions at all levels analyze vigilance data through the vigilance information network, identify and assess risks, and provide handling suggestions to the drug supervision and management departments and health authorities.
Article 110: If the registrant or filer of a medical device discovers through medical device vigilance activities that a product has caused or may cause harm to the human body, they shall take risk control measures such as issuing warning information, suspending production and operation, recalling the product, and report to the drug supervision and administration department of the people's government of
Article 111: If the registrant or filer of a medical device discovers that the risk-benefit ratio of a marketed medical device needs to be reassessed, they should proactively conduct a post-market evaluation. If necessary, the drug supervision and management departments at the provincial level and above can order medical device registrants or filers to conduct post-market evaluations or directly organize post-market evaluations.
The registrant or filer of medical devices should take measures based on the results of post-market evaluation, such as revising the instructions, labels, product technical requirements, software updates, and improving design and manufacturing processes, and make registration or filing changes as required. After evaluation, if the above measures cannot effectively control product risks or if the risk-benefit ratio is unacceptable, an application should be made to cancel the medical device registration certificate or to revoke the filing.
The drug supervision and administration department of the State Council can make decisions to eliminate certain types of medical devices based on the conclusions of post-marketing evaluations. The medical device registration certificate or product filing for eliminated products shall be revoked or canceled by the original issuing department or filing department.
Medical devices that have had their registration certificates revoked or have had their filings canceled are not allowed to be produced, operated, imported, or used.
Article 112: If the registrant or filer of a medical device discovers that the produced medical device does not comply with mandatory standards, the technical requirements of the registered or filed product, or has other defects, they must immediately stop production and sales, and inform relevant business enterprises, user units, and consumers to cease operations and usage. They must recall
Medical device contract manufacturers, operating enterprises, and user units that discover that the

medical devices they produce, operate, or use are in the aforementioned situations must immediately cease production, operation, and use, notify the medical device registrants and filers, and retain relevant records.
If the registrant or filer of medical devices fails to proactively recall products, the local drug supervision and administration department shall order them to carry out the recall.
Medical device contract manufacturers, operating enterprises, and user units should cooperate with medical device registrants and filers to carry out product recall work effectively.
Article 113: Medical device registrants, filers, manufacturers, operating enterprises, and user units shall establish and implement a traceability system for medical devices, recording production, operation, and usage-related information as required, to ensure the traceability of medical devices.
Article 114: Medical device registrants, filers, manufacturing enterprises, and operating enterprises shall implement the unique identification system for medical devices as required, ensuring that the information is true, accurate, complete, and traceable.
Article 115: Medical device registrants, filers, manufacturing enterprises, and operating enterprises shall establish a training management system to enhance training on the laws, regulations, rules, standards, and quality management knowledge related to medical devices. They should formulate an annual training plan and ensure proper assessment and record-keeping of the training.
The main responsible person of the enterprise should implement the primary responsibility for training management, conducting pre-job and continuing education training assessments for key positions such as management representatives, heads of production and operation quality management departments, and other relevant personnel, in relation to their duties and content.
Those who do not meet the corresponding management
The drug supervision and administration department can conduct random inspections of the training management situation in enterprises. If problems are found, the enterprises should rectify them immediately.

Chapter Nine: Supervision and Management

Article 116: The state establishes a system for professional and specialized medical device reviewers, inspectors, testers, alert personnel, and auditors, strengthening quality supervision and management throughout the entire lifecycle of medical devices. The State Council's drug supervision and management department is strengthening the construction of a national-level professional and specialized team. The people's governments of provinces, autonomous regions, and municipalities directly under the central government should determine the scale of the provincial medical device professional teams and equip them with corresponding law enforcement equipment and facilities based on regulatory responsibilities and the scale of the medical device industry and strengthen capacity building. The drug supervision and management departments of the people's governments of provinces, autonomous regions, and municipalities directly under the central government should be equipped with sufficient professional and specialized personnel who meet the necessary qualifications, in accordance with regulations, to ensure the needs of supervision and management.
Article 117: The drug supervision and administration department shall classify and manage medical device registrants, recorders, manufacturing enterprises, operating enterprises, domestic responsible parties for imported medical devices, and user units based on the risk level of the

products and the quality management status of the enterprises. This classification will determine the focus and frequency of supervision and inspection, and
The drug supervision and administration department has established a regulatory credit file system for medical device registrants, recorders, manufacturing enterprises, operating enterprises, domestic responsible parties for imported medical devices, and user units. For those with poor credit records, increase the frequency of supervision and inspections, and strengthen legal penalties for dishonesty.
Article 118: The drug supervision and administration department shall strengthen supervision and inspection of the research, production, operation activities, and usage of medical devices, and focus on the following situations for supervision and inspection:
(1) The research and production of high-risk medical devices such as sterile and implantable devices;
(2) Newly established operations or significant changes in production and operation conditions;
(3) Medical devices produced under contract;
(4) Serious issues identified in supervision and inspection or sampling in the previous year;
(5) Significant risks identified in the monitoring of online sales of medical devices;
(6) Administrative penalties were imposed for violating relevant laws and regulations;

(7) Other situations that require key supervision and inspection.
Article 119: The drug supervision and administration department has the following powers during supervision and inspection:
(1) To enter the site for inspection and sample collection;
(2) To review, copy, seal, and seize relevant contracts, invoices, account books, and other related materials;
(3) To seal and seize medical devices that do not meet legal requirements, illegally used components, raw materials, and tools or equipment used for the illegal production and operation of medical devices;
(4) Relevant units and individuals should cooperate with the supervision and inspection, truthfully provide relevant documents and materials, honestly answer the inquiries of the inspectors, and must not conceal, refuse, or obstruct. Refusing or failing to cooperate with inspections conducted by the drug supervision and administration department in accordance with the law may be deemed as non-compliance with relevant regulations or standards and will be dealt with according to the law.
Records and materials collected by inspectors during on-site inspections, formed in accordance with the law, can serve as evidence for administrative enforcement.
If the drug supervision and administration department take measures such as sealing or seizing, the duration of the sealing or seizing shall not exceed 90 days; in complex situations, with the approval of the head of the drug supervision and administration department, it may be extended by 30 days.
Article 120: The health authorities should strengthen supervision and inspection of the use of medical devices by medical institutions. During the implementation of supervision and inspection, one can enter medical institutions to review and copy relevant files, records, and other related materials.
Article 121: The drug supervision and administration department may conduct extended inspections on other relevant units and individuals that provide products or services for the

research, production, operation, and use of medical devices as needed.
When the drug supervision and administration department conduct extended inspections, the inspected units and individuals should promptly cooperate as required by the drug supervision and administration department, truthfully provide relevant documents and materials, and honestly answer the inquiries of the inspectors, without concealing, refusing, or obstructing. Refusing or failing to cooperate with inspections conducted by the drug supervision and administration department in accordance with the law, and if medical device research, production, and business entities cannot prove that their activities comply with legal requirements, it may be deemed non-compliant with regulations or standards, and will be dealt with according to
Article 122: When a medical device registrant entrusts production across regions, the drug supervision and administration department at the registrant's location is responsible for supervising and inspecting the registrant's compliance with legal obligations regarding the operation of the quality management system, vigilance, and product recalls. The drug supervision and administration department in the location of the entrusted manufacturing enterprise is responsible for conducting regular supervision and inspections of the production activities of the entrusted manufacturing enterprise.
The drug supervision and administration department of the location of the medical device registrant and the entrusted manufacturing enterprise should establish a collaborative regulatory mechanism, which can delegate or jointly conduct supervision and inspection to strengthen oversight.

Article 123 The drug supervision and administration department of the State Council may organize and implement overseas inspections of the overseas research and development and production-related processes of medical devices that have been marketed or are intended to be marketed in China.

The drug supervision and administration departments of the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government shall organize and strengthen the supervision and inspection of the domestic responsible persons of imported medical devices within their administrative regions. If major safety hazards are found through complaints, warnings, random inspections, etc., they may verify the relevant information of the registrants and recorders of imported medical devices through written inspections, remote inspections, etc.

Article 124 The drug supervision and administration department may conduct random inspections on the quality of medical devices according to the needs of supervision and management and shall not charge inspection fees and any other fees for random inspections.

In principle, samples should be purchased for sampling, but samples do not need to be purchased in the following circumstances:

(i) Large medical devices;

(ii) Those that can be returned after inspection;

(iii) Targeted sampling for suspected quality problems;

(iv) Other circumstances specified by the State Council Drug Administration.

The expenses required for random inspections and tests shall be included in the fiscal budget at the same level. Sampling shall be carried out by two or more sampling personnel in accordance with the provisions of the State Council Drug Administration. The sampled units shall cooperate with the sampling personnel in sampling.

Article 125 The drug administration of the people's government at or above the provincial level shall promptly issue medical device quality announcements based on the conclusions of random inspections and tests. If the announcement is inappropriate, it shall be corrected in a timely manner within the scope of the original announcement.

Article 126 The qualification certification of medical device inspection institutions shall be uniformly managed in accordance with relevant national regulations.

Only inspection institutions that have been certified and announced by the State Council Certification and Accreditation Administration in conjunction with the State Council Drug Administration in accordance with the inspection parameters may conduct inspections on medical devices. For those that are not yet covered by the scope of certification and accreditation, the drug administration may select inspection institutions with corresponding capabilities to conduct relevant inspections, and the inspection conclusions may be used as the basis for determining the quality of medical devices.

If the drug supervision and administration department need to entrust a medical device inspection agency to conduct inspections during law enforcement, it shall pay the relevant fees.

Article 127 If a party has any objection to the inspection conclusion, it may apply for re-inspection to the department that implements the sampling inspection or its higher-level drug supervision and administration department within 7 working days from the date of receipt of the inspection conclusion. The department that accepts the re-inspection application shall randomly determine the re-inspection agency from the list of re-inspection agencies for re-inspection. The medical device inspection agency that undertakes the re-inspection work shall make a re-inspection conclusion within the time specified by the drug supervision and administration department of the State Council. The re-inspection conclusion is the final inspection conclusion. The re-inspection agency shall not be the same as the initial inspection agency; if there is only one qualified inspection agency 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 supervision and administration department of the State Council.

Article 128: For medical devices that may contain harmful substances or have unauthorized changes to the design, raw materials and production processes of medical devices and have safety hazards, if the inspection items and inspection methods specified in the national standards for medical devices cannot be inspected, the medical device inspection agency may use the supplementary inspection items and inspection methods approved by the State Council Drug Supervision and Administration Department for inspection; the inspection conclusions obtained by using the supplementary inspection items and inspection methods can be used as the basis for the drug supervision and administration department to determine the quality of medical devices.

Article 129: The drug supervision and administration department of the State Council shall establish a mechanism for the exchange of information on the quality and safety risks of medical devices, communicating with departments such as health and wellness, medical insurance, customs, as well as medical device manufacturers, users, and industry associations regarding quality and safety risk information. For medical devices that involve quality and safety risks that need to be brought to the public's attention, warning information should be issued.
Article 130: In the process of research, production, and operation of medical devices, if there are potential safety hazards regarding product quality that have not been addressed in a timely manner, the drug supervision and administration department may take measures such as warnings, accountability discussions, and orders for rectification within a specified time frame.
The medical device or drug that causes harm to the human body or has evidence suggesting it may endanger human health can be subject to emergency control measures by the drug supervision and administration department, which may include ordering the suspension of production, operation, import, and use, as well as issuing safety warning information.
Article 131: In any of the following circumstances, the original licensing department shall revoke the medical device registration certificate and make it public:
(1) The registrant voluntarily requests to cancel the registration;
(2) The registration is not renewed, or the registrant fails to apply for renewal upon expiration of the medical device registration certificate;
(3) The registrant's medical device registration certificate has been legally revoked or canceled;
(4) Other circumstances under which the medical device registration certificate should
Article 132: In any of the following circumstances, the original filing department shall order the filer to make corrections within a specified time; if the filer fails to make the required corrections within the time limit, the original filing department shall cancel the product filing and make it public:
(1) The filed materials are not standardized or do not meet legal requirements;
(2) The management category of the filed medical device is adjusted to Class II or Class III;
(3) The filed medical device is adjusted to no
In the case mentioned in the first item of the preceding paragraph, if the filing materials involve the product's safety and effectiveness, the product shall not continue to be produced, operated, imported, or used from the date of cancellation of the filing.
Article 133: If the drug supervision and administration department finds that the registrant or filer of a medical device cannot be contacted for more than one year, the original issuing department or filing department may revoke the medical device registration certificate or cancel the filing after a public notice of 30 days, and announce it accordingly.
If the drug supervision and administration department finds that medical device manufacturing and operating enterprises do not meet the original production and operating conditions and cannot be contacted, the original licensing or filing department may revoke the license or cancel the filing after a public notice of 30 days, and announce it accordingly.
Article 134: It is prohibited to produce, operate, import, or use medical devices that have not been legally registered or filed, lack qualified certification documents, or are expired, invalid, obsolete, or refurbished.
It is prohibited for medical device registrants, filers, manufacturing enterprises, operating enterprises, domestic responsible parties, and medical institutions to offer or receive kickbacks or other improper benefits in the buying and selling of medical devices.

It is prohibited for medical device registrants, filers, manufacturing enterprises, operating enterprises, and domestic responsible parties to provide any property or other improper benefits to the heads, procurement personnel, physicians, and other relevant individuals of medical institutions using their medical devices, under any name. It is prohibited for the heads of medical institutions, procurement personnel, physicians, and other relevant individuals to accept any property or other improper benefits from medical device registrants, recorders, manufacturers, operating enterprises, or domestic responsible parties under any name.

Article 135: The drug supervision and administration department shall strengthen inspection and law enforcement, and promptly investigate and deal with illegal activities.

The higher drug supervision and management authority may, when deemed necessary, transfer cases under its jurisdiction to lower drug supervision and management authorities, directly investigate cases under the jurisdiction of lower authorities, or designate other lower drug supervision and management authorities to handle cases that fall under the jurisdiction of lower authorities.

The drug supervision and administration department of the State Council can supervise and guide specific legal application issues in law enforcement work by publishing guiding cases and other means.

Article 136: The dispatched agencies of the drug supervision and administration departments of the people's governments of provinces, autonomous regions, and municipalities directly under the central government may conduct supervision and inspection in their own name, implement administrative enforcement measures, and impose penalties such as warnings, fines, and confiscation of illegally produced and sold medical devices and illegal gains.

Article 137: For those who have not obtained the production and operation license or filing for medical devices, or who produce and operate medical devices that have not been registered or filed, the drug supervision and administration departments of the municipal or county-level people's government shall investigate and deal with the matter according to the law.

Article 138: The state implements a unified system for the public announcement of medical device safety information. The overall situation of national medical device safety, safety risk warning information for medical devices, major medical device safety incidents and their investigation and handling information, as well as other information that the State Council deems necessary to be uniformly disclosed, shall be published by the drug supervision and administration department of the State Council.

The safety risk warning information for medical devices and information regarding significant safety incidents and their investigations, if limited to specific areas, may also be published by the drug supervision and administration departments of the people's governments of relevant provinces, autonomous regions, and municipalities directly under the central government.

The announcement of medical device safety information should be timely, accurate, and comprehensive, along with necessary explanations.

No unit or individual shall fabricate and disseminate false information regarding the safety of medical devices.

Article 139: The drug supervision and administration department shall keep confidential any trade secrets learned during the activities of reviewing and approving medical devices, inspections, alerts, and checks.

Article 140: The drug supervision and administration department shall carry out risk consultations

in accordance with the requirements of comprehensive coverage, highlighting key points, timely handling, and focusing on effectiveness. It should promptly identify and effectively address potential quality and safety risks of medical devices, implement the primary responsibility of enterprises and the responsibilities of regulatory departments, and establish a risk management
Article 141: The departments responsible for drug supervision and management shall publish their contact information to accept inquiries, complaints, and reports. Departments such as drug supervision and administration should respond promptly to inquiries related to the supervision and management of medical devices; upon receiving complaints or reports, they should verify, address, and respond in a timely manner.
For reports regarding the research, production, operation, and use of medical devices that are found to be true upon investigation, departments such as drug supervision and administration should reward the whistleblower. The relevant authorities should keep the whistleblower's identity confidential.
Article 142: The drug supervision and administration department of the State Council shall publicly solicit opinions when formulating regulatory policies, management catalogs, and technical guidance documents related to medical devices.
The State Council's drug supervision and administration department can hold hearings, demonstration meetings, and other forms to gather opinions from experts, medical device registrants, recorders, manufacturing enterprises, operating enterprises, user units, consumers, industry associations, and relevant organizations.
Article 143: The state establishes a consultation system for expert decision-making in medical devices. The State Council's drug supervision and administration department has established a Medical Device Decision-Making Expert Advisory Committee to provide decision-making consultations on technical matters such as the technical review, inspection and verification, classification determination, and quality inspection of medical devices. When necessary, experts can vote to form decision-making consultation opinions.
Article 144: The state implements a medical device reserve system, establishing a two-tier medical device reserve at both the central and local levels.
In the event of a major disaster, epidemic, or other emergency, in accordance with the provisions of the Emergency Response Law of the People's Republic of China, the State Council's department in charge of industry and information technology, together with relevant departments, may urgently requisition medical devices.
Article 145: Local people's governments at or above the county level shall formulate emergency plans for medical device safety incidents.
Medical device registrants, filers, manufacturers, operating enterprises, and user units should develop a safety incident response plan for medical devices within their organization and organize training and emergency drills.
In the event of a medical device safety incident, the local people's government at or above the county level shall immediately organize response efforts in accordance with the emergency plan; relevant units shall take effective measures for disposal without delay to prevent further harm.
The health authorities of local people's governments at or above the county level and the units using medical devices should establish an emergency guarantee mechanism for medical devices in accordance with national regulations to meet the emergency treatment needs in the event of sudden incidents.

Article 146: If the drug supervision and administration department fails to timely identify systemic risks to the safety of medical devices or does not promptly eliminate safety hazards related to medical devices within its supervisory area, the local people's government or the drug supervision and administration department of the higher-level people's government shall conduct a discussion with the main responsible person.
If the local people's government fails to fulfill its responsibilities for medical device safety and does not promptly eliminate significant regional safety hazards related to medical devices, the higher-level people's government or the higher-level drug supervision and administration department should conduct a discussion with its main responsible person.
The departments and local people's governments that have been summoned for talks should immediately take measures to rectify the supervision and management of medical devices.
The situation of the discussions and the rectification measures should be included in the evaluation and assessment records of the relevant departments and local people's governments regarding drug supervision and management work.
Article 147: If the drug supervision and administration department discovers that the illegal activities related to medical devices are suspected of being criminal offenses, it shall promptly transfer the case to the public security authorities.
For cases where criminal responsibility does not need to be pursued according to the law or where criminal punishment can be exempted, but administrative responsibility should be pursued, public security organs, people's procuratorates, and people's courts should promptly transfer the cases to the drug supervision and administration departments.
Public security organs, people's procuratorates, and people's courts should request assistance from departments such as drug supervision and management to provide inspection conclusions, identification opinions, and to assist in the harmless treatment of medical devices involved in the case. The drug supervision and management departments should provide timely assistance.
Article 148: If the drug supervision and administration department discovers clues regarding public officials suspected of disciplinary or legal violations during administrative enforcement, it shall, in accordance with the requirements of the integrated and coordinated mechanism of administrative enforcement and disciplinary inspection and supervision, promptly transfer the clues and evidence materials to the corresponding disciplinary inspection and supervision authorities based on the management authority of

Chapter Ten: Legal Responsibility

Article 149: Those who violate the provisions of this law and constitute a crime shall be held criminally liable according to the law.
Article 150: In any of the following circumstances, the drug supervision and administration department shall order corrections, confiscate illegal gains, and confiscate medical devices produced or operated illegally, as well as tools, equipment, raw materials, and other items used for illegal production and operation; if the value of the illegally produced or operated medical devices is less than 10,000 yuan, a fine of not less than 50,000 yuan and not more than 150,000 yuan shall be imposed; if the
In cases where the first item of the preceding paragraph applies and the circumstances are serious, the original licensing department shall revoke the medical device manufacturing license or the

medical device business license.
Article 151: In any of the following circumstances, the drug supervision and administration department shall order corrections, confiscate illegal gains, and confiscate medical devices that are illegally produced, operated, or used; if the value of the illegally produced, operated, or used medical devices is less than 10,000 yuan, a fine of between 20
(1) Producing, operating, or using medical devices that do not comply with mandatory standards or do not meet the technical requirements of registered or filed products;
(2) Failing to organize production according to the technical requirements of registered or filed products;
(3) Not establishing a quality management system as required by law and failing to maintain its effective operation, which affects product safety and efficacy;
(4) Operating, importing, or using medical devices without valid certification documents, or those that are
Article 152: Those who configure and use large medical equipment without permission shall be ordered by the health authorities of the local people's government at or above the county level to cease use, receive a warning, and have illegal gains confiscated; if the illegal gains are less than 10,000 yuan, a fine of between 50,000 and
Article 153: If false information is provided or other deceptive means are employed when applying for medical device administrative permits, the application will be denied, or the department that made the administrative permit decision will revoke the already granted permit. Illegal gains and medical devices produced, operated, or used unlawfully will be confiscated. For a period of 10 years
Those who forge, alter, buy, sell, rent, or lend medical device licenses will have their licenses confiscated or revoked by the original issuing authority, and any illegal gains will be seized. If the illegal gains are less than 10,000 yuan, a fine of between 50,000 and
Article 154: In any of the following circumstances, the drug supervision and administration department shall announce the name of the unit and product to the public, and order a deadline for correction; if the correction is not made by the deadline, illegal gains and illegally produced medical devices shall be confiscated; if the value of the illegally produced medical devices is less if the value of the illegally produced medical devices is less than 10,000 yuan, a fine of between 10,000 and 50,000 yuan shall be imposed; if the value is more than 10,000 yuan, a fine of between five times and twenty times the value shall be imposed; in serious cases, the legal representative,
Article 155: If false information is provided during the filing process, the drug supervision and management department shall publicly announce the filing unit and product name, confiscate illegal gains, and medical devices produced or operated unlawfully. If the value of the illegally produced or operated medical devices is less than 10,000 yuan, a fine of between 20
Article 156: Medical device operating enterprises and user units that have fulfilled the obligations of inspection and verification as stipulated by this law, and have sufficient evidence to prove that they were unaware that the medical devices they operated or used fell under the circumstances specified in Article 150, paragraph 1, item 1, Article 151, item 1 and
Article 157: In any of the following circumstances, the drug supervision and management department shall order correction and impose a fine of not less than 10,000 yuan and not more than 50,000 yuan; if correction is refused, a fine of not less than 50,000 yuan and not more than 100,000 yuan shall be imposed; for serious violations, production and business operations shall be

ordered to cease, up to and including the revocation of the medical device production license and medical device

Article 158: In any of the following circumstances, the drug supervision and administration department and the health and wellness authority shall order corrections and issue warnings according to their respective responsibilities; if corrections are refused, a fine of not less than 10,000 yuan and not more than 100,000 yuan shall be imposed. In serious cases, production and

(1) Failure to conduct a self-inspection of the quality management system's operation as required and submit a self-inspection report;

(2) Purchasing medical devices from suppliers that do not possess legal qualifications;

(3) Medical device operating enterprises and users have not established and implemented a record-keeping system for incoming inspections of medical devices as stipulated by law;

(4) Enterprises engaged in the wholesale of Class II and Class III medical devices and the retail of Class III medical devices have not established and implemented a sales record system as required by law;

(5) Medical device registrants, filers, manufacturers, operating enterprises, and users have not conducted vigilance monitoring of medical devices as required by law, failed to report adverse events

Article 159: Those who knowingly provide production and operation venues or other conditions for the illegal activities specified in Article 150 and Article 151 of this law shall be ordered by the drug supervision and administration department of the people's government at or above the county level to cease the illegal activities, confiscate the illegal gains, and impose a fine of not less

Article 160: In any of the following circumstances, the health and wellness authorities of local people's governments at or above the county level shall order corrections and issue a warning; if corrections are refused, a fine of not less than 50,000 yuan and not more than 100,000 yuan shall be imposed; for serious violations, a fine of not less than 100,000 yuan and not more than 300,000 yuan shall be imposed, and the relevant medical device usage activities shall be suspended until the original licensing department revokes the practice license. Responsible personnel may be ordered to

Article 161: Those who import medical devices in violation of the relevant laws and administrative regulations on the inspection of import and export goods shall be dealt with by customs in accordance with the law.

Article 162: If a clinical trial is conducted without the registration of the medical device clinical trial institution, the drug supervision and administration department shall order the cessation of the clinical trial and require corrections; if corrections are refused, the data from the clinical trial shall not be used for product registration or filing. A fine of not less than 50,000

If a clinical trial sponsor conducts a clinical trial without filing for record, the drug supervision and management department shall order the cessation of the clinical trial, impose a fine of between 50,000 and 100,000 yuan on the clinical trial sponsor, and announce this to the public, if serious consequences occur. The data from this clinical trial may not be used for product registration or filing, and applications for medical device registration from the responsible individuals or units will not be accepted for five years.

If a clinical trial sponsor conducts clinical trials of Class III medical devices that pose a higher risk to humans without approval, the drug supervision and administration department shall order the immediate cessation of the clinical trial, impose a fine of between 100,000 and 300,000 yuan on

the clinical trial sponsor, and announce that the data from this clinical trial cannot be used for product registration. For a period of ten years, applications for clinical trials and registration submitted by the responsible individuals and units will not be accepted. The legal representatives, main responsible persons, directly accountable supervisors, and other responsible personnel of the violating units will have their income

Article 163: If medical device clinical trial institutions or sponsors of clinical trials conduct medical device clinical trials without adhering to clinical trial quality management standards, the drug supervision and administration department shall order them to make corrections or immediately stop the clinical trials. If they fail to correct within the specified time, they will be fined between 50,000 and 100

Article 164: If a clinical trial institution for medical devices issues false reports, the drug supervision and administration department shall impose a fine of not less than 100,000 yuan and not more than 300,000 yuan; if there are illegal gains, those gains shall be confiscated; the institution shall be prohibited from conducting relevant professional clinical trials for

Article 165: Those who violate the regulations on the management of medical device advertisements as stipulated in this law shall be punished in accordance with the Advertising Law of the People's Republic of China; those who engage in false or misleading promotion of medical devices through other means shall be punished in accordance with relevant laws.

Article 166: If the medical device technical review agency and the medical device vigilance technical agency fail to perform their duties in accordance with the provisions of this law, resulting in serious issues in the review and vigilance work the drug supervision and administration department shall order corrections, issue a notice of criticism, and give a warning; if serious consequences occur, legal representatives

Article 167: If the registrant or filer of medical devices is a foreign enterprise and its designated domestic responsible person fails to fulfill relevant obligations in accordance with this law, the provisions regarding the legal responsibilities of registrants and filers of medical devices shall apply.

Article 168: Those who engage in any of the following behaviors shall be subject to heavier penalties within the scope of punishment prescribed by this law:

(1) Producing or selling unregistered or unrecorded medical devices primarily intended for use by pregnant women and children, or medical devices that do not meet mandatory standards;

(2) Producing or selling high-risk implantable medical devices that are unregistered or do not meet mandatory standards;

(3) Producing or selling medical devices that are unregistered or

Article 169: If a medical device inspection institution issues a false inspection report, the competent department that granted its qualification shall revoke its inspection qualification. For a period of ten years, applications for qualification recognition from the responsible individuals and units will not be accepted, and a fine of between 200,000 and 1,000,000 yuan will be

Article 170: If the registrant, record-keeper, manufacturing enterprise, operating enterprise, or medical institution of medical devices violates regulations by employing personnel improperly, they shall be ordered by the drug supervision and administration department or the health and wellness authority to dismiss the personnel and shall be fined between 50,000 and 200,000 yuan.

Article 171: If medical device registrants, filers, manufacturers, operating enterprises, domestic responsible persons, or medical institutions provide or accept kickbacks or other improper benefits

during the purchase and sale of medical devices, the market supervision and management department shall confiscate the illegal gains and impose a fine of not less than 300,000 yuan and not

Those who bribe national staff during the research, production, and operation of medical devices, including registrants, recorders, manufacturing enterprises, operating enterprises, and domestic responsible persons, will face a lifetime ban on engaging in the production and operation of medical devices for the legal representative, main responsible person, directly responsible

Article 172: If the responsible persons, procurement personnel, and other relevant individuals of medical device registrants, filers, manufacturing enterprises, operating enterprises, and domestic responsible parties receive property or other improper benefits from other medical device registrants, filers, manufacturing enterprises, operating enterprises, or domestic responsible parties during the purchase and sale of medical devices,

Those responsible for medical institutions, procurement personnel, physicians, and other relevant individuals who accept property or other improper benefits from medical device registrants, filers, manufacturers, operating enterprises, or domestic responsible parties shall be punished by the health authorities or their respective units, and the health authorities shall impose penalties in accordance with

Article 173: Those who violate the provisions of this law by fabricating and disseminating false safety information about medical devices, thereby constituting a violation of public order management, shall be subject to administrative penalties by public security organs in accordance with the law.

Article 174: If the registrant, record-keeper, manufacturer, business entity, or medical institution of medical devices violates the provisions of this law and causes harm to the user, they shall bear liability for compensation in accordance with the law.

If a victim suffers damages due to quality issues with medical devices, they can seek compensation for their losses from the medical device registrant, record-keeper, or manufacturer. They can also request compensation from the operating enterprise or medical institution. Upon receiving a compensation request from the victim, the principle of primary liability should be implemented, and compensation should be paid first; after the initial payment, recovery can be pursued according to the law.

If the registrant, filer, manufacturing enterprise, operating enterprise, or medical institution of medical devices is found to be in any of the following situations, the victim or their close relatives may request not only compensation for damages but also payment of ten times the price or three times the damages; if the increased compensation amount is less than 1,000 yuan, it shall be set at 1,000 yuan.

Article 175: If the drug supervision and administration department or its designated medical device professional technical institution participates in medical device business activities, its superior authority shall order corrections and confiscate illegal income; in cases of serious circumstances, legal penalties shall be imposed on the directly responsible supervisors and other personnel directly responsible.

If the staff of the drug supervision and administration department or its designated medical device professional technical institutions participate in medical device business activities, they will be punished according to the law.

Article 176: If the drug supervision and administration department or its designated medical device

inspection agency illegally collects inspection fees during the supervision and inspection of medical devices, the relevant government department shall order a refund. Disciplinary actions shall be taken against the directly responsible supervisors and other personnel directly responsible according to the law; in severe cases, their inspection qualifications shall

Article 177: If the drug supervision and administration department or the health and wellness authority engages in any of the following actions in violation of this law, they shall revoke the relevant licenses and impose penalties on the directly responsible supervisors and other directly responsible personnel in accordance with the law:

(1) Approving clinical trials for medical devices that do not meet the required conditions;

(2) Issuing medical device registration certificates for medical devices that do not meet the required conditions;

(3) Issuing medical

Article 178: If a local people's government at or above the county level violates the provisions of this law and engages in any of the following behaviors, the directly responsible supervisors and other directly responsible personnel shall be given a reprimand or a serious reprimand; in severe cases, they shall be demoted, dismissed, or expelled:

(1) Concealing, falsely reporting, delaying reporting, or failing to report medical device safety incidents (2) F

Article 179: Those who violate the provisions of this law, and the departments responsible for drug supervision and management, shall impose penalties such as reprimands or major reprimands on the directly responsible supervisors and other directly responsible personnel for any of the following behaviors; for more serious circumstances, demotion or dismissal shall be imposed; for severe circumstances, expulsion shall be imposed:

(1) Concealing, falsely reporting, delaying reporting, or failing to report medical device safety incidents;

(2) Failing to promptly

Article 180: Those in charge of the supervision and management of medical devices who abuse their power, engage in favoritism and corruption, or neglect their duties shall be punished according to the law.

For serious violations in the investigation of medical device incidents, those responsible for dereliction of duty or misconduct will be subject to severe penalties according to the law, including the supervisory personnel and other directly responsible individuals from the drug regulatory authorities.

Article 181: Administrative law enforcement personnel for medical devices shall correctly fulfill their supervisory responsibilities in accordance with relevant work procedures. If there is no abuse of power, favoritism, or neglect of duty, they shall not be held accountable for administrative law enforcement errors.

Article 182: The value of goods specified in this chapter is calculated based on the marked price of the illegally produced or sold medical devices; if there is no marked price, it is calculated based on the market price of similar medical devices.

Article 183: If the actual controller of an enterprise engages in or organizes, instructs medical device registrants, recorders, manufacturers, or operating enterprises to engage in acts that violate the provisions of this law, and the actual controller is a corporate entity, administrative penalties shall be imposed in accordance with the relevant provisions of this law regarding medical device

registration.
Article 184: If the operators of medical device e-commerce platforms violate the provisions of this law by failing to perform qualification reviews, timely stop and report violations, or cease providing online trading platform services, they shall be ordered to correct the situation, have illegal gains confiscated, and be fined between 200,000 and 2,000,000
If operators of medical device e-commerce platforms violate regulations and fail to record their compliance with the obligations stipulated by this law, the drug supervision and administration department shall order them to make corrections; if they do not correct within the specified time, they will be fined between 20,000 and 100,000 yuan
Operators of e-commerce platforms for medical devices who violate regulations by providing information display, links, and other services for medical devices not registered domestically and outside the catalog will be ordered to rectify the situation, have their illegal gains confiscated, and face fines ranging from 200,000 to 2 million yuan;
Article 185: In determining illegal gains, all income obtained from the illegal production and sale of medical devices or the provision of services by the registrant, record-keeper, manufacturing enterprise, operating enterprise, and medical institutions should be calculated. Any amounts that the parties can provide evidence for having already paid, such as taxes and social insurance fees mandated by
The legal representative, main responsible person, directly responsible supervisors, and other responsible personnel shall disclose their income from the unit, including basic salary, bonuses, allowances, subsidies, employee welfare expenses, various insurance premiums, housing fund contributions, pensions, and any other forms of compensation received from the unit.

Chapter Eleven Supplementary Provisions

Article 186 The meanings of the following terms in this law are:
Medical devices refer to instruments, equipment, tools, in vitro diagnostic reagents and calibrators, materials, and other similar or related items that are used directly or indirectly on the human body, including the necessary computer software; their utility is primarily obtained through physical means rather than pharmacological, immunological, or metabolic means, or although these methods are involved, they only play an auxiliary role; their purposes are:
(1) Diagnosis, prevention, monitoring, treatment, or alleviation of diseases;
(2) Diagnosis, monitoring, treatment, alleviation, or functional compensation of injuries;
(3) Examination, replacement
The registrant or filer of medical devices refers to the enterprises or research institutions that have obtained a medical device registration certificate or have completed the filing of medical devices.
A medical device user unit refers to an institution that provides medical and other technical services to others using medical devices, including medical institutions, blood stations, single plasma collection stations, and rehabilitation assistive device fitting institutions, among others.
Large medical equipment refers to medical devices that are technically complex, require significant financial investment, have high operating costs, greatly impact medical expenses, and are included in directory management.
Article 187: Fees may be charged for the registration of medical device products. The specific charging items and standards are formulated by the Ministry of Finance and the pricing authorities

of the State Council in accordance with relevant national regulations.
Article 188: The management measures for medical devices developed by medical and health institutions in response to sudden public health emergencies shall be formulated by the drug supervision and administration department of the State Council in conjunction with the health and wellness authorities of the State Council.
Engaging in the storage, allocation, and supply of non-profit contraceptive medical devices must comply with the management measures established by the health authorities of the State Council in conjunction with the State Drug Administration.
The technical guidance principles for traditional Chinese medicine medical devices are formulated by the drug supervision and administration department of the State Council in conjunction with the department in charge of traditional Chinese medicine under the State Council.
Article 189: The supervision and management of the use of military medical equipment shall be carried out in accordance with this law and relevant military regulations.
Article 190 This law shall come into effect from X year X month X day.