Measures for the Administration of Registration and Recordation of Medical Devices

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(No. 47)

The Measures for the Administration of Registration and Recordation of Medical Devices, as deliberated and adopted at the 11th executive meeting of the State Administration for Market Regulation on July 22, 2021, are hereby issued and shall come into force on October 1, 2021.

Director: Zhang Gong

August 26, 2021

Measures for the Administration of Registration and Recordation of Medical Devices

Chapter I General Provisions

国家市场监督管理总局令

（第 47 号）

《医疗器械注册与备案管理办法》已经 2021 年 7 月 22 日市场监管总局第 11 次局务会议通过，现予公布，自 2021 年 10 月 1 日起施行。

局长 张工

2021 年 8 月 26 日

医疗器械注册与备案管理办法

第一章 总 则

Article 1 For the purposes of regulating the acts of registration and recordation of medical devices, and ensuring the safety, effectiveness and quality controllability of medical devices, these Measures are developed in accordance with the Regulation on the Supervision and Administration of Medical Devices.

第一条 为了规范医疗器械注册与备案行为，保证医疗器械的安全、有效和质量可控，根据《医疗器械监督管理条例》，制定本办法。

Article 2 The activities of registration, recordation, as well as supervision and administration of medical devices within the territory of the People's Republic of China shall be governed by these Measures.

第二条 在中华人民共和国境内从事医疗器械注册、备案及其监督管理活动，适用本办法。

Article 3 "Registration of medical devices" means the activities that a medical device registration applicant (hereinafter referred to as an "applicant") files an application for registration of a medical device under the legal procedures and according to the requirements, and that the medical products administrative department examines the safety, effectiveness, and quality controllability in accordance with the laws and regulations, and based on the scientific cognitions, to decide whether to agree with the activities applied for.

第三条 医疗器械注册是指医疗器械注册申请人（以下简称申请人）依照法定程序和要求提出医疗器械注册申请，药品监督管理部门依据法律法规，基于科学认知，进行安全性、有效性和质量可控性等审查，决定是否同意其申请的活动。

"Recordation of medical devices" means the activities that a party undergoing recordation of a medical device (hereinafter referred to as "recordation party") submits recordation materials to the medical products administrative department under the statutory procedures and requirements and the medical products administrative department puts the recordation materials submitted on file for future reference.

医疗器械备案是指医疗器械备案人（以下简称备案人）依照法定程序和要求向药品监督管理部门提交备案资料，药品监督管理部门对提交的备案资料存档备查的活动。

Article 4 The National Medical Products Administration ("NMPA") shall be in charge of the administration of the registration and recordation of medical devices nationwide, be responsible for establishing work systems and rules for the administration of registration and recordation of medical devices, organize evaluation and approval of Class III domestic and Class II and Class III imported medical devices in accordance with the law, recordation of Class-I imported medical devices, and relevant supervision and administration, and supervise and guide the local registration and recordation of medical devices.

第四条 国家药品监督管理局主管全国医疗器械注册与备案管理工作，负责建立医疗器械注册与备案管理工作体系和制度，依法组织境内第三类和进口第二类、第三类医疗器械审评审批，进口第一类医疗器械备案以及相关监督管理工作，对地方医疗器械注册与备案工作进行监督指导。

Article 5 The Center for Medical Device Evaluation of NMPA (hereinafter referred to as the "Center for Medical Device Evaluation") shall be responsible for the technical evaluation of clinical trial applications for medical devices that require clinical trial approval, as well as product registration applications, alteration registration applications, and renewal registration applications for Class III domestic and Class II and Class III imported medical devices.

第五条 国家药品监督管理局医疗器械技术审评中心（以下简称国家局器械审评中心）负责需进行临床试验审批的医疗器械临床试验申请以及境内第三类和进口第二类、第三类医疗器械产品注册申请、变更注册申请、延续注册申请等的技术审评工作。

The Center for Medical Device Standards Management of NMPA, the National Institutes for Food and Drug Control, the Center for Food and Drug Inspection of NMPA (hereinafter referred to as the "Center for Inspection"), the Center for Drug Reevaluation of NMPA, the Center for Administrative Services and Complaints & Reports of NMPA, the Information Center of NMPA, and other professional technical institutions shall, according to their responsibilities, undertake the standardization administration, definition of classification, inspection, verification, monitoring and evaluation, making

国家药品监督管理局医疗器械标准管理中心、中国食品药品检定研究院、国家药品监督管理局食品药品审核查验中心（以下简称国家局审核查验中心）、国家药品监督管理局药品评价中心、国家药品监督管理局行政事项受理服务和投诉举报中心、国家药品监督管理局信息中心等其他专业技术机构，依职责承担实施医疗器械监督管理所需的医疗器械标准管理、分类界定、检验、核查、监测与评价、制证送达以及相应的信息化建设与管理等相关工作。

and service of certificates, corresponding information-based construction and management, and other relevant work required for the implementation of supervision and administration of medical devices.

Article 6 The medical products administrative department of a province, autonomous region, or municipality directly under the Central Government shall be responsible for the following administration work concerning registration of medical devices within its respective administrative region:

第六条 省、自治区、直辖市药品监督管理部门负责本行政区域内以下医疗器械注册相关管理工作：

(1) Evaluation and approval of registration of Class II domestic medical devices.

（一）境内第二类医疗器械注册审评审批；

(2) Verifying the quality management system for Class II and Class III domestic medical devices.

（二）境内第二类、第三类医疗器械质量管理体系核查；

(3) Organizing the supervision and administration of clinical trial institutions for and clinical trials of medical devices in accordance with the law.

（三）依法组织医疗器械临床试验机构以及临床试验的监督管理；

(4) Supervising and guiding the recordation of Class I domestic medical devices by the medical products administrative departments at the districted city level.

（四）对设区的市级负责药品监督管理的部门境内第一类医疗器械备案的监督指导。

The professional technical institutions of medical devices established or designated by the medical products administrative department of a province, autonomous region, or municipality directly under the Central Government shall assume technical evaluation, examination, verification, monitoring, evaluation and other work required for the

省、自治区、直辖市药品监督管理部门设置或者指定的医疗器械专业技术机构，承担实施医疗器械监督管理所需的技术审评、检验、核查、监测与评价等工作。

supervision and administration of medical devices.

The medical products administrative departments at the districted city level shall be responsible for the administration of recordation of Class I domestic medical devices.

设区的市级负责药品监督管理的部门负责境内第一类医疗器械产品备案管理工作。

Article 7 The principles of compliance with the laws, scientificity, openness, fairness, and impartiality shall be followed in the administration of registration and recordation of medical devices.

第七条 医疗器械注册与备案管理遵循依法、科学、公开、公平、公正的原则。

Article 8 Class I medical devices shall be subject to administration of product recordation, while Class II and Class III medical devices shall be subject to administration of product registration.

第八条 第一类医疗器械实行产品备案管理。第二类、第三类医疗器械实行产品注册管理。

For Class I domestic medical devices, the recordation parties shall submit recordation materials to the medical products administrative departments at the districted city level.

境内第一类医疗器械备案，备案人向设区的市级负责药品监督管理的部门提交备案资料。

For Class II domestic medical devices, the medical products administrative departments of provinces, autonomous regions and municipalities directly under the Central Government shall be responsible for examination, and shall issue registration certificates for medical devices in the case of approval.

境内第二类医疗器械由省、自治区、直辖市药品监督管理部门审查，批准后发给医疗器械注册证。

For Class III domestic medical devices, the NMPA shall be responsible for examination, and shall issue registration certificates for medical devices in the case of approval.

境内第三类医疗器械由国家药品监督管理局审查，批准后发给医疗器械注册证。

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

进口第一类医疗器械备案，备案人向国家药品监督管理局提交备案资料。

For Class II and III imported medical devices, the NMPA shall be responsible for examination, and shall issue registration certificates for medical devices in the case of approval.

进口第二类、第三类医疗器械由国家药品监督管理局审查，批准后发给医疗器械注册证。

Article 9 Registrants and recordation parties of medical devices shall strengthen the quality management throughout the life cycle of medical devices, and assume liability for the safety, effectiveness and quality controllability of medical devices during the whole process of development, production, operation and use in accordance with the law.

第九条 医疗器械注册人、备案人应当加强医疗器械全生命周期质量管理，对研制、生产、经营、使用全过程中的医疗器械的安全性、有效性和质量可控性依法承担责任。

Article 10 The NMPA shall give priority to the examination and approval of medical devices with urgent clinical needs, implement special examination and approval of innovative medical devices, encourage the research and innovation on medical devices, and promote the high-quality development of the industry of medical devices.

第十条 国家药品监督管理局对临床急需医疗器械实行优先审批，对创新医疗器械实行特别审批，鼓励医疗器械的研究与创新，推动医疗器械产业高质量发展。

Article 11 The NMPA shall establish and improve the standards, technical guiding principles and other systems for medical devices in accordance with the law, regulate the technical evaluation of medical devices and the verification of the quality management systems, and guide and serve the research on, development and registration applications for medical devices.

第十一条 国家药品监督管理局依法建立健全医疗器械标准、技术指导原则等体系，规范医疗器械技术审评和质量管理体系核查，指导和服务医疗器械研发和注册申请。

Article 12 The medical products administrative departments

第十二条 药品监督管理部门依法及时公开医疗器

shall disclose information about the registration and recordation of medical devices in a timely manner according to the law, applicants may inquire about the examination and approval progress and results, and the public may consult the examination and approval results.

械注册、备案相关信息，申请人可以查询审批进度和结果，公众可以查阅审批结果。

Without consent of an applicant, the medical products administrative department, professional technical institution and its staff members, experts participating in evaluation, and other personnel shall not disclose any business secret, undisclosed information or confidential business information submitted by the applicant or recordation party, unless it is otherwise prescribed by law or when it involves national security or major social and public interests.

未经申请人同意，药品监督管理部门、专业技术机构及其工作人员、参与评审的专家等人员不得披露申请人或者备案人提交的商业秘密、未披露信息或者保密商务信息，法律另有规定或者涉及国家安全、重大社会公共利益的除外。

Chapter II Basic Requirements

第二章　基本要求

Article 13 The registration and recordation of medical devices shall comply with the relevant laws, regulations, rules, and mandatory standards, follow the basic principles of safety and performance of medical devices, with reference to the relevant technical guiding principles, prove that the medical devices for which the registration and recordation formalities have been undergone are safe, effective, and controllable in quality, and ensure that the information in the whole process is authentic, accurate, complete and traceable.

第十三条　医疗器械注册、备案应当遵守相关法律、法规、规章、强制性标准，遵循医疗器械安全和性能基本原则，参照相关技术指导原则，证明注册、备案的医疗器械安全、有效、质量可控，保证全过程信息真实、准确、完整和可追溯。

Article 14 An applicant or a recordation party shall be an enterprise or development institution that can assume corresponding legal responsibilities.

第十四条　申请人、备案人应当为能够承担相应法律责任的企业或者研制机构。

A foreign applicant or a foreign recordation party shall designate an enterprise legal person in the territory of China as an agent to handle relevant registration and recordation matters of medical devices. The agent shall assist the registrant or recordation party in performing the obligations as prescribed in paragraph 1 of Article 20 of the Regulation on the Supervision and Administration of Medical Devices in accordance with the law, and assist the overseas registrant or recordation party in performing corresponding legal liabilities.

境外申请人、备案人应当指定中国境内的企业法人作为代理人，办理相关医疗器械注册、备案事项。代理人应当依法协助注册人、备案人履行《医疗器械监督管理条例》第二十条第一款规定的义务，并协助境外注册人、备案人落实相应法律责任。

Article 15 Applicants and recordation parties shall establish quality management systems that are compatible with the products, and maintain their efficiency.

第十五条 申请人、备案人应当建立与产品相适应的质量管理体系，并保持有效运行。

Article 16 Personnel responsible for handling matters concerning the registration or recordation of medical devices shall have corresponding professional knowledge, and be familiar with the laws, regulations, and rules on the administration of registration and recordation of medical devices, and the relevant provisions on administration of registration.

第十六条 办理医疗器械注册、备案事项的人员应当具有相应的专业知识，熟悉医疗器械注册、备案管理的法律、法规、规章和注册管理相关规定。

Article 17 To apply for registration or undergo the formalities of recordation, an applicant or recordation party shall, according to the requirements of the NMPA on registration or recordation, submit relevant materials, and be responsible for the truthfulness of the materials they submit.

第十七条 申请注册或者进行备案，应当按照国家药品监督管理局有关注册、备案的要求提交相关资料，申请人、备案人对资料的真实性负责。

The registration and recordation materials shall be prepared in Chinese. If they are translated from foreign materials, the

注册、备案资料应当使用中文。根据外文资料翻译的，应

originals shall be also provided. Where the cited documentary materials have not been published, a permission granted by the right holder of such materials shall be provided.

当同时提供原文。引用未公开发表的文献资料时，应当提供资料权利人许可使用的文件。

Article 18 To apply for registration of imported medical devices and to undergo recordation of imported medical devices, the certificate of permission granted by the competent authority of the country (region) where the applicant or recordation party is registered or the production is carried out for approving sale of the medical devices on the market shall be submitted.

第十八条 申请进口医疗器械注册、办理进口医疗器械备案，应当提交申请人、备案人注册地或者生产地所在国家（地区）主管部门准许该医疗器械上市销售的证明文件。

If the product is not treated as a medical device in the country (or region) of the place of registration of the applicant or recordation party or its production country (or region), the applicant or recordation party shall provide relevant documents, including a document approving sale of the product on the market in the country (or region) of the place of registration of the party applying for its registration or undergoing its recordation formalities or its production country (or region).

申请人、备案人注册地或者生产地所在国家（地区）未将该产品作为医疗器械管理的，申请人、备案人需提供相关文件，包括注册地或者生产地所在国家（地区）准许该产品上市销售的证明文件。

No relevant documents are required to be submitted for innovative medical devices that are not sold on the market in the country (region) where the applicant or recordation party is registered or the production is carried out.

未在申请人、备案人注册地或者生产地所在国家（地区）上市的创新医疗器械，不需提交相关文件。

Article 19 Medical devices shall comply with applicable mandatory standards. Where the structural features, expected purpose, and application methods of products, among others, are inconsistent with the scope of application of the mandatory

第十九条 医疗器械应当符合适用的强制性标准。产品结构特征、预期用途、使用方式等与强制性标准的适用范围不一致的，申请人、备案人应当提出不适用强制性

standards, the applicant or recordation party shall provide an explanation for the inapplicability of the mandatory standards and provide the relevant materials.

标准的说明，并提供相关资料。

Where there are no mandatory standards, applicants or recordation parties shall be encouraged to adopt recommended standards.

没有强制性标准的，鼓励申请人、备案人采用推荐性标准。

Article 20 The registration and recordation of medical devices shall comply with the rules on classification of medical devices and satisfy the relevant requirements of the classified catalogue.

第二十条 医疗器械注册、备案工作应当遵循医疗器械分类规则和分类目录的有关要求。

Article 21 Medical products administrative departments shall continuously promote the reform of the evaluation and approval system, strengthen the scientific research on medical device supervision, establish a technical system for the administration of registration of medical devices dominated by technical evaluation and supported by verification, inspection, monitoring and evaluation, optimize the evaluation and approval process, enhance the evaluation and approval capabilities, and improve the quality and efficiency of evaluation and approval.

第二十一条 药品监督管理部门持续推进审评审批制度改革，加强医疗器械监管科学研究，建立以技术审评为主导，核查、检验、监测与评价等为支撑的医疗器械注册管理技术体系，优化审评审批流程，提高审评审批能力，提升审评审批质量和效率。

Article 22 The professional technical institutions of medical devices shall establish and improve the communication system, specify the form and content of communication, and organize communication and exchange with applicants according to the work needs.

第二十二条 医疗器械专业技术机构建立健全沟通交流制度，明确沟通交流的形式和内容，根据工作需要组织与申请人进行沟通交流。

Article 23 The professional technical institutions of medical devices shall, according to the work needs, establish an expert consultation system, request experts' opinions on major issues during the process of review, verification and inspection, among others, and fully maximize the technical supporting role of experts.

第二十三条 医疗器械专业技术机构根据工作需要建立专家咨询制度，在审评、核查、检验等过程中就重大问题听取专家意见，充分发挥专家的技术支撑作用。

Chapter III Registration of Medical Devices

第三章 医疗器械注册

Section 1 Development of Products

第一节 产品研制

Article 24 Developers of medical devices shall follow the principles of risk management, consider the existing recognized technical merit, ensure that all known and foreseeable risks and unanticipated impact of the products are minimized and acceptable, and guarantee that the benefits of products from normal use are greater than risks.

第二十四条 医疗器械研制应当遵循风险管理原则，考虑现有公认技术水平，确保产品所有已知和可预见的风险以及非预期影响最小化并可接受，保证产品在正常使用中受益大于风险。

Article 25 The experiment activities of developing medical device products shall satisfy the requirements of relevant laws, regulations and mandatory standards of China.

第二十五条 从事医疗器械产品研制实验活动，应当符合我国相关法律、法规和强制性标准等的要求。

Article 26 An applicant or a recordation party shall develop the product technical requirements for the medical device for which an application for registration or recordation is filed.

第二十六条 申请人、备案人应当编制申请注册或者进行备案医疗器械的产品技术要求。

The product technical requirements shall mainly comprise the functional and safety indicators and testing methods that may be objectively judged for finished products of medical devices.

产品技术要求主要包括医疗器械成品的可进行客观判定的功能性、安全性指标和检测方法。

Medical devices shall satisfy the technical requirements for the registered or recorded products.

医疗器械应当符合经注册或者备案的产品技术要求。

Article 27 An applicant or a recordation party shall develop specifications and labels of the medical device for which an application for registration or recordation is filed.

第二十七条 申请人、备案人应当编制申请注册或者进行备案医疗器械的产品说明书和标签。

The specifications and labels shall satisfy the requirements of Article 39 of the Regulation on the Supervision and Administration of Medical Devices and the relevant provisions.

产品说明书和标签应当符合《医疗器械监督管理条例》第三十九条要求以及相关规定。

Article 28 In the development of medical devices, non-clinical research on medical devices shall be carried out according to the scope of application and technical characteristics of the products.

第二十八条 医疗器械研制，应当根据产品适用范围和技术特征开展医疗器械非临床研究。

Non-clinical research shall include research on products' chemical and physical performance, electrical safety, radiation safety, software, biological characteristics, biological material safety, disinfection and sterilization process, animal test, and stability, among others.

非临床研究包括产品化学和物理性能研究，电气安全研究，辐射安全研究，软件研究，生物学特性研究，生物源材料安全性研究，消毒、灭菌工艺研究，动物试验研究，稳定性研究等。

To apply for registration or undergo recordation, the applicant or recordation party shall submit non-clinical evidence generated in the development activities, including a summary of non-clinical research reports, research plans and research reports.

申请注册或者进行备案，应当提交研制活动中产生的非临床证据，包括非临床研究报告综述、研究方案和研究报告。

Article 29 The functional and safety indicators and methods

第二十九条 医疗器械非临床研究过程中确定的功

determined in the non-clinical research on medical devices shall be adaptable to the expected service conditions and purposes of the products, and the research specimens shall be representative and typical. If necessary, methodological verification and statistical analysis shall be conducted.

能性、安全性指标及方法应当与产品预期使用条件、目的相适应，研究样品应当具有代表性和典型性。必要时，应当进行方法学验证、统计学分析。

Article 30 To apply for registration or undergo recordation, the applicant or recordation party shall conduct inspection in accordance with the technical requirements for the product and submit an inspection report. Only when the inspection is passed, may clinical trial be carried out, or an application be filed and recordation formalities be undergone.

第三十条 申请注册或者进行备案，应当按照产品技术要求进行检验，并提交检验报告。检验合格的，方可开展临床试验或者申请注册、进行备案。

Article 31 The products to be inspected shall be able to represent the safety and effectiveness of the products for which an application for registration filed or recordation is to be undergone, and their production shall satisfy the relevant requirements of the quality management standards for production of medical devices.

第三十一条 检验用产品应当能够代表申请注册或者进行备案产品的安全性和有效性，其生产应当符合医疗器械生产质量管理规范的相关要求。

Article 32 A product inspection report on medical devices submitted for applying for registration or undergoing recordation may be the self-inspection report of the applicant or recordation party, or an inspection report issued by a qualified medical device inspection institution on a commissioned basis.

第三十二条 申请注册或者进行备案提交的医疗器械产品检验报告可以是申请人、备案人的自检报告，也可以是委托有资质的医疗器械检验机构出具的检验报告。

Section 2 Clinical Evaluation

第二节 临床评价

Article 33 Except for the circumstances as specified in

第三十三条 除本办法第三十四条规定情形外，医

Article 34 of these Measures, clinical evaluation shall be conducted for the registration or recordation of medical device products.

疗器械产品注册、备案，应当进行临床评价。

Clinical evaluation of medical devices means the analysis on and evaluation of the clinical data by scientific and reasonable methods, to confirm the safety and effectiveness of medical devices within their scope of application.

医疗器械临床评价是指采用科学合理的方法对临床数据进行分析、评价，以确认医疗器械在其适用范围内的安全性、有效性的活动。

To apply for registration of medical devices, the applicant shall submit the clinical evaluation materials.

申请医疗器械注册，应当提交临床评价资料。

Article 34 Under any of the following circumstances, a clinical evaluation may be exempted:

第三十四条 有下列情形之一的，可以免于进行临床评价：

(1) They have clear and definite working mechanisms, finalized designs and mature production techniques, the marketed medical devices of the same category have been put into clinical application for years with no record of severe adverse event, and their general purposes remain unchanged.

（一）工作机理明确、设计定型，生产工艺成熟，已上市的同品种医疗器械临床应用多年且无严重不良事件记录，不改变常规用途的；

(2) Other circumstance under which the safety and effectiveness of such medical devices may be proved through non-clinical evaluation.

（二）其他通过非临床评价能够证明该医疗器械安全、有效的。

Where clinical evaluation is exempted, submission of clinical evaluation materials may be exempted.

免于进行临床评价的，可以免于提交临床评价资料。

The catalog of medical devices exempt from clinical evaluation shall be developed, adjusted and announced by the

免于进行临床评价的医疗器械目录由国家药品监督管理局制定、调整并公布。

NMPA.

Article 35 For clinical evaluation of medical devices, the safety and effectiveness of medical devices may be proved through carrying out clinical trial according to the product characteristics, clinical risks, existing clinical data and other circumstances, or through analysis on and evaluation of the clinical literature and clinical data of the same variety of medical devices.

第三十五条 开展医疗器械临床评价，可以根据产品特征、临床风险、已有临床数据等情形，通过开展临床试验，或者通过对同品种医疗器械临床文献资料、临床数据进行分析评价，证明医疗器械的安全性、有效性。

When clinical evaluation of medical devices is conducted in accordance with the rules of the NMPA, clinical trials shall be carried out for medical devices for which the existing clinical literature and clinical data are insufficient to confirm the safety and effectiveness of the products.

按照国家药品监督管理局的规定，进行医疗器械临床评价时，已有临床文献资料、临床数据不足以确认产品安全、有效的医疗器械，应当开展临床试验。

The NMPA shall develop guidelines for the clinical evaluation of medical devices to specify the requirements for clinical evaluation through clinical literature and clinical data of the same variety of medical devices, the circumstances under which clinical trials need to be carried out, and the requirements for preparing clinical evaluation reports, among others.

国家药品监督管理局制定医疗器械临床评价指南，明确通过同品种医疗器械临床文献资料、临床数据进行临床评价的要求，需要开展临床试验的情形，临床评价报告的撰写要求等。

Article 36 Where clinical evaluation is carried out according to the clinical literature and clinical data of the same variety of medical devices, the clinical evaluation materials shall include the comparison between the product for which an application for registration is filed and the same variety of medical devices, the analysis on and evaluation of the clinical data of the same variety of medical devices, the scientific evidence

第三十六条 通过同品种医疗器械临床文献资料、临床数据进行临床评价的，临床评价资料包括申请注册产品与同品种医疗器械的对比，同品种医疗器械临床数据的分析评价，申请注册产品与同品种产品存在差异时的科学证据以及评价结论等内容。

and evaluation conclusions when there are differences between the product for which an application for registration is filed and the same variety of medical devices, and other contents.

Where clinical evaluation is carried out through clinical trials, the clinical evaluation materials shall include clinical trial plans, opinions of the ethics committee, informed consent and clinical trial reports, among others.

通过临床试验开展临床评价的，临床评价资料包括临床试验方案、伦理委员会意见、知情同意书、临床试验报告等。

Article 37 Clinical trials of medical devices shall be carried out in clinical trial institutions for medical devices that meet corresponding conditions and have undergone the recordation formalities as required in accordance with the requirements of the quality management standards for the clinical trials of medical devices. Before the start of a clinical trial, the applicant for a clinical trial shall undergo the formalities for recordation of clinical trial with the medical products administrative department of the province, autonomous region, or municipality directly under the Central Government where it is located. The production of medical devices to be put in clinical trial shall satisfy the relevant requirements of the quality management standards for production of medical devices.

第三十七条 开展医疗器械临床试验，应当按照医疗器械临床试验质量管理规范的要求，在具备相应条件并按照规定备案的医疗器械临床试验机构内进行。临床试验开始前，临床试验申办者应当向所在地省、自治区、直辖市药品监督管理部门进行临床试验备案。临床试验医疗器械的生产应当符合医疗器械生产质量管理规范的相关要求。

Article 38 Clinical trials of Class III medical devices which may pose relatively high risks to human bodies shall be subject to the approval of the NMPA.

第三十八条 第三类医疗器械进行临床试验对人体具有较高风险的，应当经国家药品监督管理局批准。

The examination and approval of clinical trials means the process whereby the NMPA, upon the application of applicants, comprehensively analyzes the degree of risks in the

临床试验审批是指国家药品监督管理局根据申请人的申请，对拟开展临床试验的医疗器械的风险程度、临床试验

medical devices to be put in clinical trials, the clinical trial plans, and the clinical benefit and risk comparison and analysis reports to decide whether to approve the clinical trials of the medical devices.

方案、临床受益与风险对比分析报告等进行综合分析，以决定是否同意开展临床试验的过程。

The catalogue of Class III medical devices subject to examination and approval for clinical trials shall be developed, adjusted and published by the NMPA. The clinical trials of Class III medical devices whose clinical trials are subject to examination and approval shall be carried out in qualified medical institutions of Grade III and Level A.

需进行临床试验审批的第三类医疗器械目录由国家药品监督管理局制定、调整并公布。需进行临床试验审批的第三类医疗器械临床试验应在符合要求的三级甲等医疗机构开展。

Article 39 Where the clinical trial of a medical device is subject to examination and approval, the applicant shall submit summary materials, research materials, clinical materials, specifications, label sample and other application materials in accordance with the relevant requirements.

第三十九条 需进行医疗器械临床试验审批的，申请人应当按照相关要求提交综述资料、研究资料、临床资料、产品说明书和标签样稿等申请资料。

Article 40 The Center for Medical Device Evaluation shall evaluate accepted applications for clinical trial. A decision on whether to approve an application for a clinical trial shall be made within 60 days from the date of acceptance of an application, and the applicant shall be notified on the website of the Center for Medical Device Evaluation. Where it is not notified within the prescribed time limit, it shall be deemed approval.

第四十条 国家局器械审评中心对受理的临床试验申请进行审评。对临床试验申请应当自受理申请之日 60 日内作出是否同意的决定，并通过国家局器械审评中心网站通知申请人。逾期未通知的，视为同意。

Article 41 Where an applicant needs to supplement or correct application materials in the course of technical evaluation, the Center for Medical Device Evaluation shall notify the

第四十一条 审评过程中需要申请人补正资料的，国家局器械审评中心应当一次告知需要补正的全部内容。申请人应当在收到补正通知 1 年内，按照补正通知的要求

applicant of all necessary supplements and corrections at one time. An applicant shall provide supplementary materials at one time according to the requirements of the notice on supplements and corrections within one year upon receipt of the notice on supplements and corrections. After receiving the supplementary materials, the Center for Medical Device Evaluation shall complete technical evaluation within the prescribed time limit.

一次提供补充资料。国家局器械审评中心收到补充资料后，按照规定的时限完成技术审评。

An applicant with any objection to the contents mentioned in the notice on supplements and corrections may submit its opinions in writing to the Center for Medical Device Evaluation, explaining the reasons and providing corresponding technical support data.

申请人对补正通知内容有异议的，可以向国家局器械审评中心提出书面意见，说明理由并提供相应的技术支持资料。

Where an applicant fails to submit the supplementary materials within the specified time limit, the technical evaluation shall be terminated and a decision of disapproval shall be made.

申请人逾期未提交补充资料的，终止技术审评，作出不予批准的决定。

Article 42 For serious adverse events of medical devices subject to clinical trials during the clinical trial of medical devices, or other serious safety risk information, the applicant for clinical trials shall, in accordance with the relevant requirements, report to the medical products administrative department of a province, autonomous region, or municipality directly under the Central Government where it is located and where the clinical trial institution is located respectively, and adopt risk control measures. Where no risk control measures are adopted, the medical products administrative department of the province, autonomous region, or municipality directly under the Central Government shall order the applicant to

第四十二条 对于医疗器械临床试验期间出现的临床试验医疗器械相关严重不良事件，或者其他严重安全性风险信息，临床试验申办者应当按照相关要求，分别向所在地和临床试验机构所在地省、自治区、直辖市药品监督管理部门报告，并采取风险控制措施。未采取风险控制措施的，省、自治区、直辖市药品监督管理部门依法责令申办者采取相应的风险控制措施。

adopt corresponding risk control measures in accordance with the law.

Article 43 When there are large-scale serious adverse events or other serious safety problems of medical devices subject to clinical trials during the clinical trials of medical devices, the applicant shall suspend or terminate the clinical trials of such medical devices and respectively report to the medical products administrative department of the province, autonomous region, or municipality directly under the Central Government where it is located and where the clinical trial institution is located. Where the clinical trials are not suspended or terminated, the medical products administrative department of the province, autonomous region, or municipality directly under the Central Government shall order the applicant to adopt corresponding risk control measures in accordance with the law.

第四十三条 医疗器械临床试验中出现大范围临床试验医疗器械相关严重不良事件，或者其他重大安全性问题时，申办者应当暂停或者终止医疗器械临床试验，分别向所在地和临床试验机构所在地省、自治区、直辖市药品监督管理部门报告。未暂停或者终止的，省、自治区、直辖市药品监督管理部门依法责令申办者采取相应的风险控制措施。

Article 44 Where approved clinical trials fall under any of the following circumstances, the NMPA may order the applicant to terminate the clinical trials of medical devices that have been carried out:

第四十四条 已批准开展的临床试验，有下列情形之一的，国家药品监督管理局可以责令申请人终止已开展的医疗器械临床试验：

(1) The application materials for the clinical trial are false.

（一）临床试验申请资料虚假的；

(2) The latest research results prove that there are some ethical or scientific problems with the approved clinical trials.

（二）已有最新研究证实原批准的临床试验伦理性和科学性存在问题的；

(3) Other circumstances under which clinical trials shall be terminated.

（三）其他应当终止的情形。

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.

第四十五条 医疗器械临床试验应当在批准后 3 年内实施；医疗器械临床试验申请自批准之日起，3 年内未有受试者签署知情同意书的，该医疗器械临床试验许可自行失效。仍需进行临床试验的，应当重新申请。

Article 46 Medical devices undergoing clinical trials, intended for the treatment of a seriously life-threatening disease of which there has been no effective treatment, which possibly deliver benefits to patients as indicated by medical observation, may, with ethical approval and informed consent, be applied to other patients suffering from the same disease for free in the institution where such clinical trial of medical device is carried out. Its safety data may be used for applications for registration of medical devices.

第四十六条 对正在开展临床试验的用于治疗严重危及生命且尚无有效治疗手段的疾病的医疗器械，经医学观察可能使患者获益，经伦理审查、知情同意后，可以在开展医疗器械临床试验的机构内免费用于其他病情相同的患者，其安全性数据可以用于医疗器械注册申请。

Section 3 Verification of the Registration System

第三节 注册体系核查

Article 47 An applicant shall submit the relevant materials on the quality management system concerning the development and production of products when applying for registration. The medical products administrative department accepting the application for registration and deeming that it is necessary to verify the quality management system during the technical evaluation of products shall organize and carry out verification of the quality management system, and may consult the original materials according to the needs.

第四十七条 申请人应当在申请注册时提交与产品研制、生产有关的质量管理体系相关资料，受理注册申请的药品监督管理部门在产品技术审评时认为有必要对质量管理体系进行核查的，应当组织开展质量管理体系核查，并可以根据需要调阅原始资料。

Article 48 The Center for Medical Device Evaluation shall notify the medical products administrative department of the province, autonomous region, or municipality directly under the Central Government where the applicant is located of verifying the quality management system of Class III domestic medical devices.

第四十八条 境内第三类医疗器械质量管理体系核查，由国家局器械审评中心通知申请人所在地的省、自治区、直辖市药品监督管理部门开展。

The medical products administrative department of the province, autonomous region, or municipality directly under the Central Government where the applicant is located shall organize and carry out verification of the quality management system of Class II domestic medical devices.

境内第二类医疗器械质量管理体系核查，由申请人所在地的省、自治区、直辖市药品监督管理部门组织开展。

Article 49 The medical products administrative department of the province, autonomous region, or municipality directly under the Central Government shall verify the quality management system according to the requirements of the quality management standards for production of medical devices, and focus on verifying whether the applicant has established a quality management system adaptable to the products in accordance with the requirements of the quality management standards for production of medical devices, as well as the design, development, production management, quality control and other contents concerning the development and production of products.

第四十九条 省、自治区、直辖市药品监督管理部门按照医疗器械生产质量管理规范的要求开展质量管理体系核查，重点对申请人是否按照医疗器械生产质量管理规范的要求建立与产品相适应的质量管理体系，以及与产品研制、生产有关的设计开发、生产管理、质量控制等内容进行核查。

During the process of verification, the authenticity of the products for inspection and the products for clinical trials shall be verified concurrently, and the relevant records of the design and development process and the relevant records of the production process of products for inspection and products for

在核查过程中，应当同时对检验用产品和临床试验产品的真实性进行核查，重点查阅设计开发过程相关记录，以及检验用产品和临床试验产品生产过程的相关记录。

clinical trials shall be mainly consulted.

When a self-inspection report is submitted, the inspection capabilities and inspection results, among others, of the applicant, recordation party or entrusted institution during the development process shall be mainly verified.

提交自检报告的，应当对申请人、备案人或者受托机构研制过程中的检验能力、检验结果等进行重点核查。

Article 50 The medical products administrative department of the province, autonomous region, or municipality directly under the Central Government may verify the quality management system by materials review or on-site inspection. It shall, according to the applicant's specific situation, supervision and inspection, and comparison between the product for which an application for registration is filed and the product that has previously passed verifications in terms of production conditions and process, determine whether to conduct an on-site inspection and determine the inspection contents so as to avoid repeated inspections.

第五十条 省、自治区、直辖市药品监督管理部门可以通过资料审查或者现场检查的方式开展质量管理体系核查。根据申请人的具体情况、监督检查情况、本次申请注册产品与既往已通过核查产品生产条件及工艺对比情况等，确定是否现场检查以及检查内容，避免重复检查。

Article 51 Where the Center for Medical Device Evaluation deems it necessary to verify the quality management system when conducting technical evaluation of Class II and Class III imported medical devices, it shall notify the Center for Inspection of carrying out verification in accordance with the relevant requirements.

第五十一条 国家局器械审评中心对进口第二类、第三类医疗器械开展技术审评时，认为有必要进行质量管理体系核查的，通知国家局审核查验中心根据相关要求开展核查。

Section 4 Product Registration

第四节 产品注册

Article 52 An applicant shall, after completing the research on safety and effectiveness supporting the registration of

第五十二条 申请人应当在完成支持医疗器械注册的安全性、有效性研究，做好接受质量管理体系核查的准

medical devices and being effectively prepared for accepting the verification of the quality management system, file an application for registration of a medical device, and submit the following registration application materials by filing online applications for registration and other methods to the medical products administrative department in accordance with the relevant requirements:

备后，提出医疗器械注册申请，并按照相关要求，通过在线注册申请等途径向药品监督管理部门提交下列注册申请资料：

(1) The analysis materials for product risks.

（一）产品风险分析资料；

(2) They technical requirements for products.

（二）产品技术要求；

(3) The product inspection report.

（三）产品检验报告；

(4) The clinical evaluation materials.

（四）临床评价资料；

(5) The specifications and label samples.

（五）产品说明书以及标签样稿；

(6) The documents on the quality management system related to the research on and production of products.

（六）与产品研制、生产有关的质量管理体系文件；

(7) Other materials required for proving the safety and effectiveness of products.

（七）证明产品安全、有效所需的其他资料。

Article 53 A medical products administrative department shall, after receiving an application, examine the application materials, and handle them respectively under the following circumstances:

第五十三条 药品监督管理部门收到申请后对申请资料进行审核，并根据下列情况分别作出处理：

(1) Where an item of application falls under the scope of

（一）申请事项属于本行政机关职权范围，申请资料齐

functions of this administrative authority, and the application materials are complete and satisfy the requirements for formal examination, the department shall accept the application.

全、符合形式审核要求的，予以受理；

(2) Where the applicant materials have any error that could be corrected on the spot, the department shall allow the applicant to correct it on the spot.

（二）申请资料存在可以当场更正的错误的，应当允许申请人当场更正；

(3) Where the application materials are incomplete or not made in the statutory form, the medical products administrative department shall, on the spot or within five days, notify the applicant of all necessary supplements and corrections at one time; and where it fails to notify the applicant of the aforesaid contents within the prescribed time limit, the application materials shall be deemed to have been accepted on the date of receipt.

（三）申请资料不齐全或者不符合法定形式的，应当当场或者在 5 日内一次告知申请人需要补正的全部内容，逾期不告知的，自收到申请资料之日起即为受理；

(4) Where an item of application does not fall under the scope of functions of this administrative authority according to the law, a decision of denying an application shall be made immediately, and the applicant shall be notified of filing an application with the relevant administrative authority.

（四）申请事项依法不属于本行政机关职权范围的，应当即时作出不予受理的决定，并告知申请人向有关行政机关申请。

After making a decision of acceptance or denial of a medical device registration application, the medical products administrative department shall issue a notice of acceptance or denial to which the special seal of the administrative authority is affixed and on which the date is marked.

药品监督管理部门受理或者不予受理医疗器械注册申请，应当出具加盖本行政机关专用印章和注明日期的受理或者不予受理的通知书。

Where, after an application for registration of a medical device is accepted, the applicant is required to pay fees, the applicant

医疗器械注册申请受理后，需要申请人缴纳费用的，申请人应当按规定缴纳费用。申请人未在规定期限内缴纳费用

shall pay fees according to the provisions. Where the applicant fails to make payment within the specified time limit, it shall be deemed that the applicant has withdrawn the application proactively, and the medical products administrative department shall terminate its registration procedures.

的，视为申请人主动撤回申请，药品监督管理部门终止其注册程序。

Article 54 Where a technical evaluation institution requires an applicant to supplement or correct application materials in the course of technical evaluation, it shall notify the applicant at one time of all contents that need to be supplemented or corrected. The applicant shall provide supplementary materials at one time in accordance with the requirements of the notice on supplements and corrections within one year upon receipt of the notice on supplements and corrections, and after receiving the supplementary materials, the technical evaluation institution shall complete technical evaluation within the prescribed time limit.

第五十四条 技术审评过程中需要申请人补正资料的，技术审评机构应当一次告知需要补正的全部内容。申请人应当在收到补正通知 1 年内，按照补正通知要求一次提供补充资料；技术审评机构收到补充资料后，在规定的时限内完成技术审评。

Where the applicant has any objection to the contents mentioned in the notice on supplements and corrections, it may submit its opinion in writing to the technical evaluation institution, explaining the reasons and providing corresponding technical support data.

申请人对补正通知内容有异议的，可以向相应的技术审评机构提出书面意见，说明理由并提供相应的技术支持资料。

Where an applicant fails to submit the supplementary materials within the prescribed time limit, the technical evaluation shall be terminated and the medical products administrative department shall make a decision of registration denial.

申请人逾期未提交补充资料的，终止技术审评，药品监督管理部门作出不予注册的决定。

Article 55 After a registration application is accepted, the applicant may apply to the medical products administrative

第五十五条 对于已受理的注册申请，申请人可以

department having accepted the application for withdrawing the application and the relevant materials before an administrative licensing decision is made, and explain the reasons. Where withdrawal of an application is approved, the medical products administrative department shall terminate its registration procedures.

在行政许可决定作出前，向受理该申请的药品监督管理部门申请撤回注册申请及相关资料，并说明理由。同意撤回申请的，药品监督管理部门终止其注册程序。

Suspected illegal activities such as concealing the true situation or providing false information found during the process of evaluation, verification, examination and approval shall be handled according to the law, and the applicant shall not withdraw the application for registration of a medical device.

审评、核查、审批过程中发现涉嫌存在隐瞒真实情况或者提供虚假信息等违法行为的，依法处理，申请人不得撤回医疗器械注册申请。

Article 56 Where, after a registration application is accepted, there is evidence showing that the application materials may be false, the medical products administrative department may suspend evaluation and approval. Upon verification, examination shall be continuously conducted or a decision of denial shall be made according to the verification conclusions.

第五十六条 对于已受理的注册申请，有证据表明注册申请资料可能虚假的，药品监督管理部门可以中止审评审批。经核实后，根据核实结论继续审查或者作出不予注册的决定。

Article 57 Where, during the period of evaluation of an application for registration of a medical device, evaluation conclusions of failure to pass are intended to be reached, the technical evaluation institution shall notify the applicant of the reasons for failure, the applicant may raise an objection to the technical evaluation institution within 15 days, and the contents of objection shall be limited to the original items of application and the original application materials. The technical evaluation institution shall conduct comprehensive evaluation in consideration of the applicant's objection and give feedback to the applicant. The time for handling the

第五十七条 医疗器械注册申请审评期间，对于拟作出不通过的审评结论的，技术审评机构应当告知申请人不通过的理由，申请人可以在 15 日内向技术审评机构提出异议，异议内容仅限于原申请事项和原申请资料。技术审评机构结合申请人的异议意见进行综合评估并反馈申请人。异议处理时间不计入审评时限。

objection shall not be included in the time limit for evaluation.

Article 58 The medical products administrative department that accepts a registration application shall, upon completion of technical evaluation, decide whether to approve the registration. If the device satisfies the requirements for safety, effectiveness and quality controllability, the department shall make a decision of approval, issue a medical device registration certificate, and issue the confirmed technical requirements for products to the applicant in the form of annex. In the case of disapproval, the department shall explain the reasons in writing, and notify the applicant that it has the right to apply for administrative reconsideration or to institute an administrative action.

第五十八条 受理注册申请的药品监督管理部门应当在技术审评结束后，作出是否批准的决定。对符合安全、有效、质量可控要求的，准予注册，发给医疗器械注册证，经过核准的产品技术要求以附件形式发给申请人。对不予注册的，应当书面说明理由，并同时告知申请人享有依法申请行政复议或者提起行政诉讼的权利。

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

医疗器械注册证有效期为 5 年。

Article 59 After accepting a registration application, the medical products administrative department shall make a decision of denial and notify the applicant under any of the following circumstances:

第五十九条 对于已受理的注册申请，有下列情形之一的，药品监督管理部门作出不予注册的决定，并告知申请人：

(1) The research carried out by the applicant on the safety, effectiveness and quality controllability of the medical device to be marketed and the results of such research cannot prove the safety, effectiveness or quality controllability of the product.

（一）申请人对拟上市销售医疗器械的安全性、有效性、质量可控性进行的研究及其结果无法证明产品安全、有效、质量可控的；

(2) The quality management system fails to pass the verification, and the applicant refuses to accept the on-site

（二）质量管理体系核查不通过，以及申请人拒绝接受质

inspection of its quality management system.

量管理体系现场检查的；

(3) The application materials for registration are false.

（三）注册申请资料虚假的；

(4) The application materials for registration are confusing and contradictory, the contents of the application materials for registration are apparently inconsistent with the items of application, or the safety, effectiveness and quality controllability of the product cannot be proved.

（四）注册申请资料内容混乱、矛盾，注册申请资料内容与申请项目明显不符，不能证明产品安全、有效、质量可控的；

(5) Any other circumstance under which the registration application shall be disapproved.

（五）不予注册的其他情形。

Article 60 For a matter for which a hearing shall be held for implementation of administrative licensing according to the provisions of the laws, regulations and rules, or other important administrative licensing matters involving public interests for which the medical products administrative department deems that a hearing needs to be held, the medical products administrative department shall make an announcement to the public and hold a hearing therefor. Where an application for registration of a medical device directly involves the vital interest between the applicant and another party, the medical products administrative department shall, before making a decision on administrative licensing, notify the applicant and the interested party of their rights of requesting for holding a hearing.

第六十条 法律、法规、规章规定实施行政许可应当听证的事项，或者药品监督管理部门认为需要听证的其他涉及公共利益的重大行政许可事项，药品监督管理部门应当向社会公告，并举行听证。医疗器械注册申请直接涉及申请人与他人之间重大利益关系的，药品监督管理部门在作出行政许可决定前，应当告知申请人、利害关系人享有要求听证的权利。

Article 61 For medical devices that are urgently needed for the treatment of rare diseases or seriously life-threatening

第六十一条 对用于治疗罕见疾病、严重危及生命且尚无有效治疗手段的疾病和应对公共卫生事件等急需的

diseases of which there has been no effective treatment, and in response to public health events, the medical products administrative department may make a decision on conditional approval and specify the validity period, the post-marketing research work that needs to be completed, the time limit for completion and other relevant matters in the medical device registration certificate.

医疗器械，药品监督管理部门可以作出附条件批准决定，并在医疗器械注册证中载明有效期、上市后需要继续完成的研究工作及完成时限等相关事项。

Article 62 For a conditionally approved medical device, the registrant shall collect relevant data on the benefits and risks after the medical device is marketed, continue to monitor and evaluate the benefits and risks of the products, take effective measures to proactively manage and control risks, and complete the research and submit relevant materials as required within the prescribed time limit.

第六十二条 对附条件批准的医疗器械，注册人应当在医疗器械上市后收集受益和风险相关数据，持续对产品的受益和风险开展监测与评估，采取有效措施主动管控风险，并在规定期限内按照要求完成研究并提交相关资料。

Article 63 Where, for a conditionally approved medical device, the registrant fails to complete the research as required within the prescribed time limit or fails to prove that the benefits are greater than the risks, it shall apply for undergoing the formalities of canceling the medical device registration certificate in a timely manner, and the medical products administrative department may cancel the medical device registration certificate in accordance with the law.

第六十三条 对附条件批准的医疗器械，注册人逾期未按照要求完成研究或者不能证明其受益大于风险的，注册人应当及时申请办理医疗器械注册证注销手续，药品监督管理部门可以依法注销医疗器械注册证。

Article 64 For a newly developed medical device which has not been included in the classified catalogue, an applicant may directly apply for registering it as a Class III medical device, or may apply for registration or undergo formalities for recordation of product after determining its category according

第六十四条 对新研制的尚未列入分类目录的医疗器械，申请人可以直接申请第三类医疗器械产品注册，也可以依据分类规则判断产品类别并向国家药品监督管理局申请类别确认后，申请产品注册或者进行产品备案。

to the classification rules and applying to the NMPA for confirming the category.

If the applicant directly applies for registering it as a Class III medical device, the NMPA shall determine its category according to the risk degree. Where a domestic medical device is determined to be Class II or Class I, the applicant shall be notified of applying to the corresponding medical products administrative department for registration or recordation.

直接申请第三类医疗器械注册的，国家药品监督管理局按照风险程度确定类别。境内医疗器械确定为第二类或者第一类的，应当告知申请人向相应的药品监督管理部门申请注册或者进行备案。

Article 65 Where a registered medical device is downgraded, the medical device registration certificate shall remain valid during its validity period. To renew the certificate upon expiry of the validity period, the registrant shall apply to the corresponding medical products administrative department for renewal or undergo formalities for recordation based on the new management class at least six months prior to the expiry of the validity period of the medical device registration certificate.

第六十五条 已注册的医疗器械，其管理类别由高类别调整为低类别的，医疗器械注册证在有效期内继续有效。有效期届满需要延续的，应当在医疗器械注册证有效期届满 6 个月前，按照调整后的类别向相应的药品监督管理部门申请延续注册或者进行备案。

Where the management class of a medical device is upgraded, the registrant shall apply to the corresponding medical products administrative department for registration based on the new management class. The NMPA shall specify the time limit for modification in the notice of modification of the management class.

医疗器械管理类别由低类别调整为高类别的，注册人应当按照改变后的类别向相应的药品监督管理部门申请注册。国家药品监督管理局在管理类别调整通知中应当对完成调整的时限作出规定。

Article 66 Where the medical device registration certificate and its annexes are lost or damaged, the registrant shall apply to the original certificate issuer for reissuance, and the original certificate issuer shall reissue the certificate after verification.

第六十六条 医疗器械注册证及其附件遗失、损毁的，注册人应当向原发证机关申请补发，原发证机关核实后予以补发。

Article 67 Any patent dispute arising during the examination or after the approval of a registration application shall be handled in accordance with the provisions of the relevant laws and regulations.

第六十七条 注册申请审查过程中及批准后发生专利权纠纷的，应当按照有关法律、法规的规定处理。

Chapter IV Special Registration Procedures

第四章 特殊注册程序

Section 1 Registration Procedures for Innovative Products

第一节 创新产品注册程序

Article 68 For a medical device that satisfies the following requirements, the applicant may apply for undergoing the registration procedures for innovative products:

第六十八条 符合下列要求的医疗器械，申请人可以申请适用创新产品注册程序：

(1) The applicant owns patents for core technical inventions of products in China according to the law through its leading technological innovation activities, or has obtained patents for inventions in China or the rights to use them through transfer according to the law, and the time for applying for undergoing the registration procedures for innovative products is less than five years from the date of announcement of patent authorization; or the application for patents for core technical inventions has been publicized by the patent administrative department of the State Council, and the Patent Search and Consultation Center of the National Intellectual Property Administration has issued a search report, specifying that the core technical scheme of the product is novel and creative.

（一）申请人通过其主导的技术创新活动，在中国依法拥有产品核心技术发明专利权，或者依法通过受让取得在中国发明专利权或其使用权，且申请适用创新产品注册程序的时间在专利授权公告日起 5 年内；或者核心技术发明专利的申请已由国务院专利行政部门公开，并由国家知识产权局专利检索咨询中心出具检索报告，载明产品核心技术方案具备新颖性和创造性；

(2) The applicant has completed preliminary research of the product and has a basically finalized product, the research

（二）申请人已完成产品的前期研究并具有基本定型产品，研究过程真实和受控，研究数据完整和可溯源；

process is true and under control, and the research data is complete and traceable.

(3) The main working principle or mechanism of action of the product is original in China, and the performance or safety of the product is fundamentally improved in comparison with that of similar products, and the medical device is at the international leading level in technology and has significant clinical application value.

（三）产品主要工作原理或者作用机理为国内首创，产品性能或者安全性与同类产品比较有根本性改进，技术上处于国际领先水平，且具有显著的临床应用价值。

Article 69 To apply for undergoing the registration procedures for innovative products, the applicant shall, after the product is basically finalized, apply to the NMPA for examination of innovative medical devices. The NMPA shall organize experts to conduct examination, and incorporate those satisfying the requirements into the registration procedures for innovative products.

第六十九条 申请适用创新产品注册程序的，申请人应当在产品基本定型后，向国家药品监督管理局提出创新医疗器械审查申请。国家药品监督管理局组织专家进行审查，符合要求的，纳入创新产品注册程序。

Article 70 For an application for registration of a medical device to which the registration procedures for innovative products apply, the NMPA and the institutions undertaking the relevant technical work shall designate special persons to be responsible according to their respective duties, conduct communication in a timely manner, and provide guidance therefor.

第七十条 对于适用创新产品注册程序的医疗器械注册申请，国家药品监督管理局以及承担相关技术工作的机构，根据各自职责指定专人负责，及时沟通，提供指导。

For medical devices incorporated into the registration procedures for innovative products, the Center for Medical Device Evaluation may, before the acceptance of the registration applications and during the process of technical evaluation, conduct communication and exchange with the

纳入创新产品注册程序的医疗器械，国家局器械审评中心可以与申请人在注册申请受理前以及技术审评过程中就产品研制中的重大技术问题、重大安全性问题、临床试验方案、阶段性临床试验结果的总结与评价等问题沟通交流。

applicants on major technical issues, major safety issues, clinical trial plans, summary and evaluation of phased clinical trial results, and other issues in product development.

Article 71 For medical devices incorporated into the registration procedures for innovative products, if the applicants proactively request termination or the NMPA finds that the medical devices no longer satisfy the requirements of the registration procedures for innovative products, the NMPA shall terminate the registration procedures for innovative products for the relevant products and notify the applicants.

第七十一条 纳入创新产品注册程序的医疗器械，申请人主动要求终止或者国家药品监督管理局发现不再符合创新产品注册程序要求的，国家药品监督管理局终止相关产品的创新产品注册程序并告知申请人。

Article 72 For medical devices incorporated into the registration procedures for innovative products, if the applicants fail to file applications for registration within the prescribed time limit, the registration procedures for innovative products shall no longer apply.

第七十二条 纳入创新产品注册程序的医疗器械，申请人在规定期限内未提出注册申请的，不再适用创新产品注册程序。

Section 2 Priority Registration Procedures

第二节 优先注册程序

Article 73 For medical devices falling under any of the following circumstances, the applicant may apply for undergoing the priority registration procedures:

第七十三条 满足下列情形之一的医疗器械，可以申请适用优先注册程序：

(1) Medical devices that have significant clinical advantages in the diagnosis and treatment of rare diseases or malignant tumors, that are used for the diagnosis and treatment of diseases which are specifically or frequently seen in senior citizens and for which there are still no effective diagnosis or treatment methods, that are specifically for children and have

（一）诊断或者治疗罕见病、恶性肿瘤且具有明显临床优势，诊断或者治疗老年人特有和多发疾病且目前尚无有效诊断或者治疗手段，专用于儿童且具有明显临床优势，或者临床急需且在我国尚无同品种产品获准注册的医疗器械；

obvious clinical advantages, or that are in urgent clinical need and there is no similar product approved to be registered in China.

(2) Medical devices included in significant national thematic scientific and technological projects or key national research and development plans.

(3) Other medical devices to which the priority registration procedures may be applicable as prescribed by the NMPA.

Article 74 To apply for undergoing the priority registration procedures, the applicant shall, when filing an application for registration of a medical device, apply to the NMPA for undergoing the priority registration procedures. For a medical device falling under the circumstance as specified in item 1 of Article 73, the NMPA shall organize experts to conduct examination, and incorporate the one satisfying the requirements into the scope for applying the priority registration procedures; for a medical device falling under the circumstance as specified in item 2 of Article 73, the Center for Medical Device Evaluation shall conduct examination and incorporate the one satisfying the requirements into the scope for applying the priority registration procedures; and for a medical device falling under the circumstance as specified in item 3 of Article 73, the NMPA shall extensively solicit opinions and determine whether to incorporate it into the scope for applying the priority registration procedures after organizing expert argumentation.

（二）列入国家科技重大专项或者国家重点研发计划的医疗器械；

（三）国家药品监督管理局规定的其他可以适用优先注册程序的医疗器械。

第七十四条 申请适用优先注册程序的，申请人应当在提出医疗器械注册申请时，向国家药品监督管理局提出适用优先注册程序的申请。属于第七十三条第一项情形的，由国家药品监督管理局组织专家进行审核，符合的，纳入优先注册程序；属于第七十三条第二项情形的，由国家局器械审评中心进行审核，符合的，纳入优先注册程序；属于第七十三条第三项情形的，由国家药品监督管理局广泛听取意见，并组织专家论证后确定是否纳入优先注册程序。

Article 75 For applications for registration of medical devices incorporated into the scope for applying the priority registration procedures, the NMPA shall give priority to their evaluation and approval, and the medical products administrative department of a province, autonomous region, or municipality directly under the Central Government shall give priority to arranging for the verification of the quality management system for the registration of medical devices.

第七十五条 对纳入优先注册程序的医疗器械注册申请，国家药品监督管理局优先进行审评审批，省、自治区、直辖市药品监督管理部门优先安排医疗器械注册质量管理体系核查。

During the process of technical evaluation of medical device products incorporated into the scope for applying the priority registration procedures, the Center for Medical Device Evaluation shall, in accordance with the relevant provisions, proactively conduct communication and exchange with the applicant, and arrange for special exchange if necessary.

国家局器械审评中心在对纳入优先注册程序的医疗器械产品开展技术审评过程中，应当按照相关规定积极与申请人进行沟通交流，必要时，可以安排专项交流。

Section 3 Emergency Registration Procedures

第三节 应急注册程序

Article 76 The NMPA may, in accordance with the law, implement emergency registration of medical devices that are urgently needed for public health emergencies and there are no similar products marketed in China, or there are similar products marketed in China, but the similar products are not sufficiently supplied for meeting the needs of public health emergencies.

第七十六条 国家药品监督管理局可以依法对突发公共卫生事件应急所需且在我国境内尚无同类产品上市，或者虽在我国境内已有同类产品上市但产品供应不能满足突发公共卫生事件应急处理需要的医疗器械实施应急注册。

Article 77 To apply for undergoing the emergency registration procedures, the applicant shall apply to the NMPA for emergency registration. Medical devices meeting the conditions shall be incorporated into the scope for applying the

第七十七条 申请适用应急注册程序的，申请人应当向国家药品监督管理局提出应急注册申请。符合条件的，纳入应急注册程序。

emergency registration procedures.

Article 78 For applications for registration of medical devices for which emergency registration is implemented, the NMPA shall handle it according to the requirements for unified command, early intervention, immediate examination, and scientific approval, and carry out product inspection, system verification, technical evaluation and other work of medical devices concurrently.

第七十八条 对实施应急注册的医疗器械注册申请，国家药品监督管理局按照统一指挥、早期介入、随到随审、科学审批的要求办理，并行开展医疗器械产品检验、体系核查、技术审评等工作。

Chapter V Modification of Registration and Renewal of Registration

第五章 变更注册与延续注册

Section 1 Modification of registration

第一节 变更注册

Article 79 A registrant shall proactively carry out post-marketing research on a medical device, further confirm the safety, effectiveness and quality controllability of a medical device, and strengthen the continuous management of marketed medical devices.

第七十九条 注册人应当主动开展医疗器械上市后研究，对医疗器械的安全性、有效性和质量可控性进行进一步确认，加强对已上市医疗器械的持续管理。

For registered Class II and Class III medical devices, where any substantial change in their design, raw materials, production techniques, applicable scope and usage, among others, may possibly have impact on the safety and effectiveness of these medical devices, the registrants shall apply to the original registration departments for undergoing the formalities for modification of registration; and for other changes, the registrants shall undergo the formalities for recordation with the original registration departments within

已注册的第二类、第三类医疗器械产品，其设计、原材料、生产工艺、适用范围、使用方法等发生实质性变化，有可能影响该医疗器械安全、有效的，注册人应当向原注册部门申请办理变更注册手续；发生其他变化的，应当在变化之日起 30 日内向原注册部门备案。

30 days from the date of the changes.

The name, model, specifications, structure and composition, scope of application, technical requirements of product, and production address of an imported medical device, among others, as specified in the registration certificate, are the matters for which modification of registration needs to be handled as prescribed in the preceding paragraph. The name and domicile of the registrant, as well as the name and domicile of the agent, among others, are the matters for which recordation formalities need to be undergone as prescribed in the preceding paragraph. For any change in the production address of a domestic medical device, the registrant shall undergo the formalities for recordation after undergoing the corresponding procedures for change in the production license.

注册证载明的产品名称、型号、规格、结构及组成、适用范围、产品技术要求、进口医疗器械的生产地址等，属于前款规定的需要办理变更注册的事项。注册人名称和住所、代理人名称和住所等，属于前款规定的需要备案的事项。境内医疗器械生产地址变更的，注册人应当在办理相应的生产许可变更后办理备案。

For other changes, the registrant shall, according to the requirements of the quality management system, effectively complete the relevant work, and report to the medical products administrative department in accordance with the provisions.

发生其他变化的，注册人应当按照质量管理体系要求做好相关工作，并按照规定向药品监督管理部门报告。

Article 80 For any application for modification of registration, a technical evaluation institution shall focus on the modified part when carrying out evaluation, and form evaluation opinions on whether the product is safe, effective and of quality controllability after change.

第八十条 对于变更注册申请，技术审评机构应当重点针对变化部分进行审评，对变化后产品是否安全、有效、质量可控形成审评意见。

In the technical evaluation for an application for modification of registration, if it deems that it is necessary to verify the quality management system, the medical products administrative department shall organize and carry out

在对变更注册申请进行技术审评时，认为有必要对质量管理体系进行核查的，药品监督管理部门应当组织开展质量管理体系核查。

verification of the quality management system.

Article 81 The document on modification of registration of a medical device shall be used in combination with the original medical device registration certificate, and the expiration date of its valid period shall be identical with that of the original medical device registration certificate.

第八十一条 医疗器械变更注册文件与原医疗器械注册证合并使用，有效期截止日期与原医疗器械注册证相同。

Section II Renewal of Registration

第二节 延续注册

Article 82 Where a medical device registration certificate needs to be renewed upon expiry, the registrant shall apply to the original medical products administrative department for renewal of registration at least six months prior to expiry of the validity period of the medical device registration certificate, and submit application materials in accordance with the relevant requirements.

第八十二条 医疗器械注册证有效期届满需要延续注册的，注册人应当在医疗器械注册证有效期届满 6 个月前，向原注册部门申请延续注册，并按照相关要求提交申请资料。

Unless it is under any of the circumstances as specified in Article 83 of these Measures, after receiving a renewal application, a medical products administrative department shall make a decision of approval before the expiry of the medical device registration certificate. Its failure to make such a decision within the prescribed time limit shall be deemed that an approval has been granted.

除有本办法第八十三条规定情形外，接到延续注册申请的药品监督管理部门应当在医疗器械注册证有效期届满前作出准予延续的决定。逾期未作决定的，视为准予延续。

Article 83 A renewal application shall be disapproved under any of the following circumstances:

第八十三条 有下列情形之一的，不予延续注册：

(1) An application for renewal of registration is not submitted

（一）未在规定期限内提出延续注册申请；

within the prescribed time limit.

(2) The new compulsory standards for medical devices have been issued and implemented, and the medical device for which an application for renewal is filed fails to satisfy the new requirements.

（二）新的医疗器械强制性标准发布实施，申请延续注册的医疗器械不能达到新要求；

(3) For conditionally approved medical devices, the matters specified in the medical device registration certificate are not completed within the specified time limit.

（三）附条件批准的医疗器械，未在规定期限内完成医疗器械注册证载明事项。

Article 84 If the approval time for the renewal of registration is within the validity period of the original registration certificate, the start date of the validity period of the renewed registration certificate shall be the date after the expiry date of the original registration certificate; and if the approval time is not within the validity period of the original registration certificate, the start date of the validity period of the renewed registration certificate shall be the date when the renewal of registration is approved.

第八十四条 延续注册的批准时间在原注册证有效期内的，延续注册的注册证有效期起始日为原注册证到期日次日；批准时间不在原注册证有效期内的，延续注册的注册证有效期起始日为批准延续注册的日期。

Article 85 Matters concerning the procedures for the acceptance and approval of applications for modification of registration and renewal of registration of medical devices, if not specified in this Chapter, shall be governed by the relevant provisions of Chapter III of these Measures.

第八十五条 医疗器械变更注册申请、延续注册申请的受理与审批程序，本章未作规定的，适用本办法第三章的相关规定。

Chapter VI Recordation of Medical Devices

第六章 医疗器械备案

Article 86 For Class I medical devices, the recordation

第八十六条 第一类医疗器械生产前，应当进行产

procedure shall be undergone before production.

品备案。

Article 87 For recordation of a medical device, the recordation party shall submit recordation materials to the medical products administrative department and obtain the recordation number in accordance with the provisions of the Regulation on the Supervision and Administration of Medical Devices.

第八十七条 进行医疗器械备案，备案人应当按照《医疗器械监督管理条例》的规定向药品监督管理部门提交备案资料，获取备案编号。

Article 88 For a recorded medical device, where there is any change in the information indicated in the recordation form or the technical requirements for the product, the recordation party shall undergo the formalities for recordation of modification with the original recordation department, and submit an explanation on the change and the relevant documents. The medical products administrative department shall publish the modification in the modification information.

第八十八条 已备案的医疗器械，备案信息表中登载内容及备案的产品技术要求发生变化的，备案人应当向原备案部门变更备案，并提交变化情况的说明以及相关文件。药品监督管理部门应当将变更情况登载于备案信息中。

Article 89 For a recorded medical device whose management class is changed into Class II or Class III, an application for registration shall be filed in accordance with the provisions of these Measures.

第八十九条 已备案的医疗器械管理类别调整为第二类或者第三类医疗器械的，应当按照本办法规定申请注册。

Chapter VII Work Time Limit

第七章 工作时限

Article 90 The time limit as prescribed in these Measures shall be the longest time for the acceptance, technical evaluation, examination, approval, and other work of registration of a medical device. The relevant time limit for the special registration procedures shall be governed by the

第九十条 本办法所规定的时限是医疗器械注册的受理、技术审评、核查、审批等工作的最长时间。特殊注册程序相关工作时限，按特殊注册程序相关规定执行。

relevant provisions on the special registration procedures.

The Center for Medical Device Evaluation and other professional technical institutions shall specify their work procedures and time limits, and announce them to the public.

国家局器械审评中心等专业技术机构应当明确本单位工作程序和时限，并向社会公布。

Article 91 After receiving an application for registration of a medical device and an application for clinical trial, the medical products administrative department shall, within three days from the date of acceptance, forward the application materials to the technical evaluation institution. The requirements for acceptance of clinical trials shall be governed by the provisions of Article 53 of these Measures.

第九十一条 药品监督管理部门收到医疗器械注册申请及临床试验申请后，应当自受理之日起 3 日内将申请资料转交技术审评机构。临床试验申请的受理要求适用于本办法第五十三条规定。

Article 92 The time limit for technical evaluation of medical device registration shall be governed by the following provisions:

第九十二条 医疗器械注册技术审评时限，按照以下规定执行：

(1) The time limit for technical evaluation of an application for a clinical trial of a medical device is 60 days, and after the application materials are supplemented and corrected, the time limit is 40 days.

（一）医疗器械临床试验申请的技术审评时限为 60 日，申请资料补正后的技术审评时限为 40 日；

(2) The time limit for technical evaluation of an application for registration, an application for modification of registration, or an application for renewal of registration of a Class II medical device is 60 days, and after the application materials are supplemented and corrected, the time limit is 60 days.

（二）第二类医疗器械注册申请、变更注册申请、延续注册申请的技术审评时限为 60 日，申请资料补正后的技术审评时限为 60 日；

(3) The time limit for technical evaluation of an application for

（三）第三类医疗器械注册申请、变更注册申请、延续注

registration, an application for modification of registration, or an application for renewal of registration of a Class III medical device is 90 days, and after the application materials are supplemented and corrected, the time limit is 60 days.

册申请的技术审评时限为 90 日，申请资料补正后的技术审评时限为 60 日。

Article 93 The time limit for the verification of the quality management system for Class III domestic medical devices shall be governed by the following provisions:

第九十三条 境内第三类医疗器械质量管理体系核查时限，按照以下规定执行：

(1) The Center for Medical Device Evaluation shall, within 10 days after an application for registration of a medical device is accepted, notify the medical products administrative department of the relevant province, autonomous region, or municipality directly under the Central Government of launching verification.

（一）国家局器械审评中心应当在医疗器械注册申请受理后 10 日内通知相关省、自治区、直辖市药品监督管理部门启动核查；

(2) The medical products administrative department of the relevant province, autonomous region, or municipality directly under the Central Government shall, in principle, complete verification within 30 days upon receipt of a notice of verification, and report the verification situation, verification results and other relevant materials to the Center for Medical Device Evaluation.

（二）省、自治区、直辖市药品监督管理部门原则上在接到核查通知后 30 日内完成核查，并将核查情况、核查结果等相关材料反馈至国家局器械审评中心。

Article 94 The medical products administrative department accepting an application for registration shall, within 20 days from the date of receiving the evaluation opinions, make a decision.

第九十四条 受理注册申请的药品监督管理部门应当自收到审评意见之日起 20 日内作出决定。

Article 95 The medical products administrative department

第九十五条 药品监督管理部门应当自作出医疗器

shall issue and serve the relevant administrative licensing certificate within 10 days of the date of making a decision on approving registration of a medical device.

械注册审批决定之日起 10 日内颁发、送达有关行政许可证件。

Article 96 Where it is indeed necessary to extend the time limit due to special circumstances of product characteristics, technical evaluation, verification and other work, the extended limit shall not exceed half of the original time limit. With approval of the person in charge of the relevant technical institutions such as technical evaluation and verification of medical devices, the technical institution extending the time limit shall notify the applicant in writing and notify other relevant technical institutions.

第九十六条 因产品特性以及技术审评、核查等工作遇到特殊情况确需延长时限的，延长时限不得超过原时限的二分之一，经医疗器械技术审评、核查等相关技术机构负责人批准后，由延长时限的技术机构书面告知申请人，并通知其他相关技术机构。

Article 97 The original certificate issuing authority shall reissue a medical device registration certificate within 20 days from the date of receiving an application for re-issuance of a medical device registration certificate.

第九十七条 原发证机关应当自收到医疗器械注册证补办申请之日起 20 日内予以补发。

Article 98 The following time shall not be included in the time limit for relevant work:

第九十八条 以下时间不计入相关工作时限：

(1) The time occupied by an applicant for making rectification after supplementing materials and conducting verification.

（一）申请人补充资料、核查后整改等所占用的时间；

(2) The delays in verification due to reasons attributable to the applicant.

（二）因申请人原因延迟核查的时间；

(3) The time required for hiring external experts for consultation or holding expert consultation meetings, or the

（三）外聘专家咨询、召开专家咨询会、药械组合产品需要与药品审评机构联合审评的时间；

time required for joint evaluation with a medical products evaluation institution for a combination product of medical products and devices.

(4) The time occupied for suspending the procedures for evaluation and approval, where the procedures for evaluation and approval are suspended according to the provisions.

（四）根据规定中止审评审批程序的，中止审评审批程序期间所占用的时间；

(5) The time occupied for verification of the quality management system.

（五）质量管理体系核查所占用的时间。

Article 99 The time limit as prescribed in these Measures shall be calculated by working day.

第九十九条 本办法规定的时限以工作日计算。

Chapter VIII Supervision and Administration

第八章 监督管理

Article 100 Medical products administrative departments shall strengthen the supervision and inspection of the medical devices development activities, and may, if necessary, conduct extended inspections of entities and individuals that provide products or services for the development of medical devices, and relevant entities and individuals shall cooperate in providing relevant documents and materials, without refusal, concealment or obstruction.

第一百条 药品监督管理部门应当加强对医疗器械研制活动的监督检查，必要时可以对为医疗器械研制提供产品或者服务的单位和个人进行延伸检查，有关单位和个人应当予以配合，提供相关文件和资料，不得拒绝、隐瞒、阻挠。

Article 101 The NMPA shall establish and implement a unique identification system for medical devices step by step. Applicants and recordation parties shall submit information on unique identification in accordance with the relevant provisions and ensure that the data are authentic, accurate and

第一百零一条 国家药品监督管理局建立并分步实施医疗器械唯一标识制度，申请人、备案人应当按照相关规定提交唯一标识相关信息，保证数据真实、准确、可溯源。

traceable.

Article 102 The NMPA shall notify the medical products administrative departments of the provinces, autonomous regions, and municipalities directly under the Central Government at the places where agents are located of the information on agents in a timely manner. The medical products administrative departments of provinces, autonomous regions, and municipalities directly under the Central Government shall organize routine supervision and administration over agents in their respective administrative regions.

第一百零二条 国家药品监督管理局应当及时将代理人信息通报代理人所在地省、自治区、直辖市药品监督管理部门。省、自治区、直辖市药品监督管理部门对本行政区域内的代理人组织开展日常监督管理。

Article 103 The medical products administrative departments of provinces, autonomous regions, and municipalities directly under the Central Government shall, according to the recordation situation of clinical trial institutions for medical devices, organize post-recordation supervision and inspection of clinical trial institutions that have undergone the recordation formalities in their respective administrative regions. For clinical trial institutions for medical devices that have newly undergone the recordation formalities, supervision and inspection shall be carried out within 60 days after the recordation.

第一百零三条 省、自治区、直辖市药品监督管理部门根据医疗器械临床试验机构备案情况，组织对本行政区域内已经备案的临床试验机构开展备案后监督检查。对于新备案的医疗器械临床试验机构，应当在备案后 60 日内开展监督检查。

The medical products administrative departments of provinces, autonomous regions, and municipalities directly under the Central Government shall organize routine supervision and inspection of the compliance with the quality management standards for the clinical trials of medical devices by clinical trial institutions for medical devices in their respective

省、自治区、直辖市药品监督管理部门应当组织对本行政区域内医疗器械临床试验机构遵守医疗器械临床试验质量管理规范的情况进行日常监督检查，监督其持续符合规定要求。国家药品监督管理局根据需要对医疗器械临床试验机构进行监督检查。

administrative regions, and supervise their continued compliance with the prescribed requirements. The NMPA shall supervise and inspect clinical trial institutions for medical devices according to the needs.

Article 104 Where a medical products administrative department deems it necessary, it may conduct on-site inspection of the authenticity, accuracy, completeness, standardization, and traceability of clinical trials.

第一百零四条 药品监督管理部门认为有必要的，可以对临床试验的真实性、准确性、完整性、规范性和可追溯性进行现场检查。

Article 105 A medical products administrative department that assumes recordation of Class I medical device products and finds that the recordation materials are nonstandard in the post-recordation supervision shall order the recordation party to take corrective action within a prescribed time limit.

第一百零五条 承担第一类医疗器械产品备案工作的药品监督管理部门在备案后监督中，发现备案资料不规范的，应当责令备案人限期改正。

Article 106 Where a medical products administrative department fails to find systemic or regional risks in the administration of registration of medical devices in its administrative region in a timely manner, or fails to eliminate systemic or regional potential hazards in the administration of registration of medical devices in its administrative region in a timely manner, the medical products administrative department at the next higher level may hold interviews with the primary person in charge of the medical products administrative department at a lower level.

第一百零六条 药品监督管理部门未及时发现本行政区域内医疗器械注册管理系统性、区域性风险，或者未及时消除本行政区域内医疗器械注册管理系统性、区域性隐患的，上级药品监督管理部门可以对下级药品监督管理部门主要负责人进行约谈。

Chapter IX Legal Liabilities

第九章 法律责任

Article 107 Those who fail to undergo the formalities for

第一百零七条 违反本办法第七十九条的规定，未

recordation of changes as required in violation of the provisions of Article 79 of these Measures shall be ordered to take corrective action within a prescribed time limit; and those who fail to take corrective action within the prescribed time limit shall be given a fine of not less than 10,000 yuan nor more than 30,000 yuan.

按照要求对发生变化进行备案的，责令限期改正；逾期不改正的，处 1 万元以上 3 万元以下罚款。

Article 108 Those who fail to comply with the quality management standards for the clinical trials when conducting clinical trials of medical devices shall be punished in accordance with Article 94 of the Regulation on the Supervision and Administration of Medical Devices.

第一百零八条 开展医疗器械临床试验未遵守临床试验质量管理规范的，依照《医疗器械监督管理条例》第九十四条予以处罚。

Article 109 Where a technical evaluation institution for medical devices fails to perform its duties in accordance with the provisions of these Measures and has caused major errors in the evaluation, the medical products administrative department shall order it to take corrective action, circulate a note of criticism, and give it a warning; and where serious consequences have been caused, the legal representative, primary person in charge, directly responsible person in charge and other liable persons of the law-breaking entity shall be given penalties in accordance with the law.

第一百零九条 医疗器械技术审评机构未依照本办法规定履行职责，致使审评工作出现重大失误的，由负责药品监督管理的部门责令改正，通报批评，给予警告；造成严重后果的，对违法单位的法定代表人、主要负责人、直接负责的主管人员和其他责任人员，依法给予处分。

Article 110 Officials of the medical products administrative department that abuse power, neglect duties, practice favoritism and engage in malpractice in violation of the provisions shall be given penalties in accordance with the law.

第一百一十条 负责药品监督管理的部门工作人员违反规定，滥用职权、玩忽职守、徇私舞弊的，依法给予处分。

Chapter X Supplemental Provisions

第十章 附 则

Article 111 In principle, the registration or recordation units of medical devices shall be divided on the basis of the technical principles, structure and composition, performance indicators and scope of application of products.

第一百一十一条 医疗器械注册或者备案单元原则上以产品的技术原理、结构组成、性能指标和适用范围为划分依据。

Article 112 A medical device approved for registration refers to a medical device that is consistent with the content specified in the medical device registration certificate and its annexes and that is produced within the validity period of the medical device registration certificate.

第一百一十二条 获准注册的医疗器械，是指与该医疗器械注册证及附件限定内容一致且在医疗器械注册证有效期内生产的医疗器械。

Article 113 The component parts listed in the column of "Structure and Composition" of the medical device registration certificate may be sold individually on the condition that they are used for the replacement of supplies, after-sale services, and maintenance of the registered products.

第一百一十三条 医疗器械注册证中“结构及组成”栏内所载明的组合部件，以更换耗材、售后服务、维修等为目的，用于原注册产品的，可以单独销售。

Article 114 When applying for registration, modification of registration, and clinical trial approval for medical device products, an applicant may, as authorized by the owner of the master files of medical devices, quote the registered master files of medical devices. The relevant work procedures for registration of master files of medical devices shall be prescribed separately.

第一百一十四条 申请人在申请医疗器械产品注册、变更注册、临床试验审批中可以经医疗器械主文档所有者授权，引用经登记的医疗器械主文档。医疗器械主文档登记相关工作程序另行规定。

Article 115 The format of medical device registration certificates shall be determined by the NMPA in a unified manner.

第一百一十五条 医疗器械注册证格式由国家药品监督管理局统一制定。

A registration certificate shall be numbered as follows:

注册证编号的编排方式为：

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

×1 械注×2××××3×4××5××××6。其中：

×1 shall be the shortened form of the locality of the registration approval authority:

×1 为注册审批部门所在地的简称：

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.

境内第三类医疗器械、进口第二类、第三类医疗器械为“国”字；

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.

境内第二类医疗器械为注册审批部门所在地省、自治区、直辖市简称；

×2 shall be the form of registration:

×2 为注册形式：

The form of “Approved” shall apply to domestic medical devices.

“准”字适用于境内医疗器械；

The form of “Imported” shall apply to imported medical devices.

“进”字适用于进口医疗器械；

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

“许”字适用于香港、澳门、台湾地区的医疗器械；

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

××××3 为首次注册年份；

×4 shall be the management class of the product.

×4 为产品管理类别；

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

××5 为产品分类编码；

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

××××6 为首次注册流水号。

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.

延续注册的，××××3 和××××6 数字不变。产品管理类别调整的，应当重新编号。

Article 116 The recordation for a Class I medical device shall be numbered as follows:

第一百一十六条 第一类医疗器械备案编号的编排方式为：

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

×1 械备××××2××××3。其中：

×1 shall be the shortened form of the locality of the recordation authority:

×1 为备案部门所在地的简称：

For Class I imported medical devices, such shortened form shall be indicated as the character of “Guo,” which means national.

进口第一类医疗器械为“国”字；

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).

境内第一类医疗器械为备案部门所在地省、自治区、直辖市简称加所在地设区的市级行政区域的简称（无相应设区的市级行政区域时，仅为省、自治区、直辖市的简称）；

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

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

Article 117 Electronic medical device registration certificates made by the medical products administrative departments, and electronic documents on modification of registration shall have the same legal effect as paper documents.

Article 118 the NMPA may, according to the work needs, entrust the medical products administrative departments, technical institutions, or relevant social organizations of provinces, autonomous regions and municipalities directly under the Central Government with the undertaking of specific work in accordance with the law.

Article 119 The medical products administrative departments of provinces, autonomous regions, and municipalities directly under the Central Government may develop special registration procedures for Class II medical devices in their administrative regions by referring to the provisions of Chapter IV of these Measures, and report them to the NMPA for recordation.

Article 120 The charging items and rates for the registration of medical devices shall be governed by the relevant rules of the public finance department and the price department of the State Council.

××××2 为备案年份；

××××3 为备案流水号。

第一百一十七条 药品监督管理部门制作的医疗器械注册证、变更注册文件电子文件与纸质文件具有同等法律效力。

第一百一十八条 根据工作需要，国家药品监督管理局可以依法委托省、自治区、直辖市药品监督管理部门或者技术机构、社会组织承担有关的具体工作。

第一百一十九条 省、自治区、直辖市药品监督管理部门可以参照本办法第四章规定制定本行政区域内第二类医疗器械特殊注册程序，并报国家药品监督管理局备案。

第一百二十条 医疗器械产品注册收费项目、收费标准按照国务院财政、价格主管部门的有关规定执行。

Article 121 The registration and recordation of the in-vitro diagnostic reagents managed as medical devices shall be governed by the Measures for the Administration of Registration and Recordation of In-Vitro Diagnostic Reagents.

第一百二十一条 按照医疗器械管理的体外诊断试剂的注册与备案，适用《体外诊断试剂注册与备案管理办法》。

Article 122 The relevant provisions on the supervision and administration of customized medical devices shall be separately developed by the NMPA.

第一百二十二条 定制式医疗器械监督管理的有关规定，由国家药品监督管理局另行制定。

The relevant provisions on the registration administration of combination products of medical products and devices shall be separately developed by the NMPA.

药械组合产品注册管理的有关规定，由国家药品监督管理局另行制定。

The relevant provisions on the emergency use of medical devices shall be separately developed by the NMPA in conjunction with relevant departments.

医疗器械紧急使用的有关规定，由国家药品监督管理局会同有关部门另行制定。

Article 123 The registration or recordation of medical devices from Hong Kong, Macao and Taiwan shall be governed, mutatis mutandis to, the provisions governing imported medical devices.

第一百二十三条 香港、澳门、台湾地区医疗器械的注册、备案，参照进口医疗器械办理。

Article 124 These Measures shall come into force on October 1, 2021, upon which the Measures for the Registration Administration of Medical Devices issued by Order No. 4 of the former China Food and Drug Administration on July 30, 2014 shall be repealed.

第一百二十四条 本办法自 2021 年 10 月 1 日起施行。2014 年 7 月 30 日原国家食品药品监督管理总局令第 4 号公布的《医疗器械注册管理办法》同时废止。