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Regulations for the Supervision and Administration of Medical Devices

Regulations for the Supervision and Administration of Medical Devices

Chapter I General Provisions

Article 1 These Regulations are hereby formulated with a view to strengthening the supervision and administration of medical devices, ensuring their safety and effectiveness and protecting human health and life safety.

Article 2 All units or individuals engaged in the research and development, production, distribution, use, supervision and administration of medical devices within the territory of the Peoples Republic of China shall comply with the Regulation.

Article 3 "Medical devices" as defined by these regulations refers to: any instrument, apparatus, appliance, material, or other article whether used alone or in combination, including the software necessary for its proper application. It does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means; the use of which is to achieve the following intended objectives:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap conditions;
3. Investigation, replacement or modification for anatomy or a physiological process;
4. Control of conception.

Article 4 The drug regulatory authority under the State Council is responsible for supervision and administration of medical devices nationwide. The drug administration of the local government at county level and above is responsible for supervision and administration of medical devices in each administrative region. The drug regulatory authority under the State Council shall coordinate with other departments under the State Council, responsible for comprehensive economic administration, in the implementation of policies for the medical device industry.

Article 5 The State shall classify medical devices and administer them based on this classification

Class I Medical Devices are those for which safety and effectiveness can be ensured through routine administration;

Class II Medical Devices are those for which further control is required to ensure their safety and effectiveness

Class III Medical Devices are those which are implanted into the human body, or used for life support or sustenance, or pose potential risk to the human body and thus must be strictly controlled in respect to safety and effectiveness.

The classification catalogue for medical devices shall be stipulated, adjusted and promulgated by the drug regulatory authority under the State Council, in accordance with classification principles after consulting with health authority under the State Council.

Article 6 Medical devices produced and used for the purpose of providing concrete measuring values shall comply with the requirements of the metering law. The detailed product list shall be formulated and promulgated by the drug regulatory authority under the State Council, jointly with the metering authority.

Chapter II The Administration of Medical Devices

Article 7 The State encourages the research and development of new medical devices. "New medical devices" refer to the kind of brand new product varieties which have not been available in the domestic market, or for which the safety, effectiveness and product mechanism have not been recognized domestically.

The clinical trials of new medical devices of Class II and Class III can be conducted only after clinical trial approval by

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the relevant authority in accordance with the rules of the drug regulatory authority under State Council.
New medical devices that have completed clinical trials and passed experts evaluation and review organized by the drug regulatory authority under State Council, shall receive a new product certificate after being approved by the same organization.

Article 8 The State shall implement a product registration system for the manufacturing of medical devices.
Class I medical devices shall be inspected, approved and granted with a registration certificate by the drug regulatory authority of the government of the municipalities consisting of districts.
Class II medical devices shall be inspected, approved and granted with registration certificates by the drug regulatory authorities of provinces, autonomous regions and municipalities directly under the central government.
Class III medical devices shall be inspected, approved and granted with registration certificates by the drug regulatory authority directly under the State Council.
Clinical evaluation must be conducted for Class II and Class III medical devices before they are put into production.

Article 9 The drug regulatory authorities of provinces, autonomous regions and municipalities directly under the central government are responsible for the inspection and approval of the clinical trial or verification of class II medical devices in their own administrative regions. The drug regulatory authority under the State Council is responsible for the inspection and approval of clinical trial or verification of class III medical devices.
Clinical trial or verification shall be conducted in the medical institutions designated by the drug regulatory authorities of the government at provincial level and above. The medical institutions shall conduct the clinical trial or verification, in accordance with the related provisions of the drug regulatory authority under the State Council.
The qualification of medical institutions engaged in the clinical trial or verification shall be certified by the drug regulatory authority, jointly with the health authority under the State Council.

Article 10 Medical institutions may develop medical devices to serve their own clinical needs, and use them within their own institution under the guidance of licensed medical practitioners.
Class II medical devices developed by medical institutions shall be inspected and approved by the drug regulatory authority of the government at provincial level and above. Class III medical devices developed by medical institutions shall be inspected and approved by the drug regulatory authority under the State Council.

Article 11 When importing medical devices into China for the first time, the agent of the imported device, should submit the instruction for use, quality standards, testing methods, other relevant information, product samples, and marketing authorization certificates issued by the manufacturing countries (regions), for inspection and approval by the drug regulatory authority under the State Council, and receive an import product registration certificate before applying for customs formalities.

Article 12 When applying for registration of medical devices, technical standards, testing report and other relevant information shall be submitted according to provisions of the drug regulatory authority under the State Council.
The drug regulatory authority of the government of the municipality consisting of districts shall decide within 30 working days if the product can be registered, counting from the date of acceptance of the application. For those not approved for registration, a written explanation shall be given to the applicant.
The drug regulatory authority of governments of provinces, autonomous regions and municipalities directly under central government shall decide within 60 working days if the product can be registered, counting from the date of acceptance of the application. For those not approved for registration, a written explanation shall be given to the applicant.
The drug regulatory authority under the State Council shall decide within 90 working days if the product can be

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registered, counting from the date of acceptance of the application. For those not approved for registration, a written explanation shall be given to the applicant.

Article 13 In case any situation reflected in the content of the registration certificate is changed, the holder of the certificate shall apply for an amendment of the certificate accordingly, or for re-registration within 30 working days from the change.

Article 14 The term of validity for the registration certificate of medical devices is four years. The holder of the certificate shall apply for re-registration within six months before the certificate expires.

When the manufacturing of a medical device is stopped continuously for more than 2 years, its registration certificate is automatically invalidated.

Article 15 Medical devices manufactured shall meet the national standard, or professional standards when there are no relevant national standards available.

National standards of medical devices shall be formulated jointly by the standardization authority and the drug regulatory authority under the State Council. Professional standards of medical devices shall be formulated by the drug regulatory authority under the State Council.

Article 16 The instruction for use, label and package of medical devices shall comply with relevant standards or provisions in China.

Article 17 The registration number of a medical device shall be marked on the product itself and the external package according to the provisions of the drug regulatory authority under the State Council.

Article 18 The State implements a system of re-evaluation and obsolescence for medical devices, the details of which shall be formulated by drug regulatory authority under the State Council after consulting with other related authorities under the State Council.

Chapter III Administration of Production, Distribution and Use of Medical Devices

Article 19 Enterprises manufacturing medical devices shall meet the following conditions:

1. Possess professional technical personnel required for the manufacture of its medical devices;
2. Possess facility and environment required for the manufacture of its medical devices;
3. Possess equipment required for the manufacture of its medical devices;
4. Possess an establishment or personnel and equipment for quality testing required for the manufacture of its medical devices.

Article 20 Establishment of manufacturing of class I medical devices, requires that the enterprise file a record with the drug regulatory authority of provinces, autonomous regions or municipalities directly under the central government.

Establishing manufacturing of class II and/or class III medical devices, requires inspection and approval by the drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government, who will then issue a Medical Device Manufacturing Enterprise License. The industrial and commercial authority shall not issue a business license to enterprises which have not received a Medical Device Manufacturing Enterprise License.

The term of validity of the Medical Device Manufacturing Enterprise License is 5 years. Upon expiration, re-inspection and license renewal shall be conducted. Implementation details shall be formulated by the drug regulatory authority under the State Council.

Article 21 Medical device manufacturing enterprises shall not start manufacturing products before obtaining the

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manufacturing enterprise license.

Article 22 The State implements a mandatory safety certification system for certain class III medical devices. A specific product list shall be established by the drug regulatory authority under the State Council, jointly with the quality and technology supervision authority.

Article 23 Enterprises distributing medical devices shall meet the following conditions:

1. Possess appropriate facility(s) and environment for the kind of medical devices to be distributed;
2. Possess appropriate quality inspection personnel for the kind of medical devices to be distributed;
3. Possess adequate ability for technical training, maintenance and after-sales services for the kinds of medical devices to be distributed;

Article 24 Establishing of distribution of class II and/or class III medical devices, requires that the enterprise file a record with the drug regulatory authority of provinces, autonomous regions or municipalities directly under the central government.

Establishing an enterprise distributing class II and/or class III medical devices, requires inspection and approval by the drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government, who will then issue a Medical Device Distributing Enterprise License. The industrial and commercial authority shall not issue a business license to enterprises which have not received a Medical Device Distributing Enterprise License.

The term of validity of the Medical Device Distribution Enterprise License is 5 years. Upon expiration, re-inspection and license renewal shall be conducted. Implementation details shall be formulated by the drug regulatory authority under the State Council.

Article 25 The drug regulatory authority of governments of provinces, autonomous regions and municipalities directly under central government shall decide within 30 working days whether the licenses for manufacturing or distributing enterprises of medical devices can be issued, counting from the date of acceptance of the application. When a license is not issued, a written explanation shall be given to the applicant.

Article 26 Distribution enterprises and medical institutions shall purchase qualified medical devices from enterprises having a Medical Device Manufacturing Enterprise License or Medical Device Distribution Enterprise License, and shall verify the certificates of qualified products.

Distribution enterprises shall not distribute medical devices without registration certificates or certificates for qualified products, or medical devices which are beyond their expiry dates, of compromised effectiveness, or obsolete.

Medical institutions shall not use medical devices without registration, or certificate for qualified products, or medical devices which are beyond their expiry dates, of compromised effectiveness, or obsolete.

Article 27 Medical institutions shall not re-use medical devices labeled for single use, shall destroy them after use and establish a record, according to relevant provisions of the country.

Article 28 The State shall establish a quality incident reporting system and a warning system of medical devices. Implementation details shall be stipulated by the drug regulatory authority under the State Council, in conjunction with the health authority and family planning authority under the State Council.

Chapter IV Supervision of Medical Devices

Article 29 The drug regulatory authorities of governments at county level and above shall appoint medical device monitors within their organization, who are responsible for the supervision and inspection of medical device manufacturing enterprises, distribution enterprises and medical institutions within their own administrative regions. When necessary, monitors may take product samples and ask for relevant materials according to the

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provisions promulgated by the drug regulatory authority under the State Council. Institutions and individuals concerned shall not decline cooperation or be deceitful in the monitoring process. The monitors shall be responsible to keep collected samples and materials confidential.

Article 30 The State implements an accreditation system for the qualification of the testing institutions of medical devices. Only testing institutions accredited by the drug regulatory authority in conjunction with the quality and technical supervision authority under the State Council may conduct medical device test.

Medical device testing institutions and their staff members shall keep strictly confidential all technical information provided by enterprises whose products are being tested, and shall not conduct or be involved in research and development, manufacture, distribution and technical consultation related to the devices tested.

Article 31 For products having caused or which may potentially cause quality incidents, the drug regulatory authority of the governments at county level and above shall have the right to check, seal up and detain them together with materials related.

Article 32 The drug regulatory authority of the governments at provincial level and above shall revoke the registration certificates of medical devices of which safety and effectiveness can not be ensured. Medical devices whose registration certificates have been revoked shall not be manufactured, distributed and used. Those already produced or imported shall be dealt with by the drug regulatory authority of government at county level and above.

Article 33 The drug regulatory authorities of the government of the municipality consisting of districts and above, which perform product registrations in violation of these regulations, shall be ordered by the drug regulatory authority under the state council to correct the violations within a defined period. For those not corrected within the period, the product registration certificates may be revoked and the events may be made public.

Article 34 Advertisements of medical devices shall be reviewed and approved by the drug regulatory authority of governments at provincial level and above, and shall not be published, broadcasted, circulated or posted before the approval.

The contents of the advertisements shall be based on the instruction for use approved by the drug regulatory authority under the State Council or the drug regulatory authority of the governments of provinces, autonomous regions and municipalities directly under the Central Government.

Chapter V Penalties

Article 35 In cases of manufacturing medical devices without product registration certificates, in violation of provisions of these Regulations, the drug regulatory authority of governments at county level and above shall issue an order to stop the production, confiscate all of the illegally manufactured products and related illegal income. Additionally, in case the illegal incomes exceed RMB10 thousand yuan, a fine of 3 to 5 times the total sum of the illegal income shall be imposed; in case there are no illegal incomes or the illegal incomes do not exceed RMB10 thousand yuan, a fine of RMB10 thousand yuan to RMB30 thousand yuan shall be imposed; in serious cases, the drug regulatory authorities of the governments at the provinces, autonomous regions and municipalities directly under the Central Government shall revoke the Medical Device Manufacturing Enterprise License; and in case crimes are committed, criminal liability shall be investigated and handled according to the law.

Article 36 In cases of manufacturing class II and class III medical devices without a Medical Device Manufacturing Enterprise License, in violation of these regulations, the drug regulatory authority of governments at county level and above shall issue an order to stop the production, confiscate all of the illegally manufactured products and their illegal incomes. Additionally, in case the illegal incomes exceed RMB10 thousand yuan, a fine of 3 to 5 times of the total sum of the illegal incomes shall be imposed; in case there are no illegal incomes or the illegal incomes

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do not exceed RMB10 thousand yuan, a fine of RMB10 thousand yuan to RMB30 thousand yuan shall be imposed; and in case crimes are committed, criminal liability shall be investigated and handled according to the law.

Article 37 In cases of manufacturing medical devices not in conformity with national standards or professional standards for medical devices, in violation of provisions of these Regulations, the drug regulatory authority of governments at county level and above shall issue an warning, followed with an order to stop the production, confiscate all of the illegally manufactured products and their illegal incomes. Additionally, in case the illegal incomes exceed RMB 5 thousand yuan, a fine of 2 to 5 times of the total sum of the illegal incomes shall be imposed; in case there are no illegal incomes or the illegal incomes do not exceed RMB 5 thousand yuan, a fine of RMB 5 thousand to 20 thousand yuan shall be imposed; in serious cases, the product registration certificates shall be revoked by the authorities originally issued the certificates; and in case crimes are committed, criminal liability shall be investigated and handled according to the law.

Article 38 In cases of Distribution of class II and class III medical devices without a Medical Device Distributing Enterprise License, which violates provisions of these Regulations, the drug regulatory authority of governments at county level and above shall issue an order to stop the production, confiscate all of the illegally manufactured products and their illegal incomes. Additionally, in case the illegal incomes exceed RMB 5 thousand yuan, a fine of 2 to 5 times of the total sum of the illegal incomes shall be imposed; in case there are no illegal incomes or the illegal incomes do not exceed RMB 5 thousand yuan, a fine of RMB 5 thousand yuan to RMB 20 thousand yuan shall be imposed; and in case crimes are committed, criminal liability shall be investigated and handled according to the law.

Article 39 In cases of distributing medical devices without registration certificates or certificate for qualified products, or medical devices which are beyond their expiry dates, of compromised effectiveness, or obsolete, or purchasing medical devices from enterprises without Medical Device Manufacturing Enterprise License or Medical Device Distributing Enterprise License, which violates provisions of these Regulations, the drug regulatory authority of governments at county level and above shall issue an order to stop the distribution, confiscate all of the illegally distributed products and their illegal incomes. Additionally, in case the illegal incomes exceed RMB 5 thousand yuan, a fine of 2 to 5 times of the total sum of the illegal incomes shall be imposed; in case there are no illegal incomes or the illegal incomes do not exceed RMB 5 thousand yuan, a fine of RMB 5 thousand to 20 thousand yuan shall be imposed; in serious cases, the Medical Device Distributing Enterprise License shall be revoked by the authorities which originally issued the license; and in case crimes are committed, criminal liability shall be investigated and handled according to the law.

Article 40 In cases where false certificates, documents, materials, or product samples are submitted in registration applications, or obtaining medical device registration certificates are obtained using other deceitful means, which violate provisions of these Regulations, the product registration certificates shall be revoked by the authorities which originally issued the certificates, and within a period of two years, other product registration applications of the violating enterprise shall not be accepted. Additionally, a fine of RMB 10 thousand to 30 thousand yuan shall be imposed; for enterprises already started manufacturing, all of the illegally manufactured products and their illegal incomes shall be confiscated; in case the illegal incomes exceed RMB10 thousand yuan, a fine of 3 to 5 times of the total sum of the illegal incomes shall be imposed; in case there are no illegal incomes or the illegal incomes do not exceed RMB10 thousand yuan, a fine of RMB 10 thousand to 30 thousand yuan shall be imposed; and in case crimes are committed, criminal liability shall be investigated and handled according to the law.

Article 41 Violation of Article 34 of these Regulations concerning provisions for advertisement of medical devices shall be dealt with by the industrial and commercial authority according to relevant laws and regulations of the

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country.

Article 42 In cases of Medical institutions using medical devices without registration certificates or certificate for qualified products, or medical devices which are beyond their expiry dates, of compromised effectiveness, or obsolete, or purchasing medical devices from enterprises without Medical Device Manufacturing Enterprise License or Medical Device Distributing Enterprise License, which violate provisions of these Regulations, the drug regulatory authority of governments at county level and above shall issue an order for correction, launch a warning, and confiscate all of the illegally used products and illegal incomes. Additionally, in case the illegal incomes exceed RMB 5 thousand yuan, a fine of 2 to 5 times of the total sum of the illegal incomes shall be imposed; in case there are no illegal incomes or the illegal incomes do not exceed RMB 5 thousand yuan, a fine of RMB 5 thousand to 20 thousand yuan shall be imposed, and person(s) in charge and other directly responsible personnel shall receive disciplinary punishment; and in case crimes are committed, criminal liability shall be investigated and handled according to the law.

Article 43 In cases of medical institutions re-using devices for single use, or not destroying devices which should be destroyed, which violates provisions of these Regulations, the drug regulatory authority of governments at county level and above shall issue an order for correction and launch a warning, and may impose a fine of RMB 5 thousand to 30 thousand yuan; in serious cases, the medical institutions may be applied with a fine of RMB 30 thousand to 50 thousand yuan, and person(s) in charge and other directly responsible personnel be applied with disciplinary punishment; and in case crimes are committed, criminal liabilities shall be investigated and handled according to the law.

Article 44 In cases in which medical institutions undertake clinical trials or clinical verifications of medical devices and provide false reports, which violates provisions of these Regulations, the drug regulatory authority of governments at provincial level and above shall issue an order for correction and launch a warning, and may impose a fine of RM B 10 thousand to 30 thousand yuan； in serious cases, the qualification for clinical trial or clinical verification of medical devices shall be terminated, person(s) in charge and other directly responsible personnel shall receive disciplinary punishment; an d in case crimes are committed, criminal liability shall be investigated and handled according to the law.

Article 45 For cases in which testing institutions and their personnel are found to be conducting or involved in research and development, manufacturing, distribution and technical consultation of medical devices which are related to the testing, or establishing false testing reports, which violates provisions of these Regulations, the drug regulatory authority of governments at provincial level and above shall issue an order for correction and launch a warning, and may impose a fine of RMB 10 thousand to 30 thousand yuan; in serious cases, the qualification for testing shall be terminated by the drug regulatory authority under the State Council, person(s) in charge and other directly responsible personnel shall be receive disciplinary punishment; and in case crimes are committed, criminal liability shall be investigated and handled according to law.

Article 46 In cases where personnel engaged in supervision and administration of medical devices abuse their power, pursue personal benefits by deceiving, or neglecting their duties, in violation of provisions of these Regulations, to the extent to which crimes are committed, criminal liabilities shall be investigated and handled according to the law. For those not committing crimes, disciplinary punishment shall be applied according to the relevant regulations.

Chapter VI Supplementary Provisions

Article 47 Provisions governing non-profitable contraceptive devices shall be formulated separately by the drug regulatory authority in conjunction with other relevant authorities under the State Council.

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Article 48 These Regulations shall come into force from April 1, 2000.