Measures for the Administration of Registration and Recordation of Medical Devices[1]

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Chapter I: General Provisions

Article 1

These Measures are enacted pursuant to the *Regulation on the Supervision and Administration of Medical Devices* for the purpose of regulating the registration and recordation of medical devices and ensuring their safety, effectiveness, and quality control.

Article 2

All medical device registration, recordation, and related supervision and administration activities within the territory of the People's Republic of China shall be governed by these Measures.

Article 3

"Registration of medical devices" refers to the procedure by which a medical device registration applicant (hereinafter "applicant") submits an application for registration in accordance with legal procedures and requirements, after which the medical products administrative department evaluates the safety, effectiveness, and quality controllability based on scientific knowledge and decides whether to approve the application. "Recordation of medical devices" refers to the procedure by which an entity for whom recordation is sought (hereinafter "recordation party") submits recordation materials to the medical products administrative department in compliance with statutory procedures and requirements, following which the department places the submitted materials on file for future reference.

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

Article 4

The National Medical Products Administration (NMPA) shall be responsible for the nationwide administration of medical device registration and recordation. Its duties include formulating systems and rules for registration and recordation, overseeing technical evaluation and approval of Class III domestic and Class II and III imported medical devices, recordation of Class I imported devices, administering related supervision, and guiding local authorities in these matters.

Article 5

The Center for Medical Device Evaluation of the NMPA shall conduct technical evaluation of clinical trial applications for devices requiring clinical trial approval, and handle product registration applications, modification registrations, and renewals for Class III domestic and Class II and III imported medical devices. Other professional bodies under the NMPA—including the Center for Medical Device Standards Management, the National Institutes for Food and Drug Control, the Center for Food and Drug Inspection, the Center for Drug Reevaluation, the Center for Administrative Services and Complaints & Reports, the Information Center, and other technical institutions—shall, within their respective mandates, perform tasks related to standard setting, classification, inspection, verification, monitoring, evaluation, certification, information management, and other functions necessary for medical device supervision and administration.

Article 6

The provincial, autonomous regional, and directly administered municipal medical products administrative departments shall manage the following registration-related affairs within their jurisdictions:

1-Examination and approval of registration applications for Class II domestic medical devices;

2-Verification of quality management systems for Class II and III domestic medical devices;

3-Oversight of clinical trial institutions and clinical trials conducted therein in accordance with law;

4-Supervision and guidance of Class I domestic medical device recordation by municipal (district-level) administrative departments.

Professional technical institutions designated by these departments shall handle required technical evaluations, examinations, verifications, monitoring, and assessments. District-level

medical products administrative departments shall be responsible for recordation of Class I domestic medical devices.

Article 7

Administration of medical device registration and recordation shall adhere to the principles of legality, scientific rigor, transparency, fairness, and impartiality.

Article 8

Class I medical devices are subject to recordation; Class II and III medical devices are subject to registration.

1-For Class I domestic devices, recordation parties shall submit materials to district-level medical products administrative departments.

2-For Class II domestic devices, provincial-level departments shall review and, if approved, issue registration certificates.

3-For Class III domestic devices, the NMPA shall review and issue registration certificates if approved.

4-For Class I imported devices, recordation parties shall submit materials to the NMPA.

5-For Class II and III imported devices, the NMPA shall review and, if approved, issue registration certificates.

Article 9

Registrants and recordation parties must continuously strengthen quality management throughout the entire life cycle of medical devices, and bear legal responsibility for ensuring their safety, effectiveness, and quality control during development, production, operation, and use.

Article 10

The NMPA shall prioritize review and approval of devices that meet urgent clinical needs, implement special review and approval procedures for innovative devices, encourage research and innovation, and foster high-quality industry development.

Article 11

The NMPA shall establish and improve standards, technical guidance frameworks, and other systems for medical devices in accordance with law, regulate technical evaluations and quality management verification, and support research, development, and registration efforts.

Article 12

Medical products administrative departments shall disclose registration and recordation information in a timely fashion, allowing applicants to track application status and the public to access results. Except as required by law or in matters of national security or public interest, no staff, institutions, evaluation experts, or administrative personnel shall disclose applicants' or recordation parties' trade secrets, unpublished data, or confidential commercial information without consent.

Chapter II: General Provisions for Registration and Recordation of Medical Devices

Article 13

The registration and recordation of medical devices shall strictly adhere to the relevant laws, administrative regulations, departmental rules, and mandatory national standards. These processes must be aligned with the fundamental principles of safety and performance for medical devices and should refer to pertinent technical guidance documents. Applicants must substantiate that the medical devices undergoing registration or recordation are safe, efficacious, and quality-controllable. Furthermore, information generated throughout the product lifecycle shall be authentic, accurate, complete, and traceable.

Article 14

Applicants or recordation parties must be enterprises or development institutions that possess the capacity to assume corresponding legal responsibilities. Foreign applicants or recordation parties shall designate a domestic enterprise legal person within the territory of the People's Republic of China as their agent to manage all relevant registration and recordation procedures. This agent shall assist the registrant or recordation party in fulfilling the obligations stipulated in Paragraph 1 of Article 20 of the *Regulation on the Supervision and Administration of Medical Devices* and shall support the overseas entity in discharging its legal responsibilities in accordance with the law.

Article 15

Applicants and recordation parties shall establish and maintain a quality management system that is commensurate with the characteristics and risk level of the medical device in question and shall ensure the continual effectiveness of said system.

Article 16

Personnel responsible for registration or recordation activities must possess the requisite professional expertise and demonstrate familiarity with the applicable laws, regulations, and administrative rules governing the registration and recordation of medical devices, as well as relevant provisions on regulatory compliance.

Article 17

When applying for registration or undergoing recordation, the applicant or recordation party shall submit all requisite documentation as specified by the National Medical Products Administration (NMPA), and shall bear legal responsibility for the authenticity and accuracy of the submitted materials. All registration and recordation materials must be prepared in the Chinese language. Where materials are translated from foreign-language sources, the original documents must also be submitted. If cited documents are unpublished, the applicant must furnish authorization from the rights holder for their use.

Article 18

Applicants seeking registration or recordation of imported medical devices shall submit proof of market approval (e.g., a certificate of free sale or equivalent) issued by the competent regulatory authority of the country (or region) where the applicant or manufacturer is established or where the product is manufactured. If the medical device is not regulated as such in the country or region of registration or manufacture, the applicant or recordation party shall provide alternative evidence, including proof of market authorization granted in the relevant jurisdiction. However, in the case of innovative medical devices that are not yet available on the market in the jurisdiction of registration or manufacture, such documentary evidence may be waived.

Article 19

Medical devices shall conform to all applicable mandatory national standards. Where a product's structural features, intended use, or mode of application fall outside the scope of existing mandatory standards, the applicant or recordation party must provide a written

rationale justifying the inapplicability of such standards and shall submit supporting documentation. In the absence of mandatory standards, applicants and recordation parties are encouraged to adopt recommended standards to demonstrate product safety and performance.

Article 20

Registration and recordation activities shall comply with the medical device classification rules and align with the corresponding requirements as delineated in the classification catalogue.

Article 21

Administrative departments for medical products shall continue to advance reforms in the evaluation and approval system, reinforce scientific research in medical device regulation, and establish a registration management framework characterized by technical evaluation as the core, with complementary functions including verification, inspection, monitoring, and assessment. Efforts shall be made to optimize evaluation and approval procedures, enhance institutional capacity, and improve the overall quality and efficiency of regulatory reviews.

Article 22

Professional technical institutions engaged in medical device evaluation shall establish and refine mechanisms for regulatory communication. They shall clearly define the formats, scope, and content of such communications, and facilitate structured interactions with applicants based on operational requirements.

Article 23

In accordance with operational needs, professional technical institutions shall institute an expert consultation mechanism, whereby expert opinions may be solicited on significant matters arising during the course of technical evaluation, verification, and inspection. The institutions shall fully leverage the advisory role of experts to strengthen the scientific and technical basis of regulatory decision-making.

Chapter III: Registration of Medical Devices

Section 1 – Development of Products

Article 24

Developers of medical devices shall adhere to the principles of risk management, drawing upon recognized technical merit, ensuring that all known and foreseeable risks and unintended impacts are minimized and acceptable, and that the benefits of normal use exceed the risks.

Article 25

Product development activities for medical devices must comply with applicable laws, regulations, and mandatory national standards of the People's Republic of China.

Article 26

To apply for registration or recordation, an applicant or recordation party shall formulate technical specifications for the medical device, comprising essential functional and safety indicators and testing methods by which finished products can be objectively evaluated. The medical device must meet these technical specifications.

Article 27

An applicant or recordation party shall prepare product specifications and labeling for the medical device in accordance with Article 39 of the *Regulation on the Supervision and Administration of Medical Devices* and other relevant regulations.

Article 28

Non-clinical research must be conducted based on the device's intended use and technical characteristics. Such research shall include studies on chemical/physical properties, electrical safety, radiation safety, software behavior, biocompatibility, biological material safety, sterilization or disinfection processes, animal testing, and stability, among others. Applicants or recordation parties shall submit a summary of non-clinical research reports, research plans, and research reports.

Article 29

The functional and safety indicators and testing methods used in non-clinical research must be appropriate for the product's intended application, and test specimens must be representative. Method validation and statistical analysis shall be conducted if necessary.

Article 30

Applicants or recordation parties must conduct product testing per their technical standards and submit the resulting inspection report. Only if the product passes such inspection may clinical trials proceed or registration/recordation applications be submitted.

Article 31

Test samples must represent the medical device intended for registration or recordation, and their production must comply with relevant quality management standards for medical device manufacture.

Article 32

Inspection reports may originate from the applicant's internal testing or from a qualified external testing institution commissioned by the applicant or recordation party.

Section 2 – Clinical Evaluation

Article 33

Except as provided in Article 34, clinical evaluation is required for medical device registration or recordation. Clinical evaluation involves scientific analysis and assessment of clinical data to confirm device safety and efficacy. Applicants must submit clinical evaluation materials when seeking registration.

Article 34

Clinical evaluation may be exempt in the following cases:

1-Devices with established mechanisms, mature design and manufacture, well-known clinical use, no severe adverse events over years of market use, and unchanged general purpose.

2-Other situations where non-clinical evaluation sufficiently demonstrates safety and effectiveness.

The NMPA shall formulate and publish the list of exemptions for clinical evaluation.

Article 35

Clinical evaluation can be based on clinical trials or analysis of clinical literature and data from similar devices, depending on product characteristics, clinical risk, and existing data. Clinical trials are required when existing literature or data are insufficient. The NMPA shall issue guidelines detailing when clinical trials are necessary and the format of clinical evaluation reports.

Article 36

Where clinical evaluation relies on literature or clinical data from similar devices, submitted materials must include: Comparison between the application device and similar devices, Analysis and evaluation of clinical data of similar devices, Scientific justification where differences exist, Conclusions. When using clinical trials, the materials must include: Clinical trial protocols, Ethical committee opinions, Informed consent forms, Trial reports.

Article 37

Clinical trials must be conducted in qualified and registered clinical trial institutions that comply with quality management standards for medical devices. Before initiating clinical trials, applicants must register the trial with the provincial or directly administered municipal medical products administrative department. Clinical trial devices must be produced in accordance with applicable production standards.

Article 38

Clinical trials involving Class III medical devices that may present relatively high risks to human health shall be subject to prior approval by the National Medical Products Administration (NMPA). Such approval entails a comprehensive evaluation by the NMPA, upon application by the sponsor, of the potential risks associated with the device, the clinical trial protocol, and a benefit-risk analysis report, in order to determine whether to authorize the proposed trial.

The catalogue of Class III devices requiring clinical trial approval shall be formulated, periodically revised, and publicly disclosed by the NMPA. Trials for such devices shall be conducted exclusively in qualified tertiary Grade A medical institutions.

Article 39

Where clinical trial approval is required, the applicant shall submit application materials in accordance with relevant regulatory requirements. These materials shall include a summary

dossier, preclinical and research data, clinical documentation, product specifications, sample labels, and any other documentation required under applicable guidelines.

Article 40

The Center for Medical Device Evaluation (CMDE) shall conduct a technical review of duly accepted clinical trial applications. A decision shall be made within 60 calendar days from the date of acceptance, and notification of the decision shall be published on the CMDE's official website. Failure to issue a decision within the prescribed time frame shall be construed as approval by default.

Article 41

During technical evaluation, where supplementary or corrected documentation is required, the CMDE shall notify the applicant of all deficiencies in a single notice. The applicant must respond by submitting the complete set of supplementary materials within one year from the date of receipt of the notification. Upon receipt, the CMDE shall resume and complete the technical review within the designated timeline.

Applicants may raise written objections to the content of the deficiency notice, stating their rationale and submitting supporting technical evidence. Failure to provide the requested supplemental documentation within the stipulated timeframe shall result in termination of the technical review and denial of the application.

Article 42

In the event of serious adverse events (SAEs) or the emergence of significant safety concerns during a clinical trial, the trial sponsor must report the incident(s) in accordance with applicable regulations to the provincial-level medical products administration both at the sponsor's and the trial site's respective locations. The sponsor shall also implement appropriate risk control measures. Where no such measures are taken, the relevant provincial authority shall mandate their implementation in accordance with law.

Article 43

In cases involving large-scale SAEs or other critical safety issues arising during clinical trials, the sponsor shall immediately suspend or terminate the trial and report such actions to the provincial medical products authorities of both its own jurisdiction and that of the clinical trial institution. Where the sponsor fails to suspend or terminate the trial, the relevant provincial authority shall order the necessary risk control actions in accordance with law.

Article 44

The NMPA may order the termination of an approved clinical trial if any of the following circumstances arise:

1-The application materials submitted were false or misleading.

2-New scientific evidence indicates unresolved ethical or scientific issues with the approved clinical trial.

3-Other circumstances warranting termination under applicable laws and regulations.

Article 45

The clinical trial of a medical device shall be conducted within three years after it is approved. Where, from the date when an application for clinical trial of a medical device is approved, no trial subject signs an informed consent within three years, the license for clinical trial of the medical device shall be automatically invalidated. Where clinical trial still needs to be carried out, an application shall be filed anew.

Article 46

Where a medical device undergoing clinical trials is intended to treat a serious, life-threatening condition for which no effective treatment exists, and where preliminary clinical evidence suggests potential benefit, the device may—with appropriate ethics committee approval and informed patient consent—be used free of charge for other patients with the same condition at the same trial institution. Safety data derived from such use may be incorporated into the marketing authorization application dossier.

Section 3 – Quality Management System (QMS) Verification for Registration

Article 47

At the time of application for registration, the applicant shall submit materials pertaining to its quality management system (QMS) relating to product development and manufacturing. Where deemed necessary during technical evaluation, the competent medical products administrative authority shall organize a QMS inspection and may review original documentation as required.

Article 48

For domestic Class III medical devices, the CMDE shall notify the relevant provincial-level medical products administration to conduct the QMS inspection.

For domestic Class II medical devices, the provincial-level administration where the applicant is domiciled shall be responsible for organizing and conducting the QMS verification.

Article 49

The medical products administrative authority at the provincial, autonomous regional, or municipal level directly under the Central Government shall assess the applicant's quality management system in accordance with the relevant standards governing the manufacture of medical devices. The assessment shall emphasize whether the applicant has established a

system that is appropriately aligned with the characteristics of the device and consistent with the applicable quality management standards, encompassing design, development, production management, and quality control processes.

During this verification process, the authenticity of the devices submitted for inspection and clinical trials must be concurrently verified. Particular attention shall be paid to the documentary records related to the design and development processes, as well as the production processes of both inspection samples and clinical trial products.

In cases where a self-inspection report is submitted, the verification shall focus primarily on the inspection capabilities and results of the applicant, filing entity, or entrusted institution during the development phase.

Article 50

The provincial-level administrative authority may conduct the quality management system verification through document review or on-site inspection. The decision regarding the necessity and scope of an on-site inspection shall be based on the applicant's specific circumstances, prior inspection history, and comparative analysis between the current product and previously verified products, thereby minimizing redundant inspections.

Article 51

Where the Center for Medical Device Evaluation of the National Medical Products Administration deems it necessary to verify the quality management system during the technical evaluation of Class II and Class III imported medical devices, it shall notify the Center for Inspection of the National Medical Products Administration to carry out the verification in accordance with the relevant requirements.

Section 4– Product Registration

Article 52

Upon completion of research supporting the safety and effectiveness of a medical device and readiness for quality management system verification, an applicant shall submit a registration application to the medical products administrative authority via online or other designated means. The application shall include:

1-Risk analysis documentation;

2-Product technical specifications;

3-Product inspection report;

4-Clinical evaluation data;

5-Product labels and instructions for use;

6-Quality management system documentation related to research and manufacturing;

7-Additional documentation substantiating product safety and effectiveness.

Article 53

Upon receipt of an application, the administrative authority shall review the materials and proceed as follows:

1-If the application falls within its jurisdiction and meets formal requirements, the application shall be accepted.

2-Minor errors correctable on-site shall be rectified by the applicant immediately.

3-If incomplete or non-compliant with formalities, the authority shall notify the applicant once, either immediately or within five days, of all required supplements or corrections. Failure to notify within this period shall be deemed acceptance of the application.

4-If the application is outside the authority's jurisdiction, it shall be denied, and the applicant shall be advised to apply to the competent authority.

Following acceptance or denial, the authority shall issue a formal notification bearing its official seal and the corresponding date.

If payment of fees is required post-acceptance and the applicant fails to pay within the prescribed timeframe, the application shall be considered voluntarily withdrawn, and registration procedures shall be terminated.

Article 54

If, during technical evaluation, supplementary or corrective materials are needed, the evaluation institution shall issue a single, comprehensive notification. The applicant must submit all required materials within one year. Upon receipt, the evaluation shall resume and conclude within the statutory timeframe.

If the applicant disagrees with the content of the notification, it may submit written objections with supporting technical documentation. Failure to submit supplementary materials within the timeframe shall result in termination of evaluation and issuance of a registration denial.

Article 55

After registration acceptance, applicants may apply to withdraw their application and related materials prior to the issuance of an administrative licensing decision, providing justifications. If withdrawal is approved, the administrative procedure shall be terminated.

However, where illegality such as concealment of facts or submission of falsified data is discovered during the evaluation or verification process, the application cannot be withdrawn and shall be handled in accordance with law.

Article 56

Where credible evidence indicates potential falsification of submitted materials, the administrative authority may suspend the evaluation and approval process. Upon verification, proceedings shall either resume or be terminated based on the findings.

Article 57

If, during evaluation, the institution intends to issue an unfavorable conclusion, it must notify the applicant of the reasons. The applicant may raise objections within 15 days, limited to the original application content and materials. The institution shall re-evaluate the matter comprehensively and provide a response. The objection-handling period is excluded from the evaluation timeframe.

Article 58

The medical products administrative department that accepts the registration application shall, upon completion of the technical evaluation, make a decision on whether to approve the registration. For applications that meet the requirements of safety, effectiveness, and quality controllability, registration shall be granted, a medical device registration certificate shall be issued, and the approved product technical requirements shall be provided to the applicant in the form of an annex. For applications that are not approved, the reasons shall be provided in writing, and the applicant shall be informed of their right to apply for administrative reconsideration or to initiate administrative litigation in accordance with the law.

A medical device registration certificate shall be valid for five years.

Article 59

For registration applications that have already been accepted, the medical products administrative department shall decide to deny registration and notify the applicant if any of the following circumstances apply:

1-The research conducted by the applicant on the safety, effectiveness, and quality controllability of the medical device fails to demonstrate that the product is safe, effective, and of controllable quality;

2-The quality management system fails verification, or the applicant refuses to permit an on-site inspection of the quality management system;

3-The registration materials contain false information;

4-The submitted materials are disorganized or contradictory, are manifestly inconsistent with the intended registration project, or fail to substantiate the product's safety, effectiveness, or quality controllability;

5-Other circumstances warranting refusal of registration.

Article 60

Where laws, regulations, or rules require a hearing for administrative licensing matters, or where the medical products administrative department deems a hearing necessary for other significant licensing matters involving public interest, a public announcement shall be issued and a hearing held. If a medical device registration application directly affects the substantial interests between the applicant and another party, then, before making an administrative licensing decision, the department shall inform both the applicant and the concerned party of their right to request a hearing.

Article 61

For medical devices intended to treat rare diseases or life-threatening conditions with no effective existing therapies, or those urgently needed to address public health events, the medical products administrative department may grant conditional approval. Such conditions, including the validity period and post-market study requirements and deadlines, shall be specified in the medical device registration certificate.

Article 62

For conditionally approved medical devices, the registrant must, after product launch, collect data on benefits and risks, continuously monitor and assess product performance, proactively implement risk-control measures, and complete the required studies and report within the prescribed timeframe.

Article 63

If the registrant fails to complete the required studies by the deadline or cannot demonstrate that benefits outweigh risks, they must promptly apply to cancel the medical device registration certificate. The medical products administrative department may, in accordance with law, cancel the certificate.

Article 64

For newly developed medical devices not yet listed in any classification catalogue, the applicant may directly seek registration as a Class III device, or may preliminarily classify the device according to applicable rules and submit a request to the NMPA for category confirmation before proceeding with registration or recordation. If classified domestically as Class II or Class

I, the applicant shall be informed to apply for registration or recordation with the appropriate medical products administrative department, in accordance with the updated classification.

Article 65

For registered medical devices whose management category is downgraded, the registration certificate remains valid until expiration. To renew it, the registrant must apply for renewal registration or recordation six months before the original certificate expires, in accordance with the adjusted category, to the relevant department. If the management category is upgraded, the registrant must apply for registration under the new category with the relevant department. The NMPA shall specify the timeframe for completing this change in its category-adjustment notification.

Article 66

If a medical device registration certificate or its annexes are lost or damaged, the registrant shall apply to the original issuing authority for reissuance. The authority shall verify the request and issue a replacement.

Article 67

During the review of a registration application or after approval, any disputes over patent rights shall be resolved in accordance with applicable laws and regulations.

Chapter IV: Special Registration Procedures

Section 1 – Innovative Medical Device Registration Procedure

Article 68

An applicant may apply for the innovative medical device registration procedure if the device satisfies the following criteria:

1-The applicant holds core technology—via inventor's patent or legal transfer—on the product in China, either through patent authorization within five years of application or where the patent application has been published, and a patent search report issued by the China National Intellectual Property Administration's Patent Search and Consultation Center confirms novelty and inventiveness;

2-The applicant has completed preliminary research and possesses a basic standardized product, with the research process being genuine, controlled, and supported by complete, traceable data;

3-The device's primary mechanism or principle is domestically original, with fundamental improvements in performance or safety compared to similar products, is technically internationally advanced, and demonstrates significant clinical value.

Article 69

Applicants seeking to use the innovative product registration procedure must, after finalizing a basic standardized product, apply for innovative medical device review to the NMPA. The NMPA shall convene an expert panel for evaluation. Devices meeting the innovation criteria shall be admitted to the innovative product registration pathway.

Article 70

For medical device registration applications subject to the innovative product registration procedure, the National Medical Products Administration (NMPA) and relevant technical institutions shall, according to their respective responsibilities, designate dedicated personnel to ensure timely communication and guidance.

For medical devices under the innovative product registration procedure, the Center for Medical Device Evaluation (CMDE) under the NMPA may communicate with the applicant prior to acceptance of the registration application and during the technical review process regarding major technical issues in product development, major safety concerns, clinical trial protocols, and the summary and evaluation of interim clinical trial results.

Article 71

If the applicant voluntarily requests to terminate the registration procedure for an innovative product, or if the NMPA determines that the product no longer meets the requirements for the innovative product registration procedure, the NMPA shall terminate the procedure and notify the applicant accordingly.

Article 72

If the applicant fails to submit a registration application within the prescribed time for a medical device included in the innovative product registration procedure, the device shall no longer be eligible for this procedure.

Section 2- Priority Registration Procedure

Article 73

Medical devices meeting any of the following criteria may apply for the priority registration procedure:

1-Devices for diagnosing or treating rare diseases or malignant tumors with significant clinical advantages; devices for diagnosing or treating diseases specific to or commonly affecting the

elderly where effective methods are currently unavailable; pediatric-specific devices with significant clinical advantages; or devices that address urgent clinical needs for which there are currently no approved products of the same type in China.

2-Devices that are part of national major science and technology projects or the National Key R&D Program.

3-Other devices specified by the NMPA as eligible for the priority registration procedure.

Article 74

Applicants for the priority registration procedure shall submit a request to the NMPA along with the medical device registration application.

For applications under Item (1) of Article 73, the NMPA shall organize expert reviews, and if approved, include the device in the priority registration procedure; For Item (2), the CMDE shall review the application and determine eligibility; For Item (3), the NMPA shall seek broad input, conduct expert evaluations, and make a determination on inclusion.

Article 75

For devices included in the priority registration procedure:

1-The NMPA shall prioritize the review and approval of the registration application;

2-Provincial-level drug regulatory authorities shall prioritize the quality management system inspection for registration.

3-The CMDE shall actively engage with applicants during technical reviews in accordance with relevant regulations. Special communication sessions may be arranged when necessary.

Section 3 - Emergency Registration Procedure

Article 76

In the event of a public health emergency, if there are no approved products of the same type in China, or if existing products cannot meet emergency response needs, the NMPA may implement an emergency registration procedure for the required medical devices.

Article 77

Applicants seeking emergency registration shall submit a formal application to the NMPA. Applications meeting the conditions shall be included in the emergency registration procedure.

Article 78

For emergency registration of medical devices, the NMPA shall follow the principles of centralized command, early involvement, immediate review, and scientific approval. Product testing, quality system inspection, and technical review shall be conducted in parallel.

Chapter V: Registration Modification and Renewal

Section 1 - Registration Modification

Article 79

Registrants shall proactively conduct post-market research on medical devices to further confirm their safety, effectiveness, and quality control, and strengthen ongoing management of approved medical devices.

For Class II and III medical devices already registered, if there are substantial changes in design, raw materials, manufacturing processes, intended use, or usage methods that may affect safety or effectiveness, the registrant shall apply to the original registration authority for modification of registration.

Other changes must be filed with the original registration authority within 30 days from the date of the change.

Changes to the product name, model, specifications, structure and composition, intended use, product technical requirements, or manufacturing address of imported medical devices are deemed substantial and must follow the registration modification procedure. Changes to the registrant's name, address, agent's name or address, etc., are subject to filing.

For changes to domestic manufacturing addresses, registrants shall first apply for modification of the production license and then complete the filing process.

Other changes must be managed in accordance with the quality management system and reported to the regulatory authority as required.

Article 80

For modification registration applications, the technical review institution shall focus on evaluating the changed components, and issue opinions on whether the modified product remains safe, effective, and quality-controlled.

If it is deemed necessary to verify the quality management system during the review of modification applications, the regulatory authority shall organize such inspection accordingly.

Article 81

The documents for registration modification of a medical device shall be used in conjunction with the original medical device registration certificate. The date of expiration shall remain the same as that of the original certificate.

Section 2 - Renewal of Registration

Article 82

If the registration certificate of a medical device is about to expire and needs to be renewed, the registrant shall apply for renewal to the original registration authority six months before the certificate's expiration, along with the required application documents in accordance with relevant regulations.

Unless any of the circumstances listed in Article 83 apply, the drug regulatory authority shall decide on whether to approve the renewal before the certificate expires. If no decision is made within that time frame, the renewal application shall be deemed approved by default.

Article 83

Renewal of registration shall not be granted under the following circumstances:

1-Failure to submit the renewal application within the prescribed time;

2-The issuance and implementation of a new mandatory national standard for medical devices, and the device subject to renewal does not meet the new requirements;

3-For conditionally approved medical devices, the registrant fails to fulfill the specified conditions within the required time.

Article 84

If the renewal is approved before the original certificate's expiration date, the new validity period shall start from the day after the expiration of the original certificate. If the renewal is approved after the original certificate has expired, the new validity period shall start from the date of renewal approval.

Article 85

For the acceptance and review procedures of registration modification and renewal applications not explicitly addressed in this chapter, the provisions of Chapter 3 of these Measures shall apply.

Chapter VI: Medical Device Filing

Article 86

For Class I medical devices, product filing must be completed before production begins.

Article 87

To file a medical device, the filer shall submit the filing documents to the drug regulatory authority in accordance with the Regulations on the Supervision and Administration of Medical Devices, and obtain a filing number.

Article 88

If there is any change to the information recorded in the medical device filing form or in the technical requirements of the filed product, the filer shall submit a change filing to the original filing authority along with documentation explaining the change. The drug regulatory authority shall update the filing information accordingly.

Article 89

If a previously filed medical device is reclassified as a Class II or Class III device, the filer shall apply for registration in accordance with these Measures.

Chapter VII: Time Limits for Work Procedures

Article 90

The time limits specified in these Measures refer to the maximum duration for acceptance, technical review, inspection, and approval related to medical device registration. For special registration procedures, the corresponding time limits shall be governed by the respective special registration provisions.

The Center for Medical Device Evaluation (CMDE) and other specialized technical institutions shall define their internal procedures and timeframes, and publish them to the public.

Article 91

After receiving a medical device registration application or clinical trial application, the drug regulatory authority shall transfer the application materials to the technical review institution within 3 days from the date of acceptance. The acceptance requirements for clinical trial applications shall comply with the provisions of Article 53 of these Measures.

Article 92

The time limits for technical review of medical device registration applications are as follows:

1-For clinical trial applications:

60 days for initial review;

40 days after submission of supplemental documents.

2-For Class II medical device registration, change, or renewal applications:

60 days for both initial and supplemental review.

3-For Class III medical device registration, change, or renewal applications:

90 days for initial review;

60 days after submission of supplemental documents.

Article 93

The time limits for quality management system inspection of domestic Class III medical devices are as follows:

1-CMDE shall notify the relevant provincial-level drug regulatory authority to initiate the inspection within 10 days after accepting the registration application.

2-The provincial drug regulatory authority shall, in principle, complete the inspection within 30 days after receiving the notification and submit the inspection report and results to CMDE.

Article 94

The drug regulatory authority that accepted the registration application shall make a decision within 20 days after receiving the technical review opinion.

Article 95

The drug regulatory authority shall, within 10 days from making the registration decision, issue and deliver the relevant administrative license documents.

Article 96

If, due to product characteristics or special circumstances encountered during technical review or inspection, it is necessary to extend the time limit, the extension shall not exceed half of the original time limit. Such an extension must be approved by the responsible person of the relevant technical institution and be notified in writing to the applicant and other relevant institutions.

Article 97

The original issuing authority shall, upon receiving an application for re-issuance of a medical device registration certificate, issue the replacement certificate within 20 days.

Article 98

The following periods shall not be counted within the official time limits:

1-Time taken by the applicant to supplement materials or rectify after inspection;

2-Time delayed by the applicant for inspection purposes;

3-Time spent on external expert consultations, expert panel meetings, or joint review with drug evaluation agencies for combination products;

4-Time during which the review and approval process is suspended according to regulations;

5-Time used for quality management system inspection.

Article 99

The time limits stipulated in these Measures shall be calculated in working days.

Chapter VIII: Supervision and Administration

Article 100

Drug regulatory authorities shall strengthen supervision and inspection of medical device development activities. When necessary, extended inspections may be conducted on entities or individuals providing products or services for medical device development. Relevant parties must cooperate and provide the necessary documents and information; they must not refuse, conceal, or obstruct.

Article 101

The National Medical Products Administration (NMPA) shall establish and implement the Unique Device Identification (UDI) system in phases. Applicants and filing entities must submit relevant UDI information in accordance with regulations and ensure the data is authentic, accurate, and traceable.

Article 102

The NMPA shall promptly notify the drug regulatory authority in the province, autonomous region, or municipality where the agent is located of the agent's information. Local drug regulatory authorities shall conduct routine supervision and administration of agents within their jurisdiction.

Article 103

Provincial-level drug regulatory authorities shall supervise and inspect clinical trial institutions for medical devices that have been filed within their jurisdiction. For newly filed institutions, supervision and inspection must be conducted within 60 days after filing.

They shall also conduct routine inspections to ensure institutions continuously comply with the Good Clinical Practice (GCP) standards. The NMPA may also conduct inspections as needed.

Article 104

If deemed necessary, drug regulatory authorities may conduct on-site inspections to verify the authenticity, accuracy, completeness, standardization, and traceability of clinical trial data.

Article 105

If the drug regulatory authority discovers non-compliant filing materials during post-filing supervision of Class I medical devices, it shall order the filer to correct the issue within a specified time.

Article 106

Where the drug regulatory authority fails to promptly identify systemic or regional risks in the administration of medical device registration within its jurisdiction or fails to promptly eliminate such systemic or regional hazards, the higher-level drug regulatory authority may interview the principal responsible person of the lower-level authority.

Chapter IX: Legal Liability

Article 107

Any violation of Article 79 of these Measures by failing to file changes as required shall be ordered to make corrections within a prescribed time limit. If the correction is not made within the time limit, a fine of not less than 10,000 yuan and not more than 30,000 yuan shall be imposed.

Article 108

Where a clinical trial of a medical device is conducted in violation of the Good Clinical Practice for medical devices, penalties shall be imposed in accordance with Article 94 of the *Regulations on the Supervision and Administration of Medical Devices*.

Article 109

Where a medical device technical review institution fails to perform its duties as prescribed in these Measures, resulting in a significant error in the review work, the drug regulatory authority shall order rectification, issue a public criticism, and give a warning. If serious consequences are caused, the legal representative, principal person in charge, persons directly responsible, and other liable persons of the violating entity shall be subject to disciplinary action in accordance with the law.

Article 110

Where personnel of the drug regulatory authority violate regulations by abusing their powers, neglecting their duties, or engaging in malpractices for personal gain, they shall be subject to disciplinary action in accordance with the law.

Chapter X: Supplementary Provisions

Article 111

In principle, the registration or recordation units of medical devices shall be divided based on the technical principles, structure and composition, performance indicators and scope of application of products.

Article 112

A registered medical device refers to a device that conforms to the content specified in its registration certificate and attachments and is produced within the validity period of the registration certificate.

Article 113

The component parts listed in the "Structure and Composition" section of a medical device registration certificate, which are used for purposes such as consumable replacement, after-sales service, or maintenance of the originally registered product, may be sold separately.

Article 114

In the application for medical device product registration, change of registration, or clinical trial approval, the applicant may, with the authorization of the owner of a medical device master file, refer to a registered medical device master file. The procedures related to the registration of medical device master files shall be stipulated separately.

Article 115

The format of the medical device registration certificate shall be uniformly formulated by the National Medical Products Administration (NMPA).

The registration certificate number shall be structured as:

×1medical device registration×2××××3×4××5××××6, where:

×1 shall be the shortened form of the locality of the registration approval authority: For Class III domestic medical devices, and Class II or III imported medical devices, such shortened form shall be indicated as the character of “Guo,” which means national.

For Class II domestic medical devices, such shortened form shall be indicated as that of the province, autonomous region, or municipality directly under the Central Government where the registration approval authority is located.

×2 shall be the form of registration:

The form of "Approved" shall apply to domestic medical devices.

The form of "Imported" shall apply to imported medical devices.

The form of "Permitted" shall apply to medical devices from Hong Kong, Macao, and Taiwan.

××××3 shall be the year in which the first registration is made.

×4 shall be the management class of the product.

××5 shall be the category code of the product.

××××6 shall be the serial number of the first registration.

In the renewal of registration, ××××3 and ××××6 shall remain unchanged. In the adjustment to the management class of the product, the certificate shall be renumbered.

Article 116

The recordation for a Class I medical device shall be numbered as follows:

1medical device recordation××××2××××3, where:

×1 shall be the shortened form of the locality of the recordation authority: For Class I imported medical devices, such shortened form shall be indicated as the character of "Guo" (国), which means national.

For Class I domestic medical devices, such shortened form shall be indicated as that of the province, autonomous region, or municipality directly under the Central Government where the recordation authority is located plus that of the administrative region at the level of districted city at the applicant's locality (if there is no corresponding administrative region at the level of districted city, it shall be the shortened form of the province, autonomous region, or municipality directly under the Central Government).

××××2 shall be the year of recordation.

××××3 shall be the serial number of recordation.

Article 117

The electronic versions of medical device registration certificates and registration modification documents produced by the medical products administration shall have the same legal effect as their paper counterparts.

Article 118

Based on work requirements, the National Medical Products Administration (NMPA) may, in accordance with the law, entrust provincial-level medical products administrations, technical institutions, or social organizations to undertake specific tasks.

Article 119

Provincial-level medical products administrations may formulate special registration procedures for Class II medical devices within their administrative regions with reference to Chapter IV of these Measures and shall file such procedures with the NMPA for the record.

Article 120

Fees and charging standards for medical device product registration shall be implemented in accordance with the relevant provisions issued by the competent departments of finance and pricing under the State Council.

Article 121

Registration and filing of in vitro diagnostic reagents administered as medical devices shall be governed by the *Administrative Measures for the Registration and Filing of In Vitro Diagnostic Reagents*.

Article 122

The regulatory provisions on customized medical devices shall be separately formulated by the NMPA. The regulatory provisions on combination products comprising both drugs and medical devices shall be separately formulated by the NMPA. The provisions on emergency use of medical devices shall be separately formulated by the NMPA in conjunction with relevant departments.

Article 123

Registration and filing of medical devices from the Hong Kong, Macao and Taiwan region shall be handled with reference to the procedures for imported medical devices.

Article 124

These Measures shall come into force on October 1, 2021. The *Administrative Measures for the Registration of Medical Devices* promulgated by the former China Food and Drug Administration under Order No. 4 on July 30, 2014, shall be repealed simultaneously.