Regulations on the Supervision and Administration of Medical Devices of the PRC

Dan Young Business Consultancy — www.danyoungcpa.com

Unofficial English translation prepared for reference only. The official Chinese text prevails.

Contents

Table of Contents 1

Chapter I — General Provisions 1

Chapter II — Registration and Filing of Medical Device Products 2

Chapter III — Production of Medical Devices 3

Chapter IV — Distribution and Use of Medical Devices 4

Chapter V — Post-Market Surveillance of Medical Devices 5

Chapter VI — Legal Liability 5

Chapter VII — Supplementary Provisions 6

Adopted at the 39th Executive Meeting of the State Council on December 21, 1999; promulgated by Decree No. 276 of the State Council on January 4, 2000
Effective: April 1, 2000; Revised on March 7, 2014; Revised on May 30, 2017; Revised on February 9, 2021 by Decree No. 739 of the State Council, effective June 1, 2021

Table of Contents

- Chapter I — General Provisions
- Chapter II — Registration and Filing of Medical Device Products
- Chapter III — Production of Medical Devices
- Chapter IV — Distribution and Use of Medical Devices
- Chapter V — Post-Market Surveillance of Medical Devices
- Chapter VI — Legal Liability
- Chapter VII — Supplementary Provisions

Chapter I — General Provisions

Article 1 — These Regulations are formulated for the purposes of ensuring the safety and effectiveness of medical devices and safeguarding human health and life safety.

Article 2 — Anyone who engages in the research, development, production, distribution or use of medical devices, or the supervision and administration of medical devices, within the territory of the People's Republic of China shall comply with these Regulations.

Source: https://www.danyoungcpa.com/medical-device-supervision-administration-regulations-prc-2021-revision-english-translation/

Article 3 — The State shall implement classified administration of medical devices based on the degree of risk:

(1) Class I medical devices are those with a low degree of risk, the safety and effectiveness of which can be ensured through routine administration;

(2) Class II medical devices are those with a moderate degree of risk, which require strict control and administration to ensure their safety and effectiveness;

(3) Class III medical devices are those with a high degree of risk, which require special measures for strict control and administration to ensure their safety and effectiveness.

The classification catalogue of medical devices shall be formulated, adjusted and published by the medical device regulatory department of the State Council.

Article 4 — The medical device regulatory department of the State Council shall be responsible for the supervision and administration of medical devices nationwide. The relevant departments of the State Council shall be responsible for the supervision and administration of medical devices within their respective functions and duties.

The medical device regulatory departments of the local people's governments at or above the county level shall be responsible for the supervision and administration of medical devices within their respective administrative regions. The relevant departments of the local people's governments at or above the county level shall be responsible for the supervision and administration of medical devices within their respective functions and duties.

Article 5 — The State shall encourage the research, development and innovation of medical devices, promote the application and promotion of new technologies, and promote the high-quality development of the medical device industry.

Article 6 — Entities and individuals that have made outstanding contributions to the supervision and administration of medical devices shall be commended and rewarded in accordance with the relevant provisions of the State.

Chapter II — Registration and Filing of Medical Device Products

Article 7 — The registration and filing system shall apply to medical device products:

(1) Class I medical device products shall be subject to filing administration, and the filing applicant shall submit the filing materials to the medical device regulatory department of the local people's government at the level of a city divided into districts;

(2) Class II medical device products shall be subject to registration administration, and the registration applicant shall submit the registration application to the medical device regulatory department of the people's government of the province, autonomous region, or municipality directly under the Central Government;

(3) Class III medical device products shall be subject to registration administration, and the registration applicant shall submit the registration application to the medical device regulatory department of the State Council.

Article 8 — An applicant for medical device registration or filing shall meet the following conditions:

(1) Possessing the corresponding professional and technical personnel;

(2) Possessing the sites, equipment and environmental conditions required for research, development, production or use;

(3) Possessing the quality management system that can ensure the quality of the medical device;

Source: https://www.danyoungcpa.com/medical-device-supervision-administration-regulations-prc-2021-revision-english-translation/

(4) Other conditions prescribed by the medical device regulatory department of the State Council.

Article 9 — When applying for medical device registration, the applicant shall submit the technical requirements, instructions, labels, samples and other materials related to the safety and effectiveness of the medical device, as well as the documents proving compliance with the conditions specified in these Regulations.

Article 10 — For the registration of Class II and Class III medical devices, clinical evaluation shall be conducted. In any of the following circumstances, clinical trial approval shall be exempted:

(1) Where the working mechanism is clear, the design is finalized, the production process is mature, and the marketed medical devices of the same type have been used clinically for many years without serious adverse events;

(2) Where safety and effectiveness can be demonstrated through non-clinical evaluation.

Article 11 — Clinical trials of medical devices shall comply with the requirements of the quality management standards for medical device clinical trials, and shall be conducted at medical institutions that have obtained the necessary qualifications.

The medical device regulatory department of the State Council shall examine and approve clinical trial applications for Class III medical devices with high risk.

Article 12 — After accepting an application for medical device registration, the medical device regulatory department shall conduct a technical review within the statutory time limit, and shall make a decision on whether to approve the registration based on the review conclusions.

The medical device registration certificate shall specify the principal components, scope of application, instructions for use, and other content of the medical device. Where any change is required, the registration procedures shall be handled in accordance with the law.

Article 13 — An applicant for filing a Class I medical device product shall submit the filing materials to the medical device regulatory department. The medical device regulatory department shall complete the filing and publish the filing information.

The filing materials shall be true, accurate and complete. Where the filing materials are incomplete or fail to comply with the prescribed form, the medical device regulatory department shall, at one time, inform the applicant of all the materials that need to be supplemented and corrected.

Article 14 — The validity period of a medical device registration certificate shall be five years. Where continued production is required upon expiration, an application for renewal of registration shall be submitted to the original certification department within six months before the expiration.

Article 15 — Medical device registration certificates may not be forged, altered, leased, lent or otherwise transferred.

Chapter III — Production of Medical Devices

Article 16 — An enterprise engaged in the production of medical devices shall meet the following conditions:

(1) Possessing the production sites, environmental conditions, production equipment and professional and technical personnel suitable for the medical devices produced;

(2) Possessing the inspection institutions, inspection personnel and inspection equipment capable of inspecting the medical devices produced;

(3) Possessing the management system that can ensure the quality of the medical devices;

(4) Possessing the after-sales service capabilities suitable for the medical devices produced;

Source: https://www.danyoungcpa.com/medical-device-supervision-administration-regulations-prc-2021-revision-english-translation/

(5) Other conditions prescribed by the medical device regulatory department of the State Council.

Article 17 — An enterprise engaged in the production of Class II or Class III medical devices shall apply to the medical device regulatory department for a medical device production permit. An enterprise producing Class I medical devices shall file with the medical device regulatory department.

Article 18 — Medical device production enterprises shall produce in accordance with the medical device production quality management standards, establish a quality management system and maintain its effective operation.

Article 19 — Medical device production enterprises shall, in accordance with the provisions of the laws and regulations, establish and improve the medical device adverse event monitoring system, and shall be responsible for reporting adverse events and taking control measures.

Article 20 — The information printed on the labels and instructions of medical devices shall be consistent with the content approved in the registration or filing, and shall be true, accurate and complete.

The labels and instructions of medical devices shall specify the following:

(1) Generic name, model and specification;

(2) Name, address and contact information of the production enterprise;

(3) Production date and service life or expiration date;

(4) Product technical requirements and performance indicators;

(5) Contraindications, precautions and other warnings;

(6) Special storage and transportation conditions and methods;

(7) Production batch number or serial number.

Article 21 — Medical device production enterprises shall establish sales records and a traceability system for medical devices, and shall record the flow of medical devices to ensure traceability.

Chapter IV — Distribution and Use of Medical Devices

Article 22 — An enterprise engaged in the distribution of Class II medical devices shall file with the medical device regulatory department. An enterprise engaged in the distribution of Class III medical devices shall apply to the medical device regulatory department for a medical device distribution permit.

An enterprise distributing Class I medical devices is not required to obtain a permit or file.

Article 23 — Medical device distribution enterprises shall establish and implement a purchase inspection and acceptance record system. For medical devices purchased, they shall verify the supplier's qualifications and the conformity certificate or other conformity certification documents of the medical devices.

Article 24 — Medical device distribution enterprises shall not distribute medical devices that have not been registered or filed in accordance with the law, have no conformity certification documents, or have expired, been voided or eliminated.

Article 25 — Medical device user entities shall use medical devices that have been registered or filed in accordance with the law. Medical devices that are prohibited from being used by the State shall not be used.

Article 26 — Medical device user entities shall purchase medical devices from enterprises or institutions that are legally qualified to produce or distribute medical devices, and shall verify the supplier's qualifications.

Article 27 — Medical device user entities shall, in accordance with the product instructions, conduct regular inspection, calibration, maintenance and repair of medical devices and keep records.

Source: https://www.danyoungcpa.com/medical-device-supervision-administration-regulations-prc-2021-revision-english-translation/

Article 28 — For large medical equipment with a high purchase price and high operational risk, medical device user entities shall ensure that the operators have received training and possess the corresponding qualifications.

Article 29 — Medical device user entities shall properly preserve the purchased third-party medical devices and the medical device instruction manuals, labels and other materials originally provided with the medical devices.

Article 30 — Medical device user entities shall establish a tracking and traceability system for implantable and interventional medical devices with high risk, and keep the records for the service life of the medical devices or for the prescribed period.

Article 31 — Where medical device user entities discover quality problems in medical devices during use, they shall immediately stop using them and report to the medical device regulatory department.

Chapter V — Post-Market Surveillance of Medical Devices

Article 32 — The State shall establish a medical device adverse event monitoring system and a medical device recall system.

Medical device production enterprises shall, in accordance with the provisions, establish an adverse event monitoring system, collect adverse events of medical devices, and promptly analyze, evaluate and report them. Medical device distribution enterprises and user entities shall report adverse events of medical devices to the medical device production enterprises and the medical device regulatory departments.

Article 33 — Where a medical device production enterprise discovers that a medical device produced by it has potential defects or does not meet the mandatory standards and may cause harm to human health or life safety, it shall immediately recall the medical devices that have been marketed. The recalled medical devices shall be processed in accordance with the relevant provisions.

Medical device distribution enterprises and user entities shall cooperate with the recall of medical devices.

Article 34 — The medical device regulatory department shall, in accordance with the provisions, inspect the production and distribution enterprises and user entities of medical devices, and shall handle the discovered problems in accordance with the law.

Article 35 — The medical device regulatory department shall evaluate the quality of medical devices in accordance with the provisions and organize sampling inspections. The expenses for sampling inspections shall be borne by the State Treasury, and no fees may be charged to the inspected entities.

Article 36 — The medical device regulatory department shall establish a credit file for medical device production and distribution enterprises and user entities, record the results of licensing and filing, supervision and inspection results, and illegal acts and their handling results, and make the information public in accordance with the law.

Article 37 — The medical device regulatory department shall promptly publish the information on the registration, filing, production permits and distribution permits of medical devices. The published information shall be true, accurate and complete.

Chapter VI — Legal Liability

Article 38 — Where a medical device is produced or distributed without obtaining a medical device registration certificate, the medical device regulatory department shall order the cessation of production or distribution, confiscate the illegally produced or distributed medical devices and the illegal income; where the value of the illegally produced or distributed medical devices is less than RMB 10,000, a fine of not less than RMB 50,000 but not more than RMB 150,000 shall be imposed; where the value exceeds RMB 10,000, a

Source: https://www.danyoungcpa.com/medical-device-supervision-administration-regulations-prc-2021-revision-english-translation/

fine of not less than 15 times but not more than 30 times the value shall be imposed; where the circumstances are serious, the production or distribution shall be banned within five years.

Article 39 — Where a medical device is produced without obtaining a medical device production permit, the medical device regulatory department shall order the cessation of production, confiscate the illegally produced medical devices and the illegal income; where the value of the illegally produced medical devices is less than RMB 10,000, a fine of not less than RMB 50,000 but not more than RMB 100,000 shall be imposed; where the value exceeds RMB 10,000, a fine of not less than 10 times but not more than 20 times the value shall be imposed; where the circumstances are serious, the relevant responsible persons and the production enterprise shall be banned from engaging in medical device production activities within five years.

Article 40 — Where a medical device is distributed without obtaining a medical device distribution permit, the medical device regulatory department shall order the cessation of distribution, confiscate the illegally distributed medical devices and the illegal income; where the value of the illegally distributed medical devices is less than RMB 10,000, a fine of not less than RMB 50,000 but not more than RMB 100,000 shall be imposed; where the value exceeds RMB 10,000, a fine of not less than 10 times but not more than 20 times the value shall be imposed; where the circumstances are serious, the relevant responsible persons and the distribution enterprise shall be banned from engaging in medical device distribution activities within five years.

Article 41 — Where a medical device production enterprise produces medical devices that do not meet the mandatory standards, or produces medical devices without obtaining a registration certificate as required, the medical device regulatory department shall order it to make corrections, confiscate the illegally produced medical devices and the illegal income, and impose a fine; where the circumstances are serious, it shall order the suspension of production for rectification, or revoke the medical device production permit or medical device registration certificate.

Article 42 — Where a medical device production or distribution enterprise fails to produce or distribute medical devices in accordance with the provisions, the medical device regulatory department shall order it to make corrections and may impose a fine; where it refuses to make corrections, the medical device regulatory department shall revoke its medical device production permit or medical device distribution permit.

Article 43 — Where a medical device user entity uses medical devices that have not been registered or filed in accordance with the law, or uses substandard, expired, voided or eliminated medical devices, the medical device regulatory department shall order it to make corrections, confiscate the illegally used medical devices and the illegal income, and impose a fine.

Article 44 — Where a medical device clinical trial institution conducts clinical trials in violation of the provisions of these Regulations, the medical device regulatory department shall order it to make corrections and may impose a fine; where the circumstances are serious, it shall be prohibited from conducting medical device clinical trials.

Article 45 — Where a staff member of the medical device regulatory department commits any of the following acts, sanctions shall be imposed in accordance with the law; where a crime is constituted, criminal liability shall be pursued in accordance with the law:

(1) Failing to perform supervisory duties in accordance with the law;

(2) Issuing permits or certificates in violation of the prescribed conditions and procedures;

(3) Committing fraud or malpractice for personal gain in the course of supervision and administration;

(4) Other acts of dereliction of duty, abuse of power, or malpractice for personal gain.

Chapter VII — Supplementary Provisions

Source: https://www.danyoungcpa.com/medical-device-supervision-administration-regulations-prc-2021-revision-english-translation/

Article 46 — The medical device regulatory department of the State Council shall be responsible for interpreting these Regulations.

Article 47 — These Regulations shall enter into force on June 1, 2021. The Regulations on the Supervision and Administration of Medical Devices promulgated by Decree No. 650 of the State Council on March 7, 2014 and revised on May 4, 2017 shall be repealed simultaneously.

Disclaimer: This English translation is provided for reference purposes only. While every effort has been made to ensure accuracy, it is not an official translation and has no legal force. In the event of any discrepancy between this translation and the original Chinese text, the Chinese text shall prevail. Readers should consult the original Chinese text or seek professional legal advice for matters requiring legal interpretation. This translation does not create an attorney-client relationship. The publisher assumes no liability for any errors, omissions, or reliance on this translation.

Source: https://www.danyoungcpa.com/medical-device-supervision-administration-regulations-prc-2021-revision-english-translation/