

# **Decree No.7 of the State Food and Drug Administration**

*Measures for Supervision and Administration of Medical Device Production* as deliberated and adopted at the executive meeting of the China Food and Drug Administration (“CFDA”) on June 27, 2014, are hereby issued, and shall come into force on October 1, 2014.

Director: Zhang Yong

July 30, 2014

## **Measures for the Supervision and Administration of Medical Device Production**

### **Chapter I General Provisions**

Article 1 To strengthen the supervision and administration of medical device production, standardize the production of medical device, and ensure the safety and effectiveness of medical device, these measures are developed according to the *Regulations for the Supervision and Administration of Medical Device*.

Article 2 Whoever engages in the production of medical devices within the territory of the People's Republic of China and the supervision and administration thereof shall abide by these Measures.

Article 3 The CFDA shall be responsible for supervising and administering medical device production nationwide. The food and drug administration at or above the county level shall be responsible for supervising and administering medical device production within its administrative region.

The food and drug administration at a higher level shall be responsible for directing and overseeing the supervision and administration of medical device production conducted by food and drug administration at lower levels.

Article 4 The CFDA shall prepare quality management rules for medical device production and supervise the implementation thereof.

Article 5 Food and drug administration shall, in a lawful and timely manner, issue the information on the licensing and recordation of medical device production. The applicants may inquire about the approval process and results; and the public may consult approval results.

Article 6 Medical device production enterprises shall be responsible for the quality of produced medical devices. In the case of the entrusted production of medical devices, the entrusting party shall be responsible for the quality of medical devices to be produced upon entrustment.

## Chapter II Production Licensing and Recordation Administration

Article 7 To engage in medical device production, the applicant shall meet the following conditions:

(1) It has the production premise, environmental conditions, production equipment and professional technicians commensurate with the medical devices produced by it.

(2) It has the institution or full-time inspectors and the inspection equipment for the quality inspection of medical devices produced by it.

(3) It has management rules guaranteeing the quality of medical devices.

(4) It has the after-sales service capability commensurate with the medical devices produced by it.

(5) It satisfies the requirements as prescribed in production research and development and production technique documents.

Article 8 To establish an enterprise engaging in the production of Class II or Class III medical devices, the applicant shall file an application for production licensing with the local food and drug administration of the province, autonomous region, or municipality directly under the Central Government, and submit the following materials:

- (1) Photocopies of the business license and the organization code certificate.
- (2) Photocopies of the registration certificate of and product technical requirements for the produced medical devices held by the applicant.
- (3) Photocopies of the identity certificates of the legal representative and the person in charge of the enterprise.
- (4) Photocopies of the identity, educational background and professional title certificates of the persons in charge of production, quality and technology.
- (5) List of the educational background and professional titles of employees on production management and quality inspection posts.
- (6) Certification documents on the production premise, and the photocopies of certification documents on facilities and environment if there are special requirements for the production environment.
- (7) List of major production equipment and inspection equipment.
- (8) Quality manual and procedure documents.

(9) Process flow diagram.

(10) Authorization certificate for the handling person.

(11) Other certification materials.

Article 9 The food and drug administration of a province, autonomous region or municipality directly under the Central Government shall, after receiving an application, handle the application in light of the following circumstances respectively:

(1) The administration shall accept the application, if the subject matter of application falls under its scope of functions, and the application materials are complete and conform to the statutory form.

(2) If the application materials are incomplete or do not conform to the statutory form, the administration shall notify the applicant, on the spot or within five working days as of receipt of the application materials, of all the necessary supplements and corrections at one time; and if the administration fails to do so within the prescribed time limit, the application shall be deemed accepted on the date of receipt of the application materials.

(3) The administration shall allow the applicant to correct on the spot any error in the application materials that can be corrected on the spot.

(4) The administration shall immediately make a non-acceptance decision, and notify the applicant that it should file an application with the relevant administrative department, if the subject matter of application does not fall under its scope of functions.

Where the food and drug administration of a province, autonomous region or municipality directly under the Central Government makes a decision to accept or not to accept an application for a medical device production license, it shall issue an acceptance or non-acceptance notice.

Article 10 The food and drug administration of a province, autonomous region or municipality directly under the Central Government shall examine the application materials within 30 working days after the date of acceptance, and conduct on-site verification according to the requirements of quality management rules for medical device production. On-site verification shall be conducted according to the actual circumstances, and repeated verification shall be avoided. If rectification is required, the time needed for rectification shall not be included in the time for examination.

If the prescribed conditions are met, the food and drug administration shall make a written decision to approve licensing in accordance with law, and issue the Medical Device Production License within ten working days; and if the prescribed conditions are not met, shall make a written disapproval decision, and give an explanation on reasons.

Article 11 To establish an enterprise producing Class I medical devices, the applicant shall undergo the formalities for the recordation of Class I medical devices at the local food and drug administration at the level of a districted city, and submit the photocopy of the recordation certificate for the produced medical devices held by the enterprise undergoing recordation and the materials as set forth in Article 8 of these Measures (excluding item (2)).

The food and drug administration shall verify the integrity of the materials submitted by the enterprise on the spot, grant recordation if the prescribed conditions are met, and issue the recordation certificate for the production of Class I medical devices to the enterprise.

Article 12 Where an application for the production licensing of medical devices directly involves the vital interest relationship between the applicant and any other party, the food and drug administration shall inform the applicant and the interested party of the right to apply for a hearing in accordance with laws, regulations and the relevant provisions of the CFDA. Where the food and drug administration deems that any major licensing matter involves public interest when examining an application for the production licensing of medical devices, it shall make an announcement to the public and hold a hearing.

Article 13 A Medical Device Production License shall be valid for five years, indicating the license number, enterprise name, legal representative, the person in charge of the enterprise, domicile, production address, production scope, license-issuing authority, date of issuance, validity term, and other matters.

The Medical Device Production License shall include the registration form of produced medical devices, indicating the name, registration number and other information of the produced medical devices.

Article 14 To increase new products, the medical device production enterprise shall submit the relevant materials involving modified contents as set forth in Article 8 of these Measures to the original license-issuing authority.

Where the products to be increased upon application do not fall under the original scope of production, the original licensing-issuing authority shall conduct examination and on-site verification in accordance with Article 10 of these Measures, and if the prescribed conditions are met, modify the scope of production indicated in the Medical Device Production License, and indicate the product information in the registration form of produced medical devices.

Where the products to be increased upon application fall under the original scope of production and have similar production technique, production conditions and other requirements with the produced medical devices based on the original license, the original license-issuing authority shall examine the submitted materials, and if the prescribed conditions are met, indicate the product information in the registration form of produced medical devices. If the requirements for the production techniques and production conditions of the said products have material difference with those for the medical devices produced based on the original license, the original license-issuing authority shall conduct examination and on-site verification in accordance with Article 10 of these Measures, and if the prescribed conditions are met, indicate product information in the registration form of produced medical devices.

Article 15 In the case of the non-literal modification of the production address, the applicant shall file an application with the original license-issuing authority for the modification of the medical device production license, and submit the relevant materials involving the modified contents as set forth in Article 8 of these Measures. The original license-issuing authority shall conduct examination and on-site verification in accordance with Article 10 of these Measures, and make a modification approval or disapproval decision within 30 working days. If a medical device production enterprise establishes production premises across different provinces, autonomous regions or municipalities directly under the Central Government, it shall file a separate application for the medical device production license.

Article 16 In the case of the modification of the enterprise name, legal representative, person in charge of the enterprise, or the domicile, or the literal modification of the production address, the medical device production enterprise shall, within 30 working days as of the modification, undergo modification registration formalities for the Medical Device Production License at the original license-issuing authority, and submit certification materials of the relevant departments. The original license-issuing authority shall undergo modification formalities in a timely manner. If the modification materials are incomplete or do not conform to the provisions on formal examination, the enterprise shall be notified of all the necessary supplements and corrections at one time.

Article 17 To renew the validity term of the Medical Device Production License upon its expiry, the medical device production enterprise shall file an application for renewing the validity term of the Medical Device Production License with the original license-issuing authority at least six months before the validity term of the license expires.

The original license-issuing authority shall examine the extension application in accordance with Article 10 of these Measures, conduct on-site verification when necessary, and make a decision to approve or disapprove the extension before the validity term of the Medical Device Production License expires. It shall approve the extension if the prescribed conditions are met. It shall order rectification within a prescribed time limit if the prescribed conditions are not met; and if the required conditions are still not met after rectification, it shall disapprove the extension and give a written explanation on reasons. It shall be deemed approving the extension if it fails to make a decision within the time limit.

Article 18 A medical device production enterprise surviving due to split or merger shall apply for modification licensing in accordance with these Measures; a medical device production enterprise dissolved due to enterprise split or merger shall apply for deregistering the Medical Device Production License; and a medical device production enterprise newly established due to enterprise merger or split shall apply for the Medical Device Production License.

Article 19 Where a *Medical Device Production License* is lost, the medical device production enterprise shall immediately publish a statement on the loss on the media designated by the original license-issuing authority. It shall, after one month as of the date when the enterprise publishes the statement on the loss, apply to the original license-issuing authority for the re-issuance of the license. The original license-issuing authority shall reissue the Medical Device Production License in a timely manner.

Article 20 The number and validity term of the modified or reissued Medical Device Production License shall remain unchanged. The number of the renewed Medical Device Production License shall remain unchanged.

Article 21 In the case of any modification of the recordation certificate for the production of Class I medical devices, modification recordation shall be conducted.

If the recordation certificate is lost, the medical device production enterprise shall undergo reissue formalities at the original recordation department in a timely manner.

Article 22 Where a case has been docketed for investigation by the food and drug administration due to a medical device production enterprise's production in violation of any law but the case has not been concluded, or the medical device production enterprise has received any administrative penalty decision but has not implemented the decision, the food and drug administration shall suspend the licensing, until the handling of the case is concluded.

Article 23 Where a medical device production enterprise falls under any circumstance under which deregistration of its Medical Device Production License is required by any law or regulation, or the validity term does not expire but the enterprise voluntarily requests its deregistration, the food and drug administration of the province, autonomous region or municipality directly under the Central Government shall deregister its Medical Device Production License in accordance with law, and publish it on the website.

Article 24 The food and drug administration of a province, autonomous region or municipality directly under the Central Government shall establish licensing archives on the issuance, renewal, modification, reissue, revocation and deregistration of the Medical Device Production License.

The food and drug administration at the level of a districted city shall establish archives on the recordation information on the production of Class I medical devices.

Article 25 No entity or individual shall forge, alter, buy or sell, lease, or lend the Medical Device Production License and the recordation certificate for medical device production.

### Chapter III Entrusted Production Administration

Article 26 The entrusting party who entrusts the production of medical device should be the domestic register or legal manufacturer for the medical device entrusted to be produced within the territory. For the product that is entrusted to be produced does not belong to the domestic medical device that should undergo special approval formalities of innovative medical device, the entrusti

ng party should obtain the production license for the medical device entrusted to be produced or handle production filing for Class I medical device.

The entrusting party shall be the domestic manufacturing enterprise who has obtained the production license for the corresponding production scope of the medical device entrusted to be produced or handled the production filing formalities for Class I medical device.

Article 27 The entrusting party should provide the entrusted party with the quality management system of the entrusted medical device and registered and filed technical requirements and evaluate the production conditions, technical level and quality management capabilities of the entrusting party to confirm its entrusted production conditions and capacity, and provide guidance and supervision for the production process and quality control.

Article 28 The entrusted party shall organize the production according to the production quality management standard for medical device, the mandatory standard, the technical requirements of the products and the entrusting production contract, and shall keep all the documents and records of entrusted production.

Article 29 The entrusting party and the entrusted party shall sign the entrusted production contract to clarify the rights, obligations and responsibilities of both parties.

Article 30 For entrusted production of Class II and III medical devices, the entrusting party should handle entrusted production filing at the food and drug administration department of the lo

cal government of the province, autonomous region or municipality directly under the central government; for entrusted production of Class I medical device, the entrusting party should handle entrusted production filing at the food and drug administration department of the local government of the district. For any manufacturer who has met the prescribed conditions, the food and drug administration department shall issue a certificate of entrusted production for the medical device.

The following data should be submitted when filing:

- (a) Photocopies of entrusted medical device registration certificate or filing certificate;
- (b) Photocopies of the business license and the organization code certificate of the entrusting party and the entrusted party;
- (c) Photocopies of the *Medical Device Production License* or Class I medical device production filing certificate of the entrusted party;
- (d) Photocopies of entrusted production contract;
- (e) Authorization certificate for the handling person.

Except for the domestic medical device approved that is subjected to special approval procedure of the innovative medical device, photocopies of *Medical Device Production License* or Class I medical device production filing certificate of the entrusting party are required for entrusted production; for the domestic medical device approved that is subjected to special approval procedure of the innovative medical device, the proof materials for special approval procedure of the innovative medical device should be submitted.

Article 31 Anyone who is entrusted to produce Class II and III medical devices shall handle the relevant formalities in accordance with the provisions of Article 14 hereof, and record the information on the product entrusted to be produced in the medical device product production registration form.

Anyone who is entrusted to produce Class I medical device should handle the change formalities of Class I medical device production filing at the original filing authority in accordance with the provisions of Article 21 hereof.

Article 32 If the entrusted party adds the information of the product entrusted to be produced or changes Class I medical device production filing, the following information shall be submitted in addition to those specified hereof:

- (a) Photocopies of business license and organization code certificate of both entrusting and entrusted parties;
- (b) Photocopies of *Medical Device Production License* or Class I medical device production filing certificate of the entrusting party;
- (c) Photocopies of production filing certificate of medical device entrusted to be produced provided by the entrusting party;
- (d) Photocopies of entrusted production contract;
- (e) The Instructions for Use and the sample of product labels for the product;
- (f) The authorization statement on the quality management system of the entrusted party issued by the entrusting party;
- (g) The self - guarantee statement on the responsibility for the production of medical device quality, sales and after - sales service issued by the entrusting party.

Except for the domestic medical device approved that is subjected to special approval procedure of the innovative medical device, photocopies of *Medical Device Production License* or Class I medical device production filing certificate of the entrusting party are required for entrusted production; for the domestic medical device approved that is subjected to special approval procedure o

f the innovative medical device, the proof materials for special approval procedure of the innovative medical device should be submitted.

Article 33 For the product entrusted to be produced in the product registration form of the *Medical Device Production License* and production filing certificate of Class I medical device of the entrusted party, the words "entrusted production" and entrusted production period should be marked.

Article 34 Any imported medical device should have Chinese Instructions for Use and labels. The instructions for use and labels should meet the requirements set forth in these Regulations and relevant compulsory standard, while specifying company name, residence, production address, production license number or production recordation certificate number of the entrusted party.

Article 35 When the entrusted production is terminated, the entrusting party and the entrusted party shall report timely to the local food and drug supervision and administration department of the province, autonomous region, municipality directly under the central government or the district.

Article 36 The entrusting party is only entitled to entrust the production of same medical device products to a medical device manufacturer in the same period (except for absolute holding enterprises).

Article 37 The implantable medical device with higher risk should not be manufactured under entrustment. The catalogue of the medical device varieties prohibited for manufacture under entrustment should be formulated, adjusted and published by the Food and Drug Administration Department of the State Council.

#### Chapter IV Production Quality Management

Article 38 The medical device manufacturing enterprises should establish the quality management system and maintain its effective operation in accordance with the requirements of the good manufacturing practice for medical device.

Article 39 Medical device manufacturers should carry out training on laws, regulations, regulations, standards and other knowledge related to medical device, and create training files.

Production personnel should master the appropriate theoretical knowledge and practical skills.

Article 40 Medical device manufacturer should organize the production in accordance with the technical requirements of registered or filed products, to ensure that the medical device leaving factory meet the mandatory standards and technical requirements of the registered or filed product. The medical device leaving factory should pass the inspection and be attached with conformity certificate.

Article 41 Medical device manufacturers should conduct a comprehensive self-examination of the quality control system regularly in accordance with the requirements of medical device production quality management system, and submit annual self-examination report to the food and drug administration department of the local government of the province, autonomous region, municipality directly under the central government or district by the end of each year.

Article 42 If any production condition has changed and no longer met the requirements of the medical device quality management system, the medical device manufacturer should take corrective measures immediately; if it may affect the safety and effectiveness of the medical device, production activities should be immediately discontinued and reported to the county-level Food and Drug Administration where the manufacturer is located.

In case of resumption of any production of medical devices with the end of life of more than one year in absence of production of similar products, any medical device manufacturer should submit the written report in advance to the food and drug administration department of the local government of the province, autonomous region, municipality directly under the central government or the district and should not resume the production before passing the verification;

Article 43 Medical device products for one year or more and no similar products in the production, re-production, the food and drug administration department of the local government of the p

province, autonomous region, municipality directly under the central government or district, verified by the requirements After the resumption of production.

Article 44 For medical device manufacturers who do not possess the original production license conditions or meet the filed information and become lost, upon announcement issued by the original licensing or filing department, relevant authorities shall revoke their medical device production license or specify in production recordation information of Class I medical device and give notice to the public.

Article 45 Medical device manufacturer should conduct production on the site that has been approved or filed, provide maintenance for production equipment, process equipment and testing equipment and so on to maintain and ensure their normal operation.

Article 46 Medical device manufacturer should strengthen the procurement management, establish supplier review system to evaluate suppliers and ensure that the procurement of products meets the statutory requirements.

Article 47 Medical device manufacturers should record raw materials procurement, production, inspection and other processes. Records should be true, accurate, complete and consistent with traceable requirements.

Article 48 The state encourages medical device manufacturers to establish information management system by adopting advanced technology means.

Article 49 Any major quality accident that occurs to a medical device produced by a medical device manufacturer shall be reported to the food and drug administration department of the local government of the province, autonomous region or municipality directly under the central government within 24 hours, and then immediately reported by the food and drug administration department of the local government of the province, autonomous region or municipality directly under the central government to the State Food and Drug Administration.

#### Chapter V Supervision and Administration

Article 50 The Food and drug administration shall exercise classification management of medical device production in accordance with the principles of risk management.

Article 51 The food and drug administration department of the local government of the province, autonomous region or municipality directly under the central government shall be responsible for formulating the supervision and inspection plans for medical device manufacturing enterprises shall be formulated by in their respective administrative areas to determine the focus of medical device supervision, inspection frequency and coverage, and supervising the implementation.

Article 52 Relevant authorities should check how medical device manufacturers fulfill laws, regulations, rules, norms, standards and other requirements during medical device production supervision and inspection, focusing on the matters stipulated in Article 53 of the *Regulations for the Supervision and Administration of Medical Device*.

Article 53 Food and drug administration departments shall organize supervision and inspection, develop an inspection program, clarify inspection standards, truthfully record the on-site inspection, and inform the enterprise of the results of the inspection in writing. If necessary, any correction content and time limit shall be specified, and the follow-up inspection should be implemented.

Article 54 Food and drug administration departments should strengthen the spot checks of medical device.

Food and drug administration departments at or above the provincial level shall promptly release the medical device quality announcement in accordance with the conclusions of the spot checks.

Article 55 For any medical device manufacturer who has been complained and reported, or is suspected to have hidden product hazard during regular inspection or has bad behavior record, may carry out the flight inspection, food and drug administration departments may carry out the flight check.

Article 56 In any of the following circumstances, food and drug administration departments may interview with the legal representative or business person in charge of the medical device manufacturer:

- (a) Presence of serious security risks in production;
- (b) Products have been repeatedly complained or exposed by media due to quality problems;
- (c) Poor credit business;
- (d) Other conditions under which food and drug administration departments think it necessary to conduct responsibility interview.

Article 57 Local food and drug administration departments at all levels shall establish supervisory archives for medical device manufacturing enterprises in their respective administrative areas. The supervisory archives shall cover the information such as product registration and filing of the medical device manufacturer, production license and record, entrusted production, supervision and inspection, spot checks, adverse event monitoring, product recall, bad behavior record, complaint report and so on.

Article 58 The State Food and Drug Administration shall establish a unified medical device production supervision and management information platform, and local food and drug administration

ation departments at all levels should strengthen the information construction to ensure information convergence.

Article 59 Local food and drug supervision and management departments at all levels should conduct credit evaluation of medical device manufacturers based on the relevant supervision and management records of medical device manufacturing enterprises and establish credit archives. For enterprises with bad credit records, the frequency of inspection should be increased.

Enterprises included in the "blacklist" shall be handled in accordance with the relevant provisions of the State Food and Drug Administration.

Article 60 Individuals and organizations who have found illegal production activities of medical device manufacturer have the right to report to the food and drug administration departments, and the food and drug administration departments should promptly investigate and deal with such activities. If such activities are verified to be true, informers shall be rewarded in accordance with relevant provisions.

## Chapter VI Legal Liability

Article 61 In any of the following circumstances, a punishment shall be imposed in accordance with the provisions of Article 63 of the *Regulations for the Supervision and Administration of Medical Device*:

- (a) Manufacture and operate Class II and Class III medical devices without obtaining the

Medical Device Registration Certificate;

( b ) Engage in the manufacturing activities of Class II and Class III medical devices without authorization;

( c ) Production of Class II and Class III medical devices beyond the scope of production or do not comply with the information in the medical device product production registration form;

( d ) Production of Class II and Class III medical devices at unauthorized production sites;

( e ) The entrusted party continues the production of entrusted products after the termination of entrusted production of Class II and Class III medical devices.

Article 62 After the expiry of the validity period of the *Medical Device Production License*, if any medical device manufacturer who fails to handle the renewal formalities continues the production of medical device, a punishment shall be imposed in accordance with the provisions of Article 63 of the *Regulations for the Supervision and Administration of Medical Device*.

Article 63 If any medical device manufacturer obtains the *Medical Device Production License* by providing false information or taking other deceptive means, a punishment shall be imposed in accordance with the provisions of paragraph 1, Article 64 of the *Regulations for the Supervision and Administration of Medical Device*.

Article 64 An applicant engaged in production of Class I medical devices if it fails to submit a recordation to the food & drug administration department shall be punished according to the pro

visions of paragraph 1 of article 65 of the *Regulations for the Supervision and Administration of Medical Device* and shall be punished according to the provisions of paragraph 2 of article 65 of the *Regulations for the Supervision and Administration of Medical Device* if it provide false information for recordation.

Article 65 In case of falsifying, altering, buying and selling, leasing, and borrowing relevant medical device licensing certificate, it shall be punished in accordance with the provisions of Paragraph 2 of Article 64 of the *Measures for Supervision and Administration of Medical Device Production*

In case of falsifying, altering, buying and selling, leasing, and borrowing relevant medical device licensing certificate, the Food and Drug Administration Department of the people's government above the county level should order the enterprise to make correction; a penalty less than RMB 10,000 should be imposed additionally.

Article 66 In any of the following circumstances, a punishment shall be imposed in accordance with the provisions of Article 66 of the *Regulations for the Supervision and Administration of Medical Device*:

- (a) The production of medical device that does not meet the mandatory standards or does not meet the technical requirements of the registered or filed product;
- (b) Medical device manufacturers fail to organize the production in accordance with the te

chnical requirements of registered and filed products, or fail to establish a quality management system and maintain its effective operation in accordance with the provisions hereof;

(c) Entrust the enterprises who do not meet the conditions prescribed by these measures to produce medical device or fail to manage the production behavior of the entrusted party.

Article 67 Any medical device manufacturing enterprise, whose production conditions have been changed and do not comply with the requirements of quality management system of medical devices any more, if they fail to make correction, suspend production and report to the relevant authorities according to these measures, shall be punished in accordance with the provisions of Article 67 hereof.

Article 68 Any medical device manufacturing enterprise who fails to submit the self-inspect report on the operation of its own quality management system to the food and drug administration department of the local government of the province, autonomous region, municipality directly under the central government or the district shall be punished in accordance with the provisions of Article 68 of the *Regulations for the Supervision and Administration of Medical Device*.

Article 69 In any of the following circumstances, the Food and Drug Administration Department of the people's government above the county level should give a warning and instruct them to make correction within specified limit, and a penalty less than RMB 30,000 should be imposed additionally

- (a) Failure to inspect the medical device leaving factory in accordance with the provisions;
- (b) No conformity certificate attached to the medical device leaving factory in accordance with the provisions;;
- (c) Failure to undergo modification registration formalities of the *Medical Device Production License* in accordance with the provisions of Article 16 of these Measures;
- (d) Failure to handle the entrusted production recordation formalities in accordance with the provisions;
- (e) Resumption of production of medical devices with the end of life of more than one year in absence of production of similar products without approval of the municipal food and drug administration department of the local government of the province, autonomous region, municipality directly under the central government or the district;
- (d) Conceal the situation, provide false information or refuse to provide real information to reflect its activities to the food and drug administration during inspection.

In case of violation of the relevant provisions of the *Regulations for the Supervision and Administration of Medical Device*, any person who commits any act listed in the preceding paragraph should be punished according to the provisions of *Regulations for the Supervision and Administration of Medical Device*, if the circumstances are serious or the harm consequences are caused.

Article 70 Enterprises exporting medical devices should ensure that the medical device to be exported meet the requirements of the importation country (region) and report relevant information on the products to the municipal-level food and drug administration where they are located for recordation.

Any manufacturing enterprise who is entrusted by an overseas enterprise to produce medical device that will be marketed overseas shall obtain the third party certification of the medical device quality management system or the domestic production license or recordation for similar products.

Article 71 The format of *Medical Device Production License* and Class I medical device production recordation certificate shall be developed uniformly by the China State Food and Drug Administration.

The *Medical Device Production License* shall be printed by the Food and Drug Administration Department of the people's government of the province, autonomous region and municipality directly under the central government.

The number sequence of Medical Device Production License is as follows: Production License No. XXXXXXXXX of X Food And Drug Administration, wherein:

The 1<sup>st</sup> X represents the abbreviation of the province, autonomous region or municipality directly under the central government where the licensing department is located; the 2<sup>nd</sup> to the 5<sup>th</sup> X represents the four-digit license year;

The 6<sup>th</sup> to 9<sup>th</sup> X represents the 4-digit license serial number.

The sequence of the recordation number of production recordation certification for Class I medical device is as follows: Medical Device Production Number XXXXXXXXX of XX Food And Medicine Administration, wherein:

The 1<sup>st</sup> X represents the abbreviation of the province, autonomous regions and municipalities directly under the central government where the recordation authority is located;

The 2<sup>nd</sup> X represents the name of the municipal administrative area where the recordation authority is located;

The 3<sup>rd</sup> to 6<sup>th</sup> X represents the four-digit recordation year;

The 7<sup>th</sup> to 10<sup>th</sup> X represents the four-digit recordation serial number.

Article 72 The Measures shall enter into force as of October 1, 2014. The *Measures for Supervision and Administration of Medical Device Production* (Decree No. 12 of China State Food and Drug Administration) released on July 20, 2004 are annulled at the same time.