Measures for the Supervision and Administration of Medical Device Production (2022)[1]

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Chapter I: General Provisions

Article 1

These Measures are formulated in accordance with the *Regulation on the Supervision and Administration of Medical Devices* for the purposes of strengthening the regulatory oversight of medical device production, standardizing production practices, and ensuring the safety and effectiveness of medical devices.

Article 2

These Measures apply to the production of medical devices within the territory of the People's Republic of China and to the supervision and administration thereof.

Article 3

Entities engaged in the production of medical devices shall comply with applicable laws, administrative regulations, rules, mandatory standards, and Good Manufacturing Practices (GMP) for medical devices. They shall ensure that information covering the entire production process is authentic, accurate, complete, and traceable. The registrant or recordation holder of a medical device shall be responsible for the safety and effectiveness of the device throughout its time on the market.

Article 4

Medical device production shall be subject to a classification-based management system according to the risk level associated with the devices. Entities intending to produce Class II or Class III medical devices shall obtain a Medical Device Production Permit from the medical products administration of the relevant province, autonomous region, or municipality directly under the Central Government. Entities intending to produce Class I medical devices shall file

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for production recordation with the medical products administration at the municipal level (i.e., a districted city).

Article 5

The National Medical Products Administration (NMPA) is responsible for the nationwide supervision and administration of medical device production.

Provincial-level medical products administrations shall oversee the production of Class II and Class III devices within their jurisdictions, bear responsibility for the administration of Class I device production as prescribed and enhance the supervision guidance of such production within their regions.

Municipal-level (districted city) medical products administrations shall be responsible for supervising the production of Class I devices within their respective jurisdictions.

Article 6

Specialized technical agencies designated or established by the medical products administrations shall undertake reviews, inspections, testing, surveillance, and evaluation work related to medical devices, and shall provide technical support in accordance with their delegated responsibilities.

The NMPA's Center for Food and Drug Inspection shall draft inspection system standards and technical documentation, conduct key inspections—including overseas inspections—and provide guidance and assessment regarding the quality management systems of provincial-level inspection institutions.

Article 7

The NMPA shall strengthen information technology infrastructure supporting the supervision and administration of medical device production and enhance online government services.

Provincial-level medical products administrations shall be responsible for managing and developing local IT systems for production oversight and shall promote interdepartmental data sharing in accordance with NMPA guidelines.

Article 8

Medical products administrations shall publicly disclose information regarding licensing, recordation, inspections, and administrative penalties related to medical device production in a timely manner, in accordance with the law, to ensure transparency and facilitate public supervision.

Chapter II: Licensing and Recordation of Production

Article 9 Entities seeking to engage in the production of medical devices shall meet the following requirements:

1-Possess suitable production premises, environmental conditions, equipment, and professionally qualified technical personnel aligned with the devices produced.

2-Establish a dedicated inspection body or employ full-time inspectors, and maintain appropriate inspection equipment for product quality assurance.

3-Implement and maintain a quality management system compliant with relevant standards.

4-Maintain after-sales service capabilities appropriate to the devices produced.

5-Meet the technical and procedural documentation standards required for product development and manufacturing.

Article 10

Applicants intending to produce Class II or Class III medical devices shall apply for a production license to the competent provincial-level medical products administration, accompanied by the following documentation:

1-Copies of the medical device registration certificate and technical requirements.

2-Legal representative's identification document.

3-Documentation of the qualifications, educational background, and professional titles of the heads of production, quality, and technical departments.

4-A roster of personnel involved in production and quality management, detailing qualifications and titles.

5-Documents pertaining to production facilities, and, where applicable, documents demonstrating compliance with environmental and facility-specific requirements.

6-Lists of major production and inspection equipment.

7-Quality manuals and procedural documents.

8-Flowchart of the production process.

9-Supporting materials evidencing after-sales service capability.

10-Authorization letter for the applicant's representative.

All submitted materials must be lawful, truthful, accurate, complete, and traceable. If certain documents can be verified online, they may be exempt from submission.

Article 11

Upon receiving an application, the provincial-level medical products administration shall:

1-Accept the application if it falls within its jurisdiction and the materials are complete and meet statutory requirements.

2-Permit correction of minor errors on the spot.

3-Notify the applicant within five working days of any deficiencies in the application materials, requesting all necessary supplements in one notice. Failure to do so shall result in deemed acceptance.

4-Reject the application if it falls outside its legal purview and advise the applicant to file with the appropriate authority.

5-A written notice of acceptance or non-acceptance, bearing the official seal and date, shall be issued accordingly.

Article 12

Where required by law or where the licensing matter is of major public interest, the medical products administration shall hold a public hearing. If the licensing matter materially affects the rights of other parties, the applicant and stakeholders shall be informed of their right to request a hearing before the licensing decision is made.

Article 13

The competent authority shall examine application materials, conduct on-site inspections in accordance with NMPA's GMP for medical devices, and decide within 20 working days from the date of acceptance. Where rectification is required, the rectification period shall not be counted toward the review timeframe.

Upon meeting the requirements, the administration shall issue a written decision to grant the license and provide the Medical Device Production Permit within 10 working days. If the requirements are not met, a written denial with reasons and information on available legal remedies shall be provided.

Article 14

The Medical Device Production Permit shall consist of an original and a duplicate, valid for 5 years. It shall specify the permit number, enterprise name, Unified Social Credit Code, legal representative, registered address, production address, scope of production, issuing authority, issuance date, and expiration date. Modifications, including significant changes to facilities or production lines, shall be reflected in the duplicate. Information on the permit must match the business license. The NMPA shall standardize the permit format, which shall be printed by the relevant provincial authority. Both paper and electronic versions shall have equal legal validity.

Article 15

If there is a change in the production address or an expansion of the production scope, an application for modification of the medical device production permit shall be submitted to the original permit-issuing authority, along with relevant materials concerning the changes as prescribed in Article 10 of these Measures. The original permit-issuing authority shall review the application and conduct on-site inspection in accordance with the provisions of Article 13 of these Measures.

If the renovation of workshops or production lines leads to changes in production conditions that may affect the safety and effectiveness of the medical devices, the change shall be reported to the original permit-issuing authority. If such changes constitute alterations to licensing matters, the relevant license modification procedures shall be carried out in accordance with regulations.

Article 16

Changes to enterprise name, legal representative, domicile, or other registration details must be reported to the original permit-issuing authority within 30 working days. The authority shall complete the registration amendment within 5 working days.

Article 17

To renew the validity period of a medical device production permit upon its expiration, the enterprise shall submit a renewal application to the original permit-issuing authority within a time frame of ninety (90) to thirty (30) working days prior to the expiry date of the permit. Applications submitted beyond the prescribed time limit shall not be accepted.

The original permit-issuing authority shall, based on the enterprise's compliance with applicable laws, regulations on medical device supervision and administration, adherence to Good Manufacturing Practices (GMP) for medical devices, and the effective operation of the enterprise's quality management system, conduct on-site inspections as deemed necessary. Following such examination, the authority shall decide to approve or deny the renewal prior to the expiration of the current permit.

Where the enterprise satisfies the prescribed conditions upon review, the renewal shall be granted, with the serial number of the medical device production permit remaining unchanged. If the enterprise fails to meet the prescribed conditions, the authority shall issue an order requiring corrective actions within a specified timeframe. Should the enterprise fail to rectify the deficiencies within the prescribed period, the renewal application shall be rejected, accompanied by a written statement detailing the grounds for denial.

If the renewal approval is granted during the validity period of the existing permit, the renewed permit's effective date shall commence immediately following the expiration of the original permit. Conversely, if approval is granted subsequent to the expiration of the original permit, the renewal shall take effect on the date of such approval.

Article 18

Enterprises establishing production sites across different provinces, autonomous regions, or municipalities directly under the Central Government must apply for separate production permits from the local medical products administration where the new site is located.

Article 19 In case of loss of a permit, the enterprise shall apply for reissuance from the original authority. The replacement shall retain the original serial number and validity period.

Article 20

Where any information on the permit is modified, the relevant updated document (original or duplicate) shall be reissued by the authority, and the prior version shall be surrendered. The serial number and validity period shall remain unchanged.

Article 21

A Medical Device Production Permit shall be deregistered and publicly announced by the original issuing authority under any of the following circumstances:

1-Voluntary application for deregistration by the enterprise.

2-Expiration of the validity period without renewal.

3-Termination of the enterprise's legal status.

4-Revocation or cancellation of the permit in accordance with the law.

5-Other statutory circumstances requiring cancellation.

Article 22

Entities intending to produce Class I medical devices shall submit recordation documents to the municipal-level medical products administration. Upon recordation, a serial number shall be issued.

If the registrant of a Class I medical device produces it independently, production recordation may be completed concurrently with product recordation. Within 3 months of recordation, the authority shall conduct an on-site GMP compliance inspection. Non-compliance shall result in enforcement measures and, where necessary, cancellation of the recordation.

Article 23

Any changes to recordation information for Class I medical device production must be reported to the original recordation authority within 10 working days, along with the corresponding materials. On-site inspection may be conducted if necessary.

Article 24

It is strictly prohibited to forge, alter, transfer, lease, or lend a Medical Device Production Permit.

Chapter III: Production Quality Management

Article 25

Registrants or recordation holders and entrusted manufacturers of medical devices shall, in accordance with GMP for medical devices, establish and maintain a quality management system commensurate with their product scope and risk classification. They shall ensure that production strictly adheres to the registered or recorded technical requirements, and that medical devices released from the factory comply with applicable mandatory standards and meet safety and performance specifications.

Article 26

The legal representative and principal person in charge of the entity responsible for the registration or recordation of medical devices shall bear full responsibility for the quality and safety of the medical devices produced by such entity.

Article 27

The entity responsible for the registration or recordation of medical devices, as well as the entrusted manufacturer thereof, shall designate management representatives. Such management representatives shall be appointed by the legal representative or principal person in charge and shall be entrusted with responsibilities including the establishment, implementation, and maintenance of the effective operation of the quality management system.

Article 28

The entity responsible for the registration or recordation of medical devices, and the entrusted manufacturer, shall provide training on laws, regulations, rules, standards, and quality management related to medical devices, establish a systematic training program, formulate training plans, enhance assessment procedures, and duly maintain training records.

Article 29

The entity responsible for the registration or recordation of medical devices, and the entrusted manufacturer, shall, in accordance with the characteristics, process flow, and production environment of the products manufactured, reasonably establish and utilize facilities and equipment, strengthen their management, and ensure their effective operation.

Article 30

The entity responsible for the registration or recordation of medical devices shall oversee the transition from design and development to production, conducting sufficient verification and validation to ensure that design and development outputs are suitable for production.

Article 31

The entity responsible for the registration or recordation of medical devices, and the entrusted manufacturer, shall strengthen procurement management, establish a supplier evaluation system, and conduct supplier assessments to ensure that procured products and services comply with relevant provisions and requirements. Furthermore, the entity responsible for registration or recordation and the entrusted manufacturer shall establish rules governing raw material procurement acceptance inspections and maintain records that are true, accurate, complete, and traceable.

Article 32

The entity responsible for the registration or recordation of medical devices that entrusts production shall assess the quality assurance and risk management capabilities of the entrusted manufacturer. It shall enter into a quality agreement and an entrustment agreement with the entrusted party pursuant to the guidelines on quality agreements for entrusted production issued by the NMPA and supervise the entrusted party's performance of obligations under such agreements.

The entrusted manufacturer shall conduct production activities in accordance with applicable laws, regulations, rules, Good Manufacturing Practices (GMP) for medical devices, compulsory standards, product technical requirements, the quality agreement on entrusted production, and other relevant requirements. The entrusted manufacturer shall be responsible for its production acts and accept supervision by the entity responsible for the registration or recordation of medical devices.

Article 33

The entity responsible for the registration or recordation of medical devices, and the entrusted manufacturer, shall establish record management rules to ensure that records are true, accurate, complete, and traceable. The entities responsible for registration or recordation and entrusted manufacturing are encouraged to adopt advanced technical means to establish an information management system and enhance the management of the production process.

Article 34

The entity responsible for the registration or recordation of medical devices shall bear responsibility for the release of products onto the market. It shall establish procedures governing product release, specify standards and conditions for release, and examine production process records and quality inspection results of medical devices. Medical devices meeting the relevant standards and conditions may be marketed only upon the signature of authorized release personnel. In the case of entrusted production, the entity responsible for the registration or recordation shall also review the production release documentation provided by the entrusted manufacturer.

The entrusted manufacturer shall establish production release procedures, specifying the standards and conditions for release, and may deliver medical devices only if such standards and conditions are met.

Medical devices that fail to comply with applicable laws, regulations, rules, compulsory standards, or product technical requirements for registered or recorded products shall not be released from the factory nor marketed.

Article 35

The entity responsible for the registration or recordation of medical devices shall establish and implement a product traceability system to ensure traceability. The entrusted manufacturer shall assist the entity responsible for the registration or recordation in implementing product traceability.

Article 36

The entity responsible for the registration or recordation of medical devices, and the entrusted manufacturer, shall comply with national requirements for the unique identification of medical devices by assigning codes and uploading, maintaining, and updating data to ensure that such information is true, accurate, complete, and traceable.

Article 37

The entity responsible for the registration or recordation of medical devices, and the entrusted manufacturer, shall establish procedures for corrective actions to identify the causes of problems and take effective measures to prevent recurrence.

They shall also establish procedures for preventive measures to identify potential causes of problems and implement effective measures to prevent their occurrence.

Article 38

The entity responsible for the registration or recordation of medical devices shall, in accordance with GMP for medical devices, identify and control changes to raw materials, production processes, and other relevant factors that may affect product safety and efficacy. If changes necessitate modifications to registration or recordation, the prescribed formalities shall be completed in accordance with applicable administrative provisions.

Article 39

Upon the implementation of new compulsory standards, the entity responsible for the registration or recordation of medical devices shall promptly identify discrepancies between the product's technical requirements and the new compulsory standards. Should modifications to registration or recordation be required, the relevant administrative formalities shall be duly undertaken.

Article 40

The entity responsible for the registration or recordation of medical devices, and the entrusted manufacturer, shall fulfill obligations regarding the monitoring of adverse events related to medical devices as required by the state. They shall monitor adverse events and report investigation findings, analysis, evaluation, product risk control measures, and other related information to the designated technical body for adverse event monitoring.

Article 41

Where the entity responsible for the registration or recordation of medical devices discovers that the medical devices it produces fail to comply with compulsory standards or the registered product technical requirements, or present other defects, it shall immediately cease production, notify relevant businesses, users, and consumers to discontinue operation and use, recall the medical devices from the market, implement remedial or destruction measures, record relevant circumstances, disclose relevant information, and report the recall and disposal outcomes to the medical products administration and the competent health authority.

The entrusted manufacturer shall perform its responsibilities in accordance with the provisions on medical device recalls and assist the entity responsible for registration or recordation in conducting the recall.

Article 42

A medical device manufacturer shall report the types of products manufactured by it to the medical products administration.

Any increase in the types of products manufactured shall be reported to the original production licensing or recordation authority; in the case of entrusted production, the entrusting party, products manufactured on entrustment, term of entrustment, and other information shall also be provided.

Where the increase of products manufactured by a medical device manufacturer involves any change in production conditions, which may affect the safety or utility of the products, the manufacturer shall, 30 working days prior to such increase, report to the original production licensing department, and the original production licensing department shall conduct on-site inspection in a timely manner. In case of any change of licensing items, relevant licensing modification shall be completed as required.

Article 43

Where production of medical devices is suspended continuously for one year or longer and no product of the same kind is produced elsewhere, the medical device manufacturer shall conduct necessary verification and validation prior to resuming production and submit a written report to the medical products administration. If product quality or safety might be affected, the medical products administration may conduct inspections as necessary.

Article 44

Where production conditions of the entity responsible for the registration or recordation of medical devices, or the entrusted manufacturer, change such that they no longer comply with quality management system requirements, the entity shall immediately take corrective measures. If safety or efficacy of medical devices may be affected, production shall be ceased immediately and reported to the original licensing or recordation authority. The entrusted manufacturer shall promptly inform the entity responsible for registration or recordation of such changes.

Article 45

The entity responsible for the registration or recordation of medical devices, and the entrusted manufacturer, shall conduct an annual self-inspection of the operation of the quality management system and submit the self-inspection report to the local medical products administration before March 31 of the following year. For imported medical devices, the entity responsible shall submit the self-inspection report through its agent to the medical products administration of the province, autonomous region, or municipality directly under the Central Government where the agent is located.

Chapter IV: Supervision and Inspection

Article 46

The medical products administration shall, within its statutory duties, conduct supervision and inspection of production activities of the entities responsible for registration or recordation of medical devices and entrusted manufacturers in accordance with the law. When necessary, the medical products administration may extend inspections to other entities or individuals providing products or services related to medical device production activities.

Article 47

The medical products administration shall establish and improve a vocational and specialized medical device inspector system. Based on regulatory authority, industry scale, inspection tasks, and other factors, it shall appoint sufficient inspectors to effectively fulfill inspection requirements. Inspectors shall be well-versed in laws and regulations governing medical devices and possess professional knowledge and skills related to medical device inspection.

Article 48

The medical products administration shall conduct tiered administration of entities responsible for registration or recordation and entrusted manufacturers according to product and enterprise risk levels and shall make dynamic adjustments accordingly.

The NMPA shall organize the formulation of a catalogue of products subject to key regulation. Medical products administrations of provinces, autonomous regions, or municipalities directly under the Central Government shall determine the catalogue of products under key regulation within their administrative regions based on actual circumstances.

Such administrations shall organize and implement tiered supervision and administration according to the catalogue of products under key regulation, production quality management status, adverse event reports, product complaints, and enterprise credit status.

Article 49

The medical products administration of provinces, autonomous regions, or municipalities directly under the Central Government shall develop an annual supervision and inspection plan for medical device production, determine supervision priorities, specify inspection frequency and scope, and strengthen supervision through various means including routine inspections, key inspections, follow-up inspections, cause-based inspections, and special inspections.

Enterprises manufacturing products subject to key regulation shall be inspected at least once annually.

Article 50

When organizing supervision and inspection, the medical products administration shall develop an inspection plan specifying the scope and basis of the inspection, truthfully record on-site inspection details, and notify the inspected party of inspection results in writing. If rectification is required, the contents and time limits for such rectification shall be clearly specified.

Supervision and inspection shall be conducted by two or more inspectors. Law enforcement officers shall present their law enforcement certificates, and other inspectors shall produce inspector certificates or documents certifying their identities.

Article 51

During supervision and inspection of production activities of the entity responsible for the registration or recordation of medical devices, the medical products administration shall focus on the following:

1-Implementation of laws, regulations, and GMP for medical devices by the entity responsible for registration or recordation;

2-Whether production is organized in accordance with compulsory standards, registered or recorded technical product requirements, and whether actual production aligns with the contents of registration or recordation and licensing;

3-Continued compliance and effectiveness of the quality management system operation;

4-Familiarity of the legal representative, person in charge, management representative, and other personnel with laws and regulations on medical devices;

5-Performance of duties by the management representative;

6-Changes in key personnel (legal representative, person in charge, management representative, quality inspection agency, or full-time staff), production site, environmental conditions, and key production inspection equipment;

7-Corrective and preventive measures addressing problems identified via user feedback and internal enterprise inspections;

8-Implementation of rectifications for problems identified through random inspections, supervision and inspection, complaints, and reports;

9- Internal examinations, management reviews, modification control, and annual self-inspection reports;

10-Other aspects under key inspection.

Article 52

In conducting supervision and inspection of the registrant or recordation holder of medical devices that engage in entrusted manufacturing, the medical products administration shall focus on the following aspects:

1-Compliance with applicable laws, regulations, and Good Manufacturing Practices (GMP) for medical devices;

2-Continuous conformity and effectiveness of the quality management system in operation;

3-Fulfillment of responsibilities by the management representative;

4-Whether production is carried out in accordance with mandatory standards and the technical specifications of the registered or recorded products;

5-Corrective and preventive actions undertaken in response to user feedback and internal audits;

6-Internal audits, management reviews, change control, and annual self-inspection reports, among others;

7-Monitoring and re-evaluation of adverse events and collection and assessment of product safety risk information;

8-Marketing and product release activities;

9-Oversight of entrusted manufacturers, including execution of quality agreements, design changes and control, and the production and release of products manufactured under entrustment;

10-Any other matters deemed necessary for focused inspection.

Where necessary, the medical products administration may also inspect the entrusted manufacturer.

Article 53

When supervising and inspecting an entrusted manufacturer, the medical products administration shall focus on the following:

1-Consistency between actual production conditions and those stated in the registration or recordation documentation and production license;

2-Compliance with relevant laws, regulations, and GMP by the entrusted manufacturer;

3-Understanding and familiarity of key personnel (legal representative, principal of the enterprise, management representative) with medical device laws and regulations;

4-Changes in legal representatives, key personnel, quality inspection institutions, production locations, environmental conditions, and key production/testing equipment;

5-Production and release processes;

6-Implementation of corrective actions resulting from random inspections, supervision, complaints, or reports;

7-Internal audits, management reviews, annual self-inspection reports, and similar matters;

8-Any other matters subject to focused inspection.

Where necessary, the party responsible for registration or recording may also be inspected.

Article 54

If the medical products administration identifies potential serious quality or safety risks through adverse event monitoring, random inspection, complaints, or reports, it shall initiate an inspection-for-cause. Such inspections shall, in principle, be conducted without prior notice.

Article 55

The medical products administration shall carry out follow-up inspections to verify corrective actions by enterprises. Such follow-ups may include written reviews of rectification reports submitted by the enterprise or on-site re-inspections to verify problem rectification, implementation of responsibilities, and corrective and preventive measures.

Article 56

Where the party responsible for the registration of medical devices and the entrusted manufacturer are located in different provinces, autonomous regions, or municipalities directly under the Central Government, the medical products administration of the province, autonomous region, or municipality directly under the Central Government where the party responsible for registration is located shall be responsible for supervising and inspecting the performance of statutory obligations by the registrant, including the operation of the quality management system, adverse event monitoring, and product recall. Where relevant matters involve the entrusted manufacturer, the medical products administration at the location of the entrusted manufacturer shall provide cooperation.

The medical products administration of the province, autonomous region, or municipality directly under the Central Government where the entrusted manufacturer is located shall be responsible for supervising and inspecting the production activities of the entrusted manufacturer. Where relevant matters involve the registrant, the medical products administration at the registrant's location shall carry out supervision and inspection on the registrant.

The medical products administrations of the provinces, autonomous regions, and municipalities directly under the Central Government where the registrant and entrusted manufacturer are located shall, in accordance with their respective territorial regulatory responsibilities, establish a collaborative regulatory mechanism, strengthen the communication of regulatory information, and ensure effective regulatory coordination.

Article 57

Where the party responsible for registration and the entrusted manufacturer of medical devices are located in different provinces, autonomous regions, or municipalities directly under the Central Government, and a cross-regional inspection is required, the medical products administrations of their respective jurisdictions may conduct the inspection through joint inspection, entrusted inspection, or other appropriate means.

Article 58

Where any defect is identified in the quality management system of an enterprise during a cross-regional inspection, the medical products administrations of the provinces, autonomous regions, or municipalities directly under the Central Government where the registrant and the entrusted manufacturer are located shall, in accordance with their respective duties, supervise and urge the relevant enterprise to promptly and properly rectify the issues in strict accordance with the requirements, and shall promptly notify the relevant medical products administration of the inspection and rectification results.

Where issues identified in the supervision and inspection of the entrusted manufacturer involve the registrant, the medical products administration at the location of the registrant shall be notified. If there is a potential quality and safety risk in the medical devices, immediate risk control measures shall be taken, and the situation shall be reported to the medical products administration at the registrant's location. Upon receipt of such notification, the medical products administration at the registrant's location shall promptly conduct analysis and assessment and take corresponding risk control measures.

Where issues identified in the supervision and inspection of the registrant involve the entrusted manufacturer, the medical products administration at the location of the entrusted manufacturer shall be notified, and a joint inspection may be conducted, or the local administration may be entrusted to carry out the inspection.

Article 59

Where any suspected illegal act is discovered during a cross-regional inspection, the medical products administrations of the provinces, autonomous regions, or municipalities directly under the Central Government where the registrant and the entrusted manufacturer are located shall, according to their respective duties, conduct investigation and handling. The handling results of the illegal act shall be promptly notified by the relevant medical products administration.

Where cross-regional investigation and evidence collection are necessary, a joint investigation may be conducted in conjunction with the relevant medical products administration at the same level, or a letter of assistance in investigation may be issued requesting the relevant medical products administration at the same level to assist in the investigation and evidence collection.

Article 60

Where the party responsible for the recording of Class I medical devices and the entrusted manufacturer are located in different districted cities, and cross-regional supervision, inspection, or investigation and evidence collection need to be conducted in accordance with statutory duties, the provisions of Articles 56 through 59 of these Measures shall apply mutatis mutandis.

Article 61

The registrant or record-filing entity of imported medical devices shall designate an enterprise legal person located within the territory of China as its agent. The agent shall assist the registrant or record-filing entity in fulfilling obligations stipulated by the Medical Device Supervision and Administration Regulation and these Measures.

Article 62

The production of imported medical devices shall comply with relevant Chinese requirements for medical device manufacturing and shall be subject to overseas inspections organized by the National Medical Products Administration (NMPA). The agent is responsible for coordinating and assisting with the relevant work for overseas inspections.

Where the registrant, record-filing entity, or agent of imported medical devices refuses, obstructs, delays, or evades the overseas inspection organized by the NMPA, resulting in failure to conduct the inspection and inability to confirm the effective operation of the quality management system—thereby constituting a situation with evidence indicating potential harm to human health—the NMPA may handle the matter in accordance with Article 72, Paragraph 2 of the Medical Device Supervision and Administration Regulation.

Article 63

When conducting on-site inspections, medical products regulatory authorities may, as necessary, conduct sampling and testing.

Article 64

If the manufactured medical devices cause harm to human health or there is evidence indicating that they may pose a risk to human health, medical products regulatory authorities may adopt emergency control measures such as suspending production, importation, distribution, or use of the devices, and may issue safety warnings.

If it is discovered during regulatory inspections that production activities seriously violate the Good Manufacturing Practices for medical devices and cannot ensure product safety and effectiveness, posing potential health risks, the authorities shall handle the matter in accordance with the preceding paragraph.

Article 65

Medical products regulatory authorities shall regularly organize risk consultations to analyze and assess risks related to the quality and safety of medical devices within their jurisdictions and shall promptly take corresponding risk control measures.

Article 66

Where the registrant, record-filing entity, or entrusted manufacturer fails to take effective measures to eliminate identified risks to the quality and safety of medical devices, the medical products regulatory authority may conduct accountability interviews with the legal representative or responsible person of the registrant, record-filing entity, or entrusted manufacturer. Where cross-regional contract manufacturing is involved, the results of such interviews shall be communicated to the relevant regulatory authorities.

Article 67

Medical products regulatory authorities at the provincial, autonomous region, or municipality directly under the Central Government level shall establish and update credit records for registrants and entrusted manufacturers of Class II and Class III medical devices within their jurisdictions. Municipal-level regulatory authorities responsible for drug supervision and

administration shall, in accordance with their duties, establish and update credit records for record-filing entities and entrusted manufacturers of Class I medical devices.

The credit records shall include information such as manufacturing license/filing status, product varieties, contract manufacturing activities, inspection results, enforcement actions, quality sampling and testing, adverse conduct records, and complaints and reports.

For registrants, record-filing entities, and entrusted manufacturers with adverse credit records, the medical products regulatory authorities shall increase the frequency of inspections and strengthen credit-related disciplinary actions in accordance with the law.

Article 68

Medical products regulatory authorities shall include the types of products manufactured by enterprises in their credit records.

Where an entrusted manufacturer adds the production of Class II or Class III medical devices and is not located in the same province, autonomous region, or municipality as the relevant registrant, or adds the production of Class I medical devices and is not located in the same prefecture-level city as the relevant record-filing entity, the regulatory authority at the location of the entrusted manufacturer shall also notify the regulatory authority at the location of the registrant or record-filing entity.

Article 69

Medical products regulatory authorities shall publish contact information for receiving complaints and reports. Upon receipt of a report, the authority shall promptly verify, handle, and respond. Where the report is verified as true, the whistleblower shall be rewarded in accordance with relevant provisions.

Article 70

Where suspected illegal conduct is identified during supervision or inspection, the medical products regulatory authorities shall promptly collect and preserve evidence and initiate case investigation and handling in accordance with the law. Where a crime is suspected, the case shall be promptly transferred to the public security authority for handling.

Article 71

Medical products regulatory authorities and their staff shall maintain the confidentiality of trade secrets obtained during investigations and inspections.

Article 72

During supervision and inspection, medical products regulatory authorities and their personnel shall enforce the law in a strict, standardized, impartial, and civil manner, and strictly observe integrity and disciplinary rules. They shall not solicit or accept money or gifts, seek other benefits, or obstruct the normal production activities of enterprises.

Chapter V: Legal Liability

Article 73

Where the illegal conduct in medical device production is already provided for under the *Regulations on the Supervision and Administration of Medical Devices* or other laws and regulations, such provisions shall apply.

Article 74

In any of the following circumstances, penalties shall be imposed in accordance with Article 81 of the *Regulations on the Supervision and Administration of Medical Devices*:

1-Producing Class II or Class III medical devices beyond the scope specified in the medical device production license;

2-Producing Class II or Class III medical devices at an unlicensed production site;

3-Continuing to produce Class II or Class III medical devices after the expiration of the medical device production license without legally applying for renewal;

4-Failing to apply for the required license modification when increasing the variety of products produced by a medical device manufacturer.

Article 75

Where changes to the production filing of Class I medical devices are not handled in accordance with the provisions of this Administrative Measures, it shall be handled in accordance with Article 84 of the *Regulations on the Supervision and Administration of Medical Devices*.

Article 76

Where a quality management system has not been established or maintained in violation of the *Good Manufacturing Practice for Medical Devices*, the drug regulatory authority shall, based on its responsibilities, order rectification within a prescribed time limit; if the safety and

effectiveness of the medical device products are affected, penalties shall be imposed in accordance with Article 86 of the *Regulations on the Supervision and Administration of Medical Devices*.

Article 77

Where production conditions change and may affect the safety and effectiveness of the products, and production is carried out without reporting in accordance with the provisions of Paragraph 2 of Article 15 and Paragraph 3 of Article 42 of these Measures, penalties shall be imposed in accordance with Article 88 of the *Regulations on the Supervision and Administration of Medical Devices*.

Article 78

In any of the following circumstances, the drug regulatory authority shall issue a warning and impose a fine between RMB 10,000 and RMB 50,000:

1-A medical device manufacturer fails to report the types of products it produces and related information to the drug regulatory authority as stipulated in Paragraph 2 of Article 42 of these Measures;

2-After continuous production suspension for more than one year and with no similar products in production, the manufacturer resumes production without conducting necessary verification and confirmation, and fails to report to the local drug regulatory authority.

Article 79

In any of the following circumstances, the drug regulatory authority shall, based on its responsibilities, order rectification within a prescribed time limit; where rectification is refused, a fine between RMB 10,000 and RMB 50,000 shall be imposed; where the circumstances are serious, a fine between RMB 50,000 and RMB 100,000 shall be imposed:

1-Failing to handle changes in registration items of the medical device production license in accordance with Article 16 of these Measures;

2-Failing to implement tasks such as code assignment, data upload, and maintenance and updates in accordance with the national requirements for the implementation of unique device identification (UDI) for medical devices.

Article 80

Where personnel of the drug regulatory authority violate the provisions of these Measures by abusing their powers, neglecting their duties, or engaging in malpractice for personal gain, disciplinary actions shall be imposed in accordance with the law.

Chapter VI: Supplementary Provisions

Article 81

These Measures shall come into force on May 1, 2022. The *Measures for the Supervision and Administration of Medical Device Production* issued by the former China Food and Drug Administration under Order No. 7 on July 30, 2014, shall be repealed simultaneously.