Regulations on the Supervision and Administration of Medical Devices (2024 Revision) [1]

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Regulations on the Supervision and Administration of Medical Devices

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Chapter I: General Provisions

Article 1

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

Article 2

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

Article 3

The national drug regulatory authority under the State Council shall be responsible for the supervision and administration of medical devices throughout the country. Relevant

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

departments under the State Council shall, within the scope of their respective duties, be responsible for supervision and administration related to medical devices.

Article 4

People's governments at or above the county level shall strengthen leadership over the supervision and administration of medical devices within their respective administrative regions, organize and coordinate related work and emergency responses, enhance capacity-building for supervision and regulation, and provide safeguards for the safety of medical devices.

Departments in charge of drug supervision and administration at or above the county level shall be responsible for the supervision and administration of medical devices within their respective jurisdictions. Relevant departments at the same level shall, within the scope of their respective duties, undertake supervision and administration related to medical devices.

Article 5

The supervision and administration of medical devices shall adhere to the principles of risk management, whole-process control, scientific regulation, and co-governance by society.

Article 6

The State shall manage medical devices by classification based on risk levels:

-Class I medical devices present low risk and can be ensured to be safe and effective through routine administration.

-Class II medical devices present moderate risk and require strict control to ensure their safety and effectiveness.

-Class III medical devices present high risk and necessitate special measures for strict control to ensure their safety and effectiveness.

In evaluating the risk level of a medical device, factors such as the intended use, structural features, and method of use shall be considered.

The national drug regulatory authority under the State Council shall be responsible for formulating classification rules and catalogues for medical devices and, based on their production, operation, and usage, shall timely analyze and evaluate risk changes, and adjust the classification rules and catalogues accordingly. The formulation and adjustment of classification rules and catalogues shall fully solicit opinions from registrants, filers,

manufacturers, business operators, user entities, and industry organizations, and refer to international practices. The classification rules and catalogues shall be made public.

Article 7

Medical device products shall conform to mandatory national standards for medical devices; where such standards are not available, mandatory industry standards shall apply.

Article 8

The State shall formulate plans and policies for the medical device industry, incorporate medical device innovation into key development priorities, grant priority in review and approval for innovative medical devices, support their clinical promotion and use, and advance the high-quality development of the industry. The national drug regulatory authority under the State Council shall cooperate with relevant departments to implement the national plans and guiding policies for the medical device industry.

Article 9

The State shall improve the innovation system for medical devices, support both basic and applied research, and promote the adoption and application of new medical device technologies.
Support shall be provided in areas such as science and technology programs, financing, credit, bidding and procurement, and medical insurance. Enterprises shall be encouraged to establish or jointly form research and development institutions, and to cooperate with universities, research institutes, and medical institutions to carry out research and innovation in medical devices. Intellectual property protection shall be strengthened to enhance independent innovation capacity.

Article 10

The State shall strengthen the informatization of medical device supervision and administration, improve the level of online government services, and facilitate administrative licensing, filing, and other related services for medical devices.

Article 11

Industry organizations in the medical device sector shall enhance self-regulation, promote the construction of a credit system, urge enterprises to operate in compliance with laws and regulations, and guide them to act with honesty and integrity.

Article 12

Entities and individuals that make outstanding contributions to the research and innovation of medical devices shall be commended and rewarded in accordance with relevant State provisions.

Chapter II: Medical Device Product Registration and Filing

Article 13

Class I medical devices are subject to product filing management, while Class II and Class III medical devices are subject to product registration management. Medical device registrants and filers shall strengthen quality management throughout the entire lifecycle of the medical devices and shall be legally responsible for the safety and effectiveness of the medical devices throughout their research, production, operation, and use.

Article 14

For the filing of Class I medical device products and the registration application for Class II and Class III medical device products, the following materials shall be submitted:

1-Product risk analysis materials;

2-Product technical requirements;

3-Product inspection report;

4-Clinical evaluation materials;

5-Product instructions for use and label drafts;

6-Quality management system documents related to product development and production;

7-Other materials necessary to prove the product's safety and effectiveness.

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

If the clinical evaluation is exempted under the provisions of Article 24 of these regulations, clinical evaluation materials may be omitted.

Medical device registration applicants and filers shall ensure that the submitted materials are legal, authentic, accurate, complete, and traceable.

Article 15

For the filing of Class I medical device products, the filer shall submit the filing materials to the drug regulatory department of the municipal-level people's government where it is located.

For Class I medical devices exported to China from abroad, the foreign filer shall appoint a domestic enterprise legal person in China to submit the filing materials and the approval document from the competent authority in the country (region) of the filer permitting the marketing of the medical device. For innovative medical devices not yet marketed abroad, the approval document from the foreign competent authority permitting marketing may be exempted.

Once the filer submits filing materials that meet the requirements of these regulations to the competent drug regulatory department, the filing is deemed complete. The competent drug regulatory department shall, within 5 working days from receiving the materials, publish the relevant filing information through the online government service platform of the State Council's drug regulatory department.

If any item specified in the filing materials changes, it shall be changed with the original filing department.

Article 16

To apply for registration of Class II medical devices, the applicant shall submit registration application materials to the drug regulatory department of the provincial-level people's government (provinces, autonomous regions, municipalities directly under the central government) where it is located. To apply for registration of Class III medical devices, the applicant shall submit registration application materials to the drug regulatory department under the State Council.

For Class II and Class III medical devices exported to China, the foreign registration applicant shall designate a domestic enterprise legal person in China to submit the registration materials and the approval document from the competent authority in the applicant's country (region) permitting the marketing of the medical device. For innovative medical devices not yet marketed abroad, the approval document from the foreign competent authority permitting marketing may be exempted.

The drug regulatory department under the State Council shall specify the procedures and requirements for medical device registration review and strengthen supervision and guidance over the registration review work of the provincial-level drug regulatory departments.

Article 17

The drug regulatory authority that accepts the registration application shall review the safety and effectiveness of the medical device, as well as the applicant's capability to ensure the device's safety and effectiveness through quality management.

The drug regulatory authority that accepts the registration application shall, within 3 working days from the date of acceptance, transfer the application documents to a technical evaluation institution. After completing the technical evaluation, the institution shall submit its evaluation opinions to the drug regulatory authority as the basis for approval.

If, during the technical evaluation process, the drug regulatory authority believes it is necessary to verify the quality management system, it shall organize a quality management system inspection.

Article 18

The drug regulatory department shall decide within 20 working days from receiving the review opinions. If the application meets the requirements, registration shall be approved and a medical device registration certificate issued. If the application does not meet the requirements, registration shall be denied with written reasons.

The department shall, within 5 working days after granting registration, publish the relevant registration information on the online government service platform of the drug regulatory department under the State Council.

Article 19

For medical devices used for the treatment of rare diseases, life-threatening conditions with no effective treatment, or in response to public health emergencies, the drug regulatory department may grant conditional approval and indicate relevant matters in the medical device registration certificate.

In the event of major public health emergencies or other serious threats to public health, the National Health Department and the National Disease Control Department may propose emergency use of medical devices as needed for prevention and control. Upon expert assessment and approval by the drug regulatory department under the State Council, such devices may be used in a limited scope and timeframe.

Article 20

Medical device registrants and filers shall fulfill the following obligations:

-Establish and effectively operate a quality management system appropriate to the product;

-Develop and implement post-market research and risk control plans;

-Legally conduct adverse event monitoring and re-evaluation;

-Establish and implement product traceability and recall systems;

-Fulfill other obligations prescribed by the drug regulatory department under the State Council.

The domestic enterprise legal person designated by foreign medical device registrants and filers shall assist in fulfilling the above obligations.

Article 21

For registered Class II and Class III medical device products, if there are substantive changes in design, raw materials, production process, intended use, or usage methods that may affect safety and effectiveness, the registrant shall apply for registration modification with the original registration department. For other changes, the registrant shall file or report them according to the provisions of the drug regulatory department under the State Council.

Article 22

The medical device registration certificate is valid for 5 years. To renew the registration, the registrant shall apply for renewal at least 6 months before the expiry date.

Unless otherwise stated in the third paragraph of this article, the drug regulatory department shall decide on the renewal application before the certificate expires. If no decision is made by the expiry date, it shall be deemed as approved.

Renewal shall not be granted in the following cases:

-The application for renewal was not submitted within the required timeframe;

-The mandatory standards for medical devices have been revised and the device no longer meets the new standards;

-The conditions of a conditionally approved device were not met within the prescribed period.

Article 23

For newly developed medical devices not yet included in the classification catalogue, the applicant may either directly apply for registration in accordance with the provisions for Class III medical devices, or determine the category based on classification rules and apply to the drug regulatory department under the State Council for category confirmation before proceeding with registration or filing according to these regulations.

If applying directly for Class III registration, the department shall determine the category based on the risk level and, once approved, include the device in the classification catalogue. If applying for category confirmation, the department shall determine the category and notify the applicant within 20 working days from acceptance.

Article 24

Clinical evaluation must be conducted for medical device registration and filing, except in the following cases where it may be exempted:

-The working mechanism is clear, the design is finalized, the production process is mature, the same type of product has been in clinical use for many years without serious adverse events, and the intended use has not changed;

-The safety and effectiveness of the product can be demonstrated through non-clinical evaluation.

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

Article 25

To conduct a clinical evaluation of a medical device, depending on the product characteristics, clinical risks, and existing clinical data, one may conduct clinical trials or analyze clinical literature and data of similar products to prove the device's safety and effectiveness.

If the existing clinical literature and data are insufficient to confirm the device's safety and effectiveness, a clinical trial must be conducted according to the provisions of the drug regulatory department under the State Council.

Article 26

To conduct clinical trials of medical devices, the trials shall comply with the Good Clinical Practice (GCP) for medical devices, be conducted in qualified institutions, and be filed with the provincial-level drug regulatory department where the sponsor is located. The accepting department shall notify the drug regulatory and health departments where the trial institution is located.

Clinical trial institutions for medical devices shall be subject to filing management. The conditions required for such institutions, filing procedures, and GCP guidelines shall be formulated and published by the drug regulatory department and the health department under the State Council.

The state encourages medical institutions to conduct clinical trials and includes trial capabilities in hospital grading assessments, encouraging innovation in clinical trials.

Article 27

For Class III medical devices with high risks to humans in clinical trials, approval from the drug regulatory department under the State Council is required. The department shall evaluate the equipment, personnel qualifications of the trial institution, the risk level of the device, the implementation plan, and the benefit-risk analysis report, and decide within 60 working days from the date of application. If no decision is made within the time limit, the trial is deemed approved. Approval shall be notified to the trial institution's provincial drug regulatory and health departments.

The catalogue of high-risk Class III medical devices requiring clinical trial approval shall be formulated and updated by the drug regulatory department under the State Council.

Article 28

Clinical trials must undergo ethical review, and trial participants must be informed of the trial's purpose, use, and potential risks, with written informed consent obtained. If the participant is a person with no or limited civil capacity, written consent must be obtained from their legal guardian.

No fees related to clinical trials may be charged to participants in any form.

Article 29

The medical devices that are undergoing clinical trials and used for the treatment of serious life-threatening diseases for which there has been no effective treatment method, and may possibly benefit patients as indicated by medical observation may, upon ethical review and informed consent, be used free of charge to treat patients suffering from the same diseases in

the institutions that conduct the clinical trials of medical devices, and the safety data on such medical devices may be used for medical device registration applications.

Chapter III: Production of Medical Devices

Article 30

Those engaged in medical device production activities shall meet the following conditions:

1-Possess production premises, environmental conditions, production equipment, and professional technical personnel suited to the medical devices being produced;

2-Possess institutions or full-time inspection personnel and inspection equipment capable of conducting quality inspection of the medical devices produced;

3-Possess a quality management system to ensure the quality of medical devices;

4-Possess after-sales service capabilities suited to the medical devices being produced;

5-Meet the requirements stipulated in product development and production process documents.

Article 31

The enterprises engaging in the production of the medical devices of Class I shall undergo the recordation formalities with the medical products administrations of the local people's governments at the districted city level, and recordation formalities are completed once the enterprises submit the relevant materials that meet the conditions as prescribed in Article 30 of this Regulation.

The medical device recordation entities which produce the medical devices of Class I by themselves may, when undergoing the product recordation formalities in accordance with the provisions of Article 15 of this Regulation, submit the relevant materials that meet the conditions specified in Article 30 of this Regulation, then that is completing the production recordation formalities.

Article 32

Those engaged in the production of Class II and Class III medical devices shall apply for a production license from 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, and submit materials proving compliance with the conditions in Article 30 of these Regulations, along with the registration certificate of the medical devices to be produced.

The drug supervision and administration department accepting the production license application shall review the application materials, conduct verification according to the medical device Good Manufacturing Practice formulated by the national drug supervision and administration department, and decide within 20 working days from the date of accepting the application.

For those meeting the prescribed conditions, permission shall be granted, and a medical device production license shall be issued. For those not meeting the conditions, permission shall not

be granted, and reasons shall be provided in writing. The medical device production license shall be valid for five years. If an extension is needed upon expiration, extension procedures shall be handled in accordance with relevant laws on administrative licensing.

Article 33

The medical device Good Manufacturing Practice shall explicitly stipulate matters affecting the safety and effectiveness of medical devices, such as design and development, production equipment conditions, procurement of raw materials, control of production processes, product release, enterprise organizational structure, and personnel allocation.

Article 34

Medical device registrants and filers may produce medical devices on their own or may entrust enterprises that meet the conditions stipulated in these Regulations and possess corresponding capabilities to produce medical devices.

Where medical device production is entrusted, the medical device registrant or filer shall be responsible for the quality of the entrusted medical devices and shall strengthen management of the production behavior of the entrusted enterprise, ensuring that it conducts production according to legal requirements. The medical device registrant or filer shall sign an entrustment agreement with the entrusted production enterprise, clearly defining both parties' rights, obligations, and responsibilities.

The entrusted production enterprise shall organize production in accordance with laws and regulations, the medical device Good Manufacturing Practice, mandatory standards, product technical requirements, and the entrustment agreement shall be responsible for its production behavior and shall accept the supervision of the entrusting party. High-risk implantable medical devices must not be entrusted for production. The specific catalog shall be formulated, adjusted, and published by the national drug supervision and administration department.

Article 35

Medical device registrants, filers, and entrusted production enterprises shall, in accordance with the medical device Good Manufacturing Practice, establish and improve quality management systems suited to the medical devices they produce and ensure effective operation; they shall organize production strictly in accordance with the product technical requirements that have been registered or filed, and ensure that medical devices released from the factory comply with mandatory standards as well as the registered or filed technical requirements.

Medical device registrants, filers, and entrusted production enterprises shall regularly conduct self-inspections on the operation of the quality management system and submit self-inspection reports in accordance with the provisions of the national drug supervision and administration department.

Article 36

Where changes occur in the production conditions of medical devices that result in non-compliance with the requirements of the quality management system, the medical device registrant, filer, or entrusted production enterprise shall immediately take corrective measures; if safety and effectiveness of the medical devices may be affected, production activities shall be suspended immediately, and reported to the original production licensing or filing department.

Article 37

Medical devices shall use generic names. Generic names shall comply with the medical device naming rules formulated by the national drug supervision and administration department.

Article 38

The State shall, according to the categories of medical device products, implement the Unique Device Identification (UDI) system step by step, to realize traceability of medical devices. The specific methods shall be formulated by the national drug supervision and administration department in conjunction with relevant departments of the State Council.

Article 39

Medical devices shall have instruction manuals and labels. The content of the instruction manuals and labels shall be consistent with the content registered or filed and shall ensure authenticity and accuracy.

The instruction manuals and labels of medical devices shall indicate the following:

(1) Generic name, model, and specifications;

(2) Names, addresses, and contact information of the registrant, filer, and entrusted production enterprise;

(3) Production date, usage period or expiration date;

(4) Product performance, main structure, and applicable scope;

(5) Contraindications, precautions, and other content requiring warnings or prompts;

(6) Installation and usage instructions or illustrations;

(7) Maintenance and repair methods, special conditions and methods for transportation and storage;

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

Class II and Class III medical devices shall also indicate the registration certificate number. Medical devices for personal use by consumers shall also include special instructions for safe use.

Chapter IV: Distribution and Use of Medical Devices

Article 40

Enterprises engaged in the distribution of medical devices shall possess business premises and storage conditions appropriate to the scale and scope of their operations. They shall also establish and maintain a quality management system and retain quality management structures or personnel appropriate to the classes of medical devices they distribute.

Article 41

Enterprises distributing Class II medical devices shall complete a filing procedure with the medical products administration of the municipal people's government at the prefecture level and submit relevant documentation demonstrating compliance with the requirements stipulated in Article 40 of this Regulation. Pursuant to regulations issued by the medical products administration under the State Council, certain Class II medical devices, where safety and efficacy are not compromised by distribution activities, may be exempted from the filing requirement.

Article 42

Enterprises intending to distribute Class III medical devices shall apply for a distribution license from the medical products administration of the municipal people's government at the prefecture level. The application must include documentation verifying compliance with Article 40. The receiving authority shall review the application materials, conduct verifications as needed, and decide within 20 working days of the date of acceptance. If requirements are met, the authority shall grant and issue a Medical Device Distribution License; if not, it shall issue a written explanation of the denial. The license shall be valid for five years. Applications for renewal upon expiration shall comply with relevant laws governing administrative licensing.

Article 43

Medical device registrants and recordation entities distributing their own registered or filed products are not required to obtain separate business licenses or complete distribution filings but must comply with the distribution conditions set forth in this Regulation.

Article 44

Entities engaged in the distribution of medical devices shall establish and maintain a quality management system in accordance with applicable laws, regulations, and the Good Supply Practice (GSP) for medical devices issued by the State Council's medical products administration. This system shall be commensurate with the types and scale of distributed devices and shall operate effectively.

Article 45

Medical device distributors and user institutions shall procure medical devices from legally qualified registrants, recordation entities, or manufacturing and distribution enterprises. In the procurement process, entities must verify the qualifications of suppliers and the

conformity certifications of the medical devices, and establish a procurement verification and inspection recording system. Distributors engaged in wholesale of Class II or Class III devices and retail of Class III devices must also establish sales recording systems. Such records shall include:

1-Name, model, specifications, and quantity of the devices;

2-Batch number, service life or expiration date, and date of sale;

3-Name of the registrant, recordation entity, and contract manufacturer (if any);

4-Name, address, and contact details of supplier or purchaser;

5-Relevant license or certificate document numbers.

Procurement and sales records shall be authentic, accurate, complete, and traceable, and retained for periods stipulated by the State Council's medical products administration. The use of advanced technologies to enhance recordkeeping is encouraged.

Article 46

Online sales of medical devices may only be conducted by registrants, recordation entities, or licensed distribution enterprises. Except for Class I devices and certain Class II devices exempted under Article 41(2), distributors selling medical devices online must notify the municipal-level medical products administration of their activities.

E-commerce platforms facilitating such transactions shall register distributors under their real names, verify licenses, and confirm the registration or filing status of distributed devices. They must oversee business conduct on the platform and, upon discovering regulatory violations, promptly intervene and report such incidents to the competent local authorities. In cases of serious violations, they must suspend platform services to the offending distributor.

Article 47

The transportation and storage of medical devices must comply with the specifications outlined in their instructions and labeling. For devices requiring special environmental conditions (e.g., temperature or humidity), appropriate measures shall be taken to maintain their safety and effectiveness.

Article 48

Entities using medical devices shall maintain suitable storage facilities and conditions based on the device types and volumes in use. Staff shall receive appropriate technical training to ensure device use in accordance with instructions, operating protocols, and other applicable requirements.

For procurement of large-scale medical equipment, user entities must follow acquisition plans issued by the State Council's health authority. They must demonstrate alignment with clinical needs, possess necessary technical and infrastructural capacity, and employ qualified personnel. Approval and purchase permits must be obtained from provincial-level health departments.

Administrative measures for large-scale equipment and its catalog shall be jointly developed and promulgated by the health and other relevant departments under the State Council.

Article 49

Reusable medical devices must be disinfected and managed per protocols issued by the State Council's health authority.

Single-use medical devices shall not be reused; they must be destroyed and documented in accordance with national regulations. The catalog of single-use medical devices is formulated, adjusted, and published jointly by the State Council's medical products and health departments. Devices shall only be included in the single-use catalog if substantial evidence shows that reuse cannot ensure safety and effectiveness. Devices whose reuse becomes safe and effective through improvements in design, production, disinfection, or sterilization technologies shall be removed from the catalog.

Article 50

Medical device user entities shall inspect, test, calibrate, maintain, and preserve medical devices regularly as specified in the product instructions. Such actions must be recorded and evaluated to ensure performance and use quality. For long-lifespan large-scale devices, use archives must be maintained, documenting usage, maintenance, transfer, and actual runtime. These records shall be retained for at least five years following the device's expiration of its designated service life.

Article 51

Entities using medical devices shall preserve original procurement documents for Class III devices to ensure traceability.

When using large-scale, implantable, or interventional devices, key technical parameters and information necessary to ensure safety must be recorded in patient medical records or other relevant documentation.

Article 52

Upon discovery of potential safety risks, user entities must immediately cease using affected devices and notify the registrant, recordation entity, or other responsible institution for inspection. Devices that remain non-compliant after inspection shall be permanently withdrawn from use.

Article 53

Where no in vitro diagnostic reagents of the same type are marketed domestically, qualified medical institutions may, based on clinical needs, develop such reagents for internal use under the guidance of licensed physicians. Administrative measures governing this activity shall be formulated by the State Council's medical products administration in collaboration with the health department.

Article 54

Medical products administrations and health authorities shall, within their respective mandates, supervise and regulate the quality and usage of medical devices in clinical practice.

Article 55

Medical device distributors and users are prohibited from selling or using devices that:

1-Haven't been registered or unfiled as required by law,

2-Lack conformity certification,

3-Have been expired, invalidated, or officially decommissioned.

Article 56

In the transfer of medical devices between user entities, the transferor shall ensure that the devices are safe and effective. Expired, invalid, decommissioned, or noncompliant devices may not be transferred.

Article 57

Imported medical devices must be registered or filed in accordance with Chapter II of this Regulation.
They must be accompanied by instructions and labels in Chinese, which must comply with this Regulation and applicable mandatory standards. The place of origin and the name, address, and contact details of the designated domestic legal representative must be included. Devices lacking compliant Chinese instructions or labels shall not be imported. Medical institutions may, with appropriate approvals, import small quantities of Class II and Class III devices to meet urgent clinical needs. These devices may only be used within the designated institutions and for specified purposes. It is strictly prohibited to import expired, invalid, decommissioned, or previously used devices.

Article 58

Entry-exit inspection and quarantine authorities shall inspect imported medical devices in accordance with applicable laws. Devices failing inspection shall not be permitted entry. The State Council's medical products administration shall promptly notify national inspection and quarantine departments of the registration or filing status of imported medical devices. Port-based inspection authorities shall, in turn, notify local medical products administrations of import clearance details in a timely manner.

Article 59

Exporting enterprises shall ensure that their medical devices comply with the import requirements of the destination countries or regions.

Article 60

Medical device advertisements must be authentic and lawful. The content shall conform to the instructions of the medical devices as registered or filed with the medical products administrations. Advertisements must not contain false, exaggerated, or misleading information.

Before publication, medical device advertisements must be reviewed by the advertisement censoring authorities designated by the provincial-level people's governments. Approval numbers for medical device advertisements must be obtained, and no advertisement may be published without prior approval.

Advertisements may not be published for medical devices whose production, importation, distribution, or use has been suspended by medical products administrations at or above the provincial level during the suspension period.

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

Chapter V: Handling of Adverse Events and Recalls of Medical Devices

Article 61

The state shall establish a monitoring system for adverse medical device events to ensure timely collection, analysis, evaluation, and control of such incidents.

Article 62

Medical device registrants and filing entities shall establish their own adverse event monitoring systems, with appropriate institutions and staff proportional to their products. They must actively monitor, investigate, analyze, and assess adverse events and report the findings and risk control measures to the technical institutions responsible for monitoring adverse medical device events, in accordance with regulations set by the State Council's medical products administration.

Producers, distributors, and users of medical devices must support registrants and filing entities in monitoring adverse events and report any adverse or suspected adverse events as required.

Other entities or individuals who become aware of adverse or suspected adverse events may report them to the relevant medical products administrations or technical monitoring institutions.

Article 63

The medical products administration of the State Council shall enhance the development of the adverse event monitoring information network.

Technical institutions shall proactively collect and monitor adverse event data. Upon identifying or receiving reports of adverse events, they must promptly verify, investigate, analyze, and assess them, and report to relevant medical and health authorities along with recommendations for handling.

These institutions must publish their contact details to facilitate reporting by all relevant parties, including registrants, filing entities, producers, distributors, and users.

Article 64

Based on adverse event evaluations, medical products administrations shall issue warnings, suspend production, import, distribution, or use, or adopt other control measures as necessary.

For serious or widespread incidents causing injury or death, provincial-level medical products administrations must collaborate with health and other departments to investigate and monitor similar devices more closely.

Medical device users' adverse event data shall be shared with the corresponding health departments.

Article 65

All parties involved in medical devices—including registrants, filing entities, producers, distributors, and users—must cooperate with investigations conducted by monitoring institutions, medical products administrations, and health departments.

Article 66

Under any of the following circumstances, medical device registrants and recordation entities shall take the initiative to organize the re-evaluation of the marketed medical devices.

1-There are cognitional changes in the safety and effectiveness of medical devices according to the development of scientific research.

2-The results of the monitoring and evaluation of adverse medical device events show that medical devices may have defects.

3- Other circumstances as prescribed by the medical products administration of the State Council.

Medical device registrants and recordation entities shall, based on the re-evaluation results, take corresponding control measures to improve the medical devices that have been marketed, and undergo the formalities for registration or recordation modification as required. Where the re-evaluation results show that the safety and effectiveness of the medical devices that have been marketed cannot be ensured, medical device registrants and recordation entities shall take the initiative to apply for canceling medical device registration certificates or canceling recordation. Where medical device registrants or recordation entities fail to apply for cancelling medical device registration certificates or canceling recordation, the medical products administrations shall cancel medical device registration certificates or cancel recordation.

The medical products administrations of the people's governments at or above the provincial level shall conduct re-evaluation of the medical devices that have been marketed based on the monitoring and assessment of adverse medical device events, among others. Where the re-

evaluation results show that the safety and effectiveness of the medical devices that have been marketed cannot be ensured, medical device registration certificates or recordation shall be cancelled.

Medical products administrations shall release to the general public the information on the cancellation of medical device registration certificates and cancellation of recordation in a timely manner. It is not allowed to continue to produce, import, distribute or use the medical devices whose medical device registration certificates have been cancelled or whose recordation has been cancelled.

Article 67

Where the registrant or record-filing entity of a medical device discovers that the device it produces fails to comply with mandatory standards, the registered or filed product technical specifications, or is otherwise found to be defective, it shall immediately cease production, notify the relevant distributors, users, and consumers to stop distribution and use, initiate a recall of the medical device already marketed, and take remedial or disposal measures such as repair or destruction. It shall also document the relevant circumstances, issue public notices, and report the recall and handling of the medical device to the competent drug regulatory authority and the health administration department.

Where a commissioned manufacturer or distributor of medical devices discovers any of the above-mentioned issues in the medical devices it produces or distributes, it shall immediately suspend production or distribution, notify the registrant or record-filing entity, and record the suspension and notification actions. If the registrant or record-filing entity deems the situation to warrant a recall in accordance with the preceding paragraph, it shall initiate the recall without delay.

If the registrant, record-filing entity, commissioned manufacturer, or distributor fails to recall or cease production or distribution as required under this Article, the competent drug regulatory authority may order them to do so.

Chapter VI: Supervisory Inspection

Article 68

The state shall establish a system of professional inspectors to enhance the supervision and inspection of medical devices.

Article 69

Medical products administrations shall intensify inspection of all stages of medical device development, production, distribution, and use, focusing on:

1-Compliance with product technical requirements;

2-Maintenance of effective quality management systems;

3-Continuous adherence to statutory production/distribution conditions.

If necessary, inspections may be extended to related parties providing services or components.

Article 70

The department responsible for drug supervision and administration shall have the following powers during supervision and inspection:

1-To enter premises for inspection and to collect samples;

2-To review, reproduce, seal, or seize relevant contracts, invoices, account books, and other related documents;

3-To seal or seize medical devices that do not comply with statutory requirements, as well as illegally used components, raw materials, and tools or equipment used for the unlawful production or distribution of medical devices;

4-To seal premises engaged in the production or distribution of medical devices in violation of the provisions of these Regulations.

When conducting supervision and inspection, law enforcement officers shall present their official identification and shall maintain the confidentiality of the inspected entity's trade secrets.

Relevant entities and individuals shall cooperate with the supervision and inspection, provide relevant documents and materials, and shall not conceal, refuse, or obstruct such inspection.

Article 71

Health departments shall supervise the use of medical devices in healthcare institutions. They may access and copy relevant records and materials during inspections.

Article 72

If production/distribution presents safety risks and no corrective measures are taken, the administration may issue warnings, hold responsible parties accountable, or mandate corrective actions.

If evidence shows a device has caused harm or poses health risks, emergency measures such as suspensions and safety warnings may be issued.

Article 73

The department responsible for drug supervision and administration shall strengthen random inspections and testing of medical devices manufactured, distributed, or used by registrants, record-filing entities, production and business enterprises, and user institutions. No inspection fees or any other charges shall be collected for such random inspections; all related expenses

shall be included in the budget of the respective level of government. Drug supervision and administration departments at the provincial level and above shall promptly issue public notices on medical device quality based on the conclusions of such inspections.

The health authority shall supervise and assess the use of large-scale medical equipment. Upon discovering violations in use, excessive examinations, or overtreatment related to such equipment, it shall immediately correct such behavior and handle the matter in accordance with the law.

Article 74

Where the department responsible for drug supervision and administration fails to timely identify systemic risks to the safety of medical devices or eliminate potential hazards within its jurisdiction, the people's government at the same level or a higher-level drug regulatory authority shall conduct a formal interview with its principal responsible person.

Where a local people's government fails to fulfill its responsibilities regarding medical device safety or fails to promptly eliminate major regional risks, the higher-level people's government or its drug supervision and administration department shall interview the principal responsible person.

Departments and local people's governments subject to such interviews shall immediately take corrective measures to rectify medical device regulatory work.

Article 75

Accreditation of medical device inspection institutions shall be uniformly managed in accordance with relevant national regulations. Only those inspection institutions accredited by the certification and accreditation regulatory authority of the State Council, in coordination with the drug regulatory authority under the State Council, may perform inspections on medical devices.

Where the drug supervision and administration department require inspection of medical devices in the course of law enforcement, it shall commission a qualified inspection institution and cover the associated costs.

Where the concerned party disputes the inspection conclusion, they may, within 7 working days from receipt of the conclusion, apply for re-inspection with the department that conducted the sampling inspection or its superior drug regulatory authority. The department accepting the re-inspection request shall randomly select an institution from the published list of re-inspection agencies to conduct the re-inspection.

The re-inspection institution shall issue its conclusion within the timeframe prescribed by the drug regulatory authority under the State Council. The result of the re-inspection shall be deemed final. The re-inspection institution shall not be the same as the initial inspection institution. Where there is only one qualified institution for the relevant inspection item, the department or personnel responsible for the inspection shall be changed for the re-inspection.

The list of re-inspection institutions shall be published by the drug regulatory authority under the State Council.

Article 76

For medical devices suspected of containing harmful substances or where the design, raw materials, or manufacturing processes have been altered without authorization and present safety risks—and where such devices cannot be tested using the testing items and methods specified in the national or industry standards for medical devices—inspection institutions may use supplementary testing items and methods approved by the drug regulatory authority under the State Council. Inspection conclusions derived from such supplementary methods may serve as the basis for determining medical device quality by the drug supervision and administration departments.

Article 77

Market supervision and administration departments shall, in accordance with laws and administrative regulations governing advertising, supervise and inspect medical device advertisements and investigate and handle illegal activities.

Article 78

The department responsible for drug supervision and administration shall, via the State Council's drug regulatory online government service platform, lawfully and promptly publish routine regulatory information such as licensing, record-filing, inspection and testing, and the handling of violations related to medical devices. However, it shall not disclose any trade secrets of the parties concerned.

The drug supervision and administration department shall establish credit records for registrants, record-filing entities, production and business enterprises, and user institutions. It shall increase the frequency of inspections for those with negative credit records and strengthen punitive measures for acts of dishonesty in accordance with the law

Article 79

The department responsible for drug supervision and administration and other relevant departments shall publish their contact information to receive inquiries, complaints, and reports.Upon receiving inquiries related to medical device supervision, they shall respond promptly; upon receiving complaints or reports, they shall promptly verify, handle, and reply. All inquiry, complaint, and report cases, as well as the corresponding replies, verifications, and handling outcomes, shall be recorded and archived.

Where a report concerning the research, production, distribution, or use of medical devices is found to be substantiated upon investigation, the drug supervision and administration department or other relevant departments shall grant a reward to the whistleblower. Departments shall protect the confidentiality of the whistleblower.

Article 80

In developing, adjusting, and modifying the catalogues as prescribed by this Regulation and relevant norms on medical device supervision and administration, the medical products administration under the State Council shall solicit public comments and seek opinions from experts; medical device registrants; recordation entities; production and distribution enterprises; user entities; consumers; industry associations; and other relevant organizations. Such consultation shall be conducted through methods including but not limited to hearings and discussion meetings.

Chapter VII: Legal Liability

Article 81

Where any entity commits any of the following acts, the medical products administration shall confiscate the illegal income, the medical devices produced or distributed in violation of laws, and the tools, equipment, raw materials, and other articles used in such illegal production and distribution. A fine of not less than 50,000 yuan but not more than 150,000 yuan shall be imposed if the value of the medical devices involved is less than 10,000 yuan; or a fine of not less than fifteen times but not more than thirty times the value shall be imposed if the value of the medical devices is 10,000 yuan or more. If the circumstances are serious, the administration shall order suspension of production or business, refuse to accept medical device licensing applications filed by the relevant liable persons and entities within ten years, confiscate the income obtained by the legal representative, the primary person in charge, the directly responsible person in charge, and other liable persons during the period of the violation, impose a fine of not less than 30% but not more than three times the income obtained, and prohibit such individuals from engaging in the production and distribution of medical devices for life:

1-Producing or distributing Class II or Class III medical devices without obtaining medical device registration certificates;

2-Engaging in the production of Class II or Class III medical devices without permission;

3-Engaging in the distribution of Class III medical devices without permission.

Under any of the circumstances as prescribed in subparagraph (1) of the preceding paragraph, if the circumstance is serious, the original certificate issuing department shall revoke its medical device production license or the medical device distribution permit.

Article 82

Where any entity purchases or uses large-scale medical equipment without permission, the health department of the people's government at or above the county level shall order cessation of use and issue a warning and confiscate the illegal income. A fine of not less than 50,000 yuan but not more than 100,000 yuan shall be imposed if the illegal income is less than 10,000 yuan; or a fine of not less than ten times but not more than thirty times the illegal income shall be imposed if it is 10,000 yuan or more. If the circumstances are serious, applications for large-scale medical equipment purchase permits submitted by the relevant liable persons and entities shall not be accepted for five years; the income obtained by the legal representative, the primary person in charge, the directly responsible person in charge, and other liable persons during the period of violation shall be confiscated; a fine of not less than 30% but not more than three times the income shall be imposed; and disciplinary actions shall be taken according to law.

Article 83

Where any entity submits false materials or engages in other fraudulent conduct when applying for a medical device administrative license, the administrative license shall not be granted. If the license has already been granted, the licensing authority shall revoke it, confiscate the illegal income and the medical devices produced, distributed, or used in violation of laws, and refuse to accept licensing applications from the relevant liable persons and entities for ten years. A fine of not less than 50,000 yuan but not more than 150,000 yuan shall be imposed if the value of the medical devices involved is less than 10,000 yuan; or a fine of not less than fifteen times but not more than thirty times the value shall be imposed if the value is 10,000 yuan or more. If the circumstances are serious, the administration shall order suspension of production or business, confiscate the income of the legal representative, the primary person in charge, the directly responsible person in charge, and other liable persons during the period of violation, impose a fine of not less than 30% but not more than three times the income obtained, and prohibit them from engaging in medical device production and distribution for life.

Where licenses are forged, altered, traded, leased, or lent, the original certificate issuing department shall confiscate or revoke such licenses and confiscate the illegal income. If the illegal income is less than 10,000 yuan, a fine of not less than 50,000 yuan but not more than 100,000 yuan shall be imposed; or if the illegal income is 10,000 yuan or more, a fine of not less than ten times but not more than twenty times the income shall be imposed. Where public security administrative violations are involved, public security organs shall impose corresponding penalties according to law.

Article 84

Where any entity commits any of the following acts, the medical products administration shall publicize the name of the entity and its products, and order rectification. If rectification is not made within the specified time, the illegal income and the medical devices produced or distributed in violation of law shall be confiscated. A fine of not less than 10,000 yuan but not more than 50,000 yuan shall be imposed if the value of the devices is less than 10,000 yuan; or a fine of not less than five times but not more than twenty times the value shall be imposed if the value is 10,000 yuan or more. If the circumstances are serious, the income obtained by the legal representative, the primary person in charge, the directly responsible person in charge, and other liable persons shall be confiscated; a fine of not less than 30% but not more than twice the income shall be imposed; and they shall be prohibited from engaging in the production and distribution of medical devices for five years:

1-Producing or distributing Class I medical devices without completing recordation formalities;

2-Engaging in the production of Class I medical devices without recordation;

3-Failing to complete required recordation for the distribution of Class II medical devices;

4-Filing recordation materials that do not meet regulatory requirements.

Article 85

Where an entity provides false materials during recordation, the medical products administration shall publicize the name of the recordation entity and its products, and confiscate illegal income and medical devices produced or distributed in violation of laws. A fine of not less than 20,000 yuan but not more than 50,000 yuan shall be imposed if the value is less than 10,000 yuan; or a fine of not less than five times but not more than twenty times the value shall be imposed if the value is 10,000 yuan or more. If the circumstances are serious, the administration shall order suspension of production or business, confiscate the income obtained by responsible persons during the period of violation, impose a fine of not less than 30% but not more than three times the income, and prohibit them from engaging in medical device production and distribution for ten years.

Article 86

Where any entity commits any of the following acts, the medical products administration shall order rectification and confiscate the devices involved. A fine of not less than 20,000 yuan but not more than 50,000 yuan shall be imposed if the value is less than 10,000 yuan; or a fine of not less than five times but not more than twenty times the value shall be imposed if the value is 10,000 yuan or more. If the circumstances are serious, the administration shall order suspension of business until the original certificate issuing department revokes the registration certificate, production license, and distribution permit; confiscate the income obtained by responsible persons during the period of violation; impose a fine of not less than 30% but not more than three times the income; and prohibit them from engaging in production and distribution of medical devices for ten years:

1-Producing, distributing, or using devices that fail to meet mandatory standards or technical requirements for registration or recordation;

2-Failing to organize production according to registered or recorded technical requirements, or failing to establish and maintain a quality management system, thereby affecting product safety and effectiveness;

3-Distributing or using devices lacking a conformity certificate, or that are expired, invalid, eliminated, or unregistered;

4-Failing to recall products after being ordered to do so or continuing illegal activities after an order to suspend or stop;

5-Commissioning production to an enterprise that does not meet regulatory conditions or failing to supervise such enterprise;

6-Importing expired, invalid, eliminated, or used medical devices.

Article 87

Where a medical device distribution enterprise or use entity has fulfilled its obligations under this Regulation—such as purchase checks and inspections—and there is sufficient evidence proving it was unaware that the devices fell under Article 81(1), Article 84(1), or Article 86(1) and (3), and can truthfully explain the source of the purchased devices, the administration shall confiscate the non-compliant devices, and may exempt the entity from administrative punishment.

Article 88

Where any entity commits any of the following acts, the medical products administration shall order rectification and impose a fine of not less than 10,000 yuan but not more than 50,000 yuan. If it refuses to rectify, a fine of not less than 50,000 yuan but not more than 100,000 yuan shall be imposed. If the circumstances are serious, the administration shall order suspension of business until the original certificate issuing department revokes relevant licenses, confiscate the income of responsible persons, impose a fine of not less than 30% but not more than twice the income obtained, and prohibit them from engaging in production and distribution of medical devices for five years:

1-Failing to rectify, stop production, or report when production conditions no longer meet quality management requirements;

2-Producing or distributing devices with labels or instructions that do not comply with regulations;

3-Failing to store or transport devices as indicated in their labels or instructions;

4-Transferring expired, invalid, eliminated, or unqualified medical devices in use.

Article 89

Where any of the following acts are committed, the medical products administration and health department shall, within their respective responsibilities, order rectification and issue a warning. If the entity refuses to rectify, a fine of not less than 10,000 yuan but not more than 100,000 yuan shall be imposed. If the circumstances are serious, the administration shall order suspension of business until the original certificates are revoked and impose a fine of not less than 10,000 yuan but not more than 30,000 yuan on responsible persons:

1-Failing to submit the self-examination report on the quality management system;

2-Purchasing devices from unqualified suppliers;

3-Failing to establish and implement the purchase check and inspection record system;

4-Failing to establish and implement the sales recording system for wholesale of Class II/III or retail of Class III devices;

5-Failing to conduct or report adverse event monitoring or support investigations;

6-Failing to develop or implement post-marketing research and risk control plans;

7-Failing to establish and implement product traceability systems;

8-Failing to notify authorities about online medical device sales;

9-Failing to inspect, test, calibrate, maintain, and preserve devices regularly or to evaluate performance as required;

10-Failing to maintain source materials for purchasing Class III devices.

Article 90

Where any of the following violations occur, the health department of the people's government at or above the county level shall order rectification and issue a warning. If the entity refuses to rectify, a fine of not less than 50,000 yuan but not more than 100,000 yuan shall be imposed. If the circumstances are serious, a fine of not less than 100,000 yuan but not more than 300,000 yuan shall be imposed; the use of relevant devices shall be suspended until the practicing license is revoked; responsible persons shall be suspended from practice for six months to one year or have their practicing certificates revoked. The income obtained by such individuals during the period of violation shall be confiscated, a fine of not less than 30% but not more than three times the income shall be imposed, and disciplinary action shall be taken in accordance with the law:

1-Failing to disinfect and manage reused medical devices in accordance with regulations;

2-Reusing single-use devices or failing to destroy them after use;

3-Failing to properly record information on large-scale or implantable/interventional devices;

4-Failing to cease using or issue maintenance alerts for unsafe devices, or continuing to use non-compliant devices;

5-Using large-scale medical equipment in violation of regulations, compromising medical safety or quality.

Article 91

The importation of medical devices in violation of relevant laws or administrative regulations concerning the inspection of import and export commodities shall be handled by entry-exit inspection and quarantine authorities in accordance with the law.

Article 92

Where an e-commerce platform operator providing services for online medical device transactions violates the provisions of this Regulation by failing to fulfill administrative responsibilities—such as conducting real-name registration of medical device vendors on the platform, verifying relevant permits, registrations, and filings, halting and reporting unlawful conduct, or ceasing provision of online transaction platform services—the medical products administration shall impose penalties in accordance with the *E-Commerce Law of the People's Republic of China*.

Article 93

Entities conducting clinical trials without completing the required recordation of the medical device clinical trial institution shall be ordered by the medical products administration to cease the clinical trial and rectify the situation. If they refuse to comply, the clinical trial data shall not be used for product registration or filing, and a fine ranging from 50,000 to 100,000 yuan shall be imposed, along with a public announcement. If serious consequences result, the entity shall be prohibited from conducting clinical trials in the relevant medical device profession for five years and fined between 100,000 and 300,000 yuan. The health department shall confiscate any income obtained by the legal representative, principal person in charge, directly responsible personnel, and other liable individuals during the period of the violation and impose a fine of 30% to 300% of such income, along with disciplinary actions in accordance with the law.

If a clinical trial sponsor conducts a trial without prior recordation, it shall be ordered to stop the trial and fined between 50,000 and 100,000 yuan, with a public announcement. If serious consequences result, a fine of 100,000 to 300,000 yuan shall be imposed. The trial data shall not be accepted for product registration or filing, and registration applications submitted by the individuals responsible or entity shall be rejected for five years.

If a clinical trial sponsor conducts a clinical trial of Class III medical devices without obtaining approval, the medical products administration shall order immediate cessation of the trial, impose a fine of 100,000 to 300,000 yuan, and make a public announcement. If serious consequences result, a fine of 300,000 to 1,000,000 yuan shall be imposed. The clinical trial data shall not be used for registration, and applications for clinical trial and registration of medical devices from the responsible individuals and entity shall not be accepted for ten years. Income obtained by the legal representative and other responsible people during the violation shall be confiscated, with a fine of 30% to 300% of that income.

Article 94

Where a medical device clinical trial institution fails to comply with Good Clinical Practice (GCP) standards while conducting trials, the medical products administration shall order rectification or immediate cessation of the trial and impose a fine ranging from 50,000 to 100,000 yuan. If serious consequences occur, the institution shall be prohibited from conducting clinical trials in the relevant profession for five years. The health department shall confiscate income obtained by the legal representative and other liable persons during the violation and impose a fine of 30% to 300% of such income, along with disciplinary actions in accordance with the law.

Article 95

If a medical device clinical trial institution issues a false report, the medical products administration shall impose a fine of 100,000 to 300,000 yuan and confiscate any illegal gains. The institution shall be prohibited from conducting clinical trials in the relevant profession for ten years. The health department shall confiscate income obtained by liable individuals during the violation and impose fines ranging from 30% to 300% of that income, and apply disciplinary measures as required by law.

Article 96

Where a medical device inspection institution issues a false inspection report, the competent authority that granted its qualification shall revoke its inspection qualification and shall not accept qualification accreditation applications submitted by the relevant liable persons and the institution for a period of ten years. A fine of not less than 100,000 yuan and not more than 300,000 yuan shall be imposed. If there are illegal gains, such gains shall be confiscated. The legal representative, principal person in charge, directly responsible supervisor, and other responsible persons of the violating entity shall have their income obtained during the period of the illegal conduct confiscated and shall be fined not less than 30% and not more than three times the amount of such income. Disciplinary actions shall be taken in accordance with the law. Those who are dismissed as a disciplinary measure shall be prohibited from engaging in medical device inspection work for ten years.

Article 97

Violations of the provisions regarding medical device advertising shall be penalized in accordance with the *Advertising Law of the People's Republic of China*.

Article 98

Where the domestic enterprise legal person designated by an overseas medical device registrant or recordation entity fails to fulfill its obligations in accordance with the provisions of these Regulations, the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the central government shall order it to make corrections, issue a warning, and impose a fine of not less than 50,000 yuan and not more than 100,000 yuan. Where the circumstances are serious, a fine of not less than 100,000 yuan and not more than 500,000 yuan shall be imposed, and the legal representative, principal responsible person, directly responsible supervisors, and other liable persons shall be prohibited from engaging in the production and operation of medical devices for a period of five years.

Where an overseas medical device registrant or recordation entity refuses to comply with an administrative penalty decision made under these Regulations, the import of its medical devices shall be prohibited for a period of ten years.

Article 99

Where medical device research, manufacturing, distribution entity, or inspection institution employs personnel prohibited from engaging in such activities, the medical products administration shall order rectification and issue a warning. If the entity refuses to comply, it may be ordered to cease operations or have its license revoked.

Article 100

If a medical device technical review institution or adverse event monitoring institution fails to perform its duties under this Regulation, resulting in serious errors in review or monitoring, the medical products administration shall order rectification, circulate a notice of criticism, and issue a warning. If serious consequences occur, disciplinary action shall be taken against the legal representative and other responsible individuals in accordance with the law.

Article 101

If staff of the medical products administration or other relevant authorities abuse their power, neglect their duties, or engage in malfeasance in violation of this Regulation, they shall be subject to disciplinary actions in accordance with the law.

Article 102

Where violations of this Regulation constitute a crime, criminal liability shall be pursued according to law. Where personal, property, or other damage is caused, the liable party shall bear civil liability for compensation in accordance with the law.

Chapter VIII: Supplementary Provisions

Article 103

For the purposes of this Regulation, the following terms shall have the meanings set forth below:

Medical device refers to any instrument, apparatus, appliance, in vitro diagnostic reagent and calibrator, material, and other similar or related articles, including the necessary software, which is intended to be used, directly or indirectly, on the human body. Its primary intended action is not achieved by pharmacological, immunological, or metabolic means, although such means may assist its function. Its intended purposes include:

1-Diagnosis, prevention, monitoring, treatment, or alleviation of disease;

2-Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury;

3-Investigation, replacement, regulation, or support of the anatomical structure or physiological process;

4-Supporting or sustaining life;

5-Control of conception;

6-Providing information for medical or diagnostic purposes by examining specimens derived from the human body.

Registrant or record-filing entity of a medical device refers to an enterprise or research institution that has obtained a medical device registration certificate or completed record-filing procedures for a medical device.

Medical device user entity refers to institutions that use medical devices to provide medical or technical services to others. These include medical institutions, blood stations, single-plasma collection stations, rehabilitation assistive device adaptation institutions, etc.

Large-scale medical equipment refers to complex medical devices that involve advanced technology, significant capital investment, high operational costs, and have a major impact on medical expenses, and are subject to catalog-based management.

Article 104

Fees may be charged for the registration of medical device products. The specific items and standards for such fees shall be determined by the competent departments of finance and pricing under the State Council in accordance with relevant national regulations.

Article 105

The administrative measures for medical devices developed by medical and health institutions in response to public health emergencies shall be formulated by the drug regulatory authority under the State Council in conjunction with the health authority under the State Council.

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

The technical guidance principles for traditional Chinese medicine (TCM) medical devices shall be formulated by the drug regulatory authority under the State Council in conjunction with the TCM administration under the State Council.

Article 106

The supervision and administration of medical devices used by the military shall be conducted in accordance with this Regulation and relevant military regulations.

Article 107

[Omitted]