
Administrative Measures for the Supervision of Medical Device Manufacturing

Chapter I General Provisions

Article 1

The administrative measures are formulated in accordance with the Regulations on the Supervision and Administration of Medical Devices, with a view to strengthen the supervision and administration of medical device manufacture, standardize the manufacturing behaviors of medical device, to ensure the safety and effectiveness of medical devices.

Article 2

All the medical device activities in the manufacture, supervision and administration within the territory of the People's Republic of China shall comply with the administrative measures

Article 3

Food and drug administration department under the State Council is responsible for supervision and administration of medical devices manufacturing nationwide. Food and drug administration department of the local government at county level and above is responsible for supervision and administration of medical devices manufacturing in each administrative region.

Superior food and drug administration department shall be responsible for guiding and supervising the supervision and administration on medical device manufacture conducted by subordinate food and drug administration department.

Article 4

The State Food and Drug administration shall formulate the administrative measures for the supervision of medical device manufacturing and supervise the implementation.

Article 5

The Food and Drug administration shall publish the information about the manufacture certificate and record for medical device manufacture lawfully in time. The applicant can search the approval progress and results; and the public can look up about the approval results.

Article 6

The medical device manufacturers shall be responsible for the quality of the medical devices

which are manufactured by them. For commissioned manufacture, the commissioning party shall be responsible for the medical devices manufactured.

Chapter II Manufacturing Approval and Filing Management

Article 7

Enterprises engaged in medical device manufacture shall meet the following conditions:

1. Manufacturing site, environmental conditions, manufacturing equipment, and professional technical personnel appropriate to the medical devices manufactured;
2. Institution undertaking the quality inspection on the medical devices manufactured or professional inspection personnel and inspection equipment;
3. Management system guaranteeing the quality of the medical devices;
4. After-sales service capability appropriate to the medical device manufactured;
5. Comply with the requirements specified in product R&D and manufacturing process documents.

Article 8

The enterprises engaged in Class II and Class III medical device manufacture shall apply for manufacture certificate to the food and drug regulatory authority of the provinces, autonomous regions or municipalities directly under the central government where it is located and submit the following documents:

1. A copy of Business License and Business Code Certificate;
2. A copy of *Registration Certificate for Medical Device* and product technical requirement of the applicant ;
3. A copy of the Identification Card of legal representative and responsible person of the enterprise;
4. A copy of Identification Card, academic and title certificate of responsible person of manufacture, quality and technology;
5. List of degree of employees for manufacture management and quality inspection;
6. Supporting documents on manufacturing site and the copies of the supporting documents of facilities and environment shall be also submitted based on the requirements of special manufacturing environment;
7. List of main manufacturing equipment and inspection equipment;

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8. Quality manual and procedure documents;
 9. Process flow chart;
 10. Authorization certification of responsible person;
 11. Other supporting documents.

Article 9

After receiving application, the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall handle respectively according to the following situations:

1. If the items applied are within the terms of reference, the application documents are complete and comply with the legal form, the application shall be accepted;
2. If the application documents are incomplete or do not comply with the legal form, the applicant shall be informed of all contents to be supplemented or corrected in one time on site or within 5 working days; if failing to inform the applicant within the specified time, the application documents shall be accepted from the receipt date;
3. If application documents exist with the error that can be corrected on the spot, the applicant is allowed to make rectification on the spot;
4. If the items applied are not within the terms of reference, the decision on non-acceptance shall be immediately made and the applicant shall be notified to apply with relevant administrative department;

Whether the application for Manufacture Certificate of Medical Device is accepted or not, the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall issue the notice of acceptance or notice of non-acceptance.

Article 10

The food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall review the application documents within 30 working days from the date of acceptance and conduct on-site inspection according to the requirements of the GMP for medical devices. On-site inspection shall be conducted according to the actual situation so as to avoid repeated inspection and the rectification time shall not be included in the review period.

For those complying with the specified conditions, the written decision on approval shall be made according to laws and the Manufacture Certificate for Medical Device shall be granted within 10 working days; for those not complying with the specified conditions, the written

decision on disapproval shall be made and the reasons shall be specified;

Article 11

The enterprises engaged in the Class I medical device manufacture shall file a record on the manufacturing of Class I medical device with the food and drug regulatory authority of the municipality consisting of districts where the enterprise is located and submit the copy of Filing Certificate for medical devices manufactured and relevant documents of the enterprises as specified in Article 8 of the Provisions (Item 2 excluded).

The food and drug regulatory authority shall review the completeness of the documents submitted by the enterprise on the spot; those complying with the specified conditions shall be filed and granted with the Filing Certificate for Manufacturing Class I Medical Device.

Article 12

In case the application for Manufacture Certificate for Medical Device is directly involved with the vital interest between the applicant and others, the food and drug regulatory authority shall inform the applicant and interested parties that they have the right to apply for hearing in accordance with relevant regulations prescribed by CFDA; for vital approval issues CFDA deems related to the public interest while conducting review and approval on Manufacture Certificate for Medical Device, the CFDA shall make an announcement to the society and hold a hearing.

Article 13

The valid period of Manufacture Certificate for Medical Device is 5 years, which shall indicate the certificate number, name of enterprise, legal representative, responsible person of the enterprise, domicile, manufacturing site, manufacturing range, certificate-issuing department, issuing date, valid period, and other matters.

The Manufacture Certificate for Medical Device shall be attached with registration form for medical device products manufactured, indicating the product name, registration number and other information.

Article 14

In case the manufacturing products are added, medical device manufacturer shall submit documents related to the contents of change to the original certificate-issuing department according to Article 8 of the Provisions.

If the added manufacturing products are beyond the original manufacturing range, the original certificate-issuing department shall conduct review and on-site inspection in accordance with Article 10 of the Provisions. For products meeting relevant regulations, the manufacturing

range stipulated in Manufacture Certificate for Medical Device shall be changed, and product information recorded in the registration form for medical device products manufactured.

If the added manufacturing products are within the original manufacturing range and have manufacturing process and manufacturing conditions similar to the product approved to manufacture, the original certificate-issuing department shall review the application documents. For products meeting relevant regulations, the product information shall be recorded in the registration form for medical device products manufactured; if the added manufacturing products have manufacturing process and manufacturing conditions that are materially different from the product approved to manufacture, the original certificate-issuing department shall conduct review and on-site inspection in accordance with Article 10 of the Provisions. For products meeting relevant regulations, the product information shall be recorded in the registration form for medical device products manufactured.

Article 15

For non-literal change to the manufacturing site, the medical device manufacturer shall apply for change of Manufacture Certificate for Medical Device with the original certificate-issuing department and submit documents involving the contents of changes according to Article 8 of the Provisions. The change application shall be reviewed by the original certificate-issuing department according to Article 10 of the Provisions; if necessary, on-site inspection shall be conducted, and the decisions for change shall be made within 30 working days. If a medical device manufacturer builds a manufacturing site in another province, autonomous region or municipality, a separate Manufacture Certificate for Medical Device shall be applied for.

Article 16

In case of change to the name of enterprise, legal representative, responsible person of enterprise or domicile or literal change to the manufacturing site, the medical device manufacturer shall within 30 working days after such change apply for change registration of Manufacture Certificate for Medical Device to the original certificate-issuing department and submit supporting documents granted by relevant departments. If the application documents are incomplete or do not comply with the legal form, the applicant shall be informed of all contents to be supplemented in one time.

Article 17

If the valid period of Manufacture Certificate for Medical Device is expired and needs to be renewed, the medical device manufacturer shall put forward the renewal application for Manufacture Certificate for Medical Device to the original certificate-issuing department 6 months prior to the expiration of the valid period.

The renewal application shall be reviewed by the original certificate-issuing department according to Article 10 of the Provisions; if necessary, on-site inspection shall be conducted

and decision for renewal shall be made before the expiration of the valid period of Manufacture Certificate for Medical Device. For those complying with the specified conditions, application for renewal shall be approved. For those not complying with the specified conditions, rectification shall be made within a specified period. For those not complying with the specified conditions after rectification, application for renewal shall be disapproved and the written decision on disapproval shall be made and the reasons shall be specified. If decision is not made within the specified period, the application for renewal shall be considered as approved.

Article 18

If the medical device manufacturer still existed after merger and split, it shall apply for change of approval according to the Provisions; if the medical device manufacturer has dissolved after merger and split, it shall apply for the cancellation of Manufacture Certificate for Medical Device; if the medical device manufacturer is new established after merger and split, it shall apply for Manufacture Certificate for Medical Device.

Article 19

If Manufacture Certificate for Medical Device is lost, medical device manufacturers shall immediately report to the original certificate-issuing department and publish the loss announcement on the media designated by the original certificate-issuing department. After 1 month expired since the loss announcement has been published, medical device manufacturers shall apply for regrant with the original certificate-issuing department. And the original certificate-issuing department shall grant the Manufacture Certificate for Medical Device after receiving the application for regrant.

Article 20

The number and the valid period of the Manufacture Certificate for Medical Device regrant due to change shall remain unchanged, while due to renewal, the number of that shall remain unchanged.

Article 21

If changes on the contents of the Filing Certificate for Class I Medical Device Manufacture take place, the filing shall be changed.

For the loss of the filing certificate, the medical device manufacturer shall apply for regrant with the original filing department.

Article 22

If the medical device manufacturer was investigated but not settled or served the administrative punishment decision but not yet fulfilled by food and drug regulatory authority due to illegal manufacture, the food and drug regulatory authority shall stop handle of the application submitted by such medical device manufacturer until the case is settled.

Article 23

In case the circumstances specified in the laws and regulations under which cancellation of the Manufacture Certificate for Medical Device shall be made exist or the medical device manufacturer apply for cancellation before its expiration, food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall cancel the Manufacture Certificate for Medical Device of the enterprise according to laws and publish on its website.

Article 24

Food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall establish the approval archives including the grant, renewal, change, regrant, withdrawal, and cancellation, etc. of the Manufacture Certificate for Medical Device.

Food and drug regulatory authority of the municipality consisting of districts shall establish the filing information archive for Class I medical device manufacture.

Article 25

Any unit or individual shall not fabricate, alter, buy and sell, lease, or lend Manufacture Certificate for Medical Device and Filing Certificate for Medical Device Manufacture.

Chapter III Commissioned Manufacture Management

Article 26

The commissioning party of the medical device manufacture shall be the domestic registration applicant or filing applicant of the medical device.

If the medical device commissioned for manufacture are domestic medical device not subject to the Special Procedure for the Examination and Approval of Innovative Medical Device, the commissioning party shall obtain the Manufacture Certificate of commissioned products or the Filing Certificate for Class I Medical Device Manufacture.

The commissioned party of the medical device manufacture shall be the domestic manufacturer who obtained the Manufacture Certificate of commissioned products or the Filing Certificate for Class I Medical Device Manufacture. The commissioned party shall be responsible for the quality of medical devices manufactured under commissioned manufacture.

Article 27

The commissioning party shall provide the commissioned party with quality management system documents and technical requirements registered or filed for the medical device products under commissioned manufacture, evaluate the manufacturing conditions, technical level and quality management capability of the commissioned party, verify the conditions and capability of the commissioned party for commissioned manufacture, and carry out guidance and supervision on the manufacture course and quality control.

Article 28

The commissioned party shall organize manufacture in accordance with the GMP for medical devices, compulsory standards, product technical requirements and commissioned manufacture contract and maintain the documents and records of all commissioned manufacture.

Article 29

The commissioning party and commissioned party shall sign commissioned manufacture contract which shall clearly determine the rights, obligations and responsibilities of both parties.

Article 30

In case of the commissioned manufacture of Class II and Class II medical devices, the filing for commissioned manufacture shall be conducted by the commissioning party to the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government where the enterprise is located; in case of the commissioned manufacture of Class I medical devices, the commissioning party shall put on record for the filing for commissioned manufacture to the food and drug regulatory authority of the municipality consisting of districts where the enterprise is located. For those complying with the specified conditions, the food and drug regulatory authorities shall grant the filing certificate for the commissioned manufacture of medical devices. The following documents shall be submitted as the filing for commissioned manufacture:

1. A copy of Registration Certificate or filing certificate for the commissioned manufacture of products under commissioned manufacture;
2. A copy of Business License and Business Code Certificate of commissioning party and

commissioned party;

3. A copy of Manufacture Certificate for Medical Device or the Filing Certificate for Class I Medical Device Manufacture of the commissioned party.
4. A copy of the Commissioned Manufacture Contract;
5. Authorization certification of the responsible person.

If the medical device commissioned for manufacture are domestic medical device not subject to the Special Procedure for the Examination and Approval of Innovative Medical Device, the commissioning party shall submit its Manufacture Certificate for Medical Device or the Filing Certificate for Class I Medical Device Manufacture; If the medical device commissioned for manufacture are domestic medical device subject to the Special Procedure for the Examination and Approval of Innovative Medical Device, supporting documents on the special examination and approval of innovative medical device shall be submitted.

Article 31

If Class II and Class II medical devices are commissioned for manufacture, the commissioned party shall go through relevant procedures in accordance with Article 14 of the Provisions and record related information on commissioned product in the registration form for medical device products manufactured.

If Class I medical devices are commissioned for manufacture, the commissioned party shall apply for the filing change of Class I medical device manufacture to the original filing department in accordance with Article 21 of the Provisions.

Article 32

When applying for the adding of information for medical device products which are commissioned for manufacturing or the filing change of Class I medical device manufacture, the commissioned party shall also submit the following documents in addition to the documents specified in the Provisions:

1. A copy of Business License and Business Code Certificate of commissioning party and commissioned party;
2. A copy of Manufacture Certificate for Medical Device or the Filing Certificate for Class I Medical Device Manufacture of the commissioned party.
3. A copy of filing certificate for the commissioned manufacture of medical devices;
4. A copy of Commissioned Manufacture Contract;

5. Sample instruction for use and labels to be used by the medical devices manufactured under commission;
6. Statement of commissioning party on recognition of the quality management system of the commissioned party;
7. Self-assurance statement of commissioning party on the quality of medical device manufactured under commission, sales and after-sales service responsibility;

If the medical device commissioned for manufacture are domestic medical device not subject to the Special Procedure for the Examination and Approval of Innovative Medical Device, the commissioning party shall submit its Manufacture Certificate for Medical Device or the Filing Certificate for Class I Medical Device Manufacture; If the medical device commissioned for manufacture are domestic medical device subject to the Special Procedure for the Examination and Approval of Innovative Medical Device, supporting documents on the special examination and approval of innovative medical device shall be submitted.

Article 33

The words “commissioned manufacture” and the commissioned manufacture deadline shall be indicated on the registration form for medical device products manufactured for the Manufacture Certificate for Medical Device and the Filing Certificate for Class I Medical Device Manufacture.

Article 34

In addition to meeting relevant regulations, the instruction for use, labels and packaging marks of the medical devices under commissioned manufacture shall also indicate the name of the enterprise, domicile, manufacturing site, and Manufacture Certificate number or number of filing certificate for manufacture of the commissioned party.

Article 35

In case that the commissioned manufacture is terminated, the commissioning party and the commissioned party shall report to the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government where they are located respectively or the food and drug regulatory authority of the municipality consisting of districts.

Article 36

For the same medical device product, only one medical device manufacturer can be commissioned for manufacture during the same period, except for the absolute holding enterprises.

Article 37

High-risk implantable medical devices shall not be commissioned for manufacture. The specific catalog shall be developed, adjusted by CFDA and published.

Chapter IV Manufacturing Quality Control

Article 38

Medical device manufacturers shall establish quality management system and keep it in effective operation according to the requirements of the GMP for medical devices.

Article 39

Medical device manufacturers shall carry out training on knowledge concerning laws, regulations, rules, and standards for medical devices and keep training records.

The operators for manufacture shall have appropriate theoretical knowledge and practical operating skills.

Article 40

Medical device manufacturers shall organize manufacture in accordance with the product technical requirements registered or filed and make sure the medical devices manufactured shall comply with compulsory standard and the product technical requirements registered or filed. The delivered medical devices shall be qualified in inspection and attached with the supporting document of conformity.

Article 41

Medical device manufacturers shall periodically conduct comprehensive self-inspection on the operation of quality management system according to the requirements of the GMP for medical devices and submit annual self-inspection report to the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government where the enterprise is located before the end of each year.

Article 42

In case that the manufacturing conditions change, the requirements of the quality management system for the medical device are not met any more, the medical device manufacturer shall immediately take rectification measures; in case that the safety and effectiveness of medical devices are affected, the medical device manufacturer shall immediately stop manufacture and

distribution activities and report to the food and drug regulatory authority at county level where it is located.

Article 43

In case of re-organizing the manufacture of the medical device products that the manufacture has been suspended for more than one year, the medical device manufacturer shall submit written report to the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government where the enterprise is located, and shall not resume manufacture until inspected as complying with requirements.

Article 44

In case that medical device manufacturer does not have the original manufacturing conditions and meet the filing information as well as cannot be contacted, the Manufacture Certificate for Medical Device shall be cancelled or the status of filing information for Class I medical device manufacture shall be indicated and be announced to the public.

Article 45

Medical device manufacturers shall organize manufacture at approved or filed manufacturing site, maintain manufacturing equipment, process devices, inspection instruments and other facilities and keep them in normal operation.

Article 46

Medical device manufacturers shall strengthen procurement management, establish supplier inspection system, evaluate suppliers and ensure the compliance of procured products with legal requirements.

Article 47

Medical device manufacturers shall record the process of material procurement, manufacture, inspection, etc. Such record shall be true, accurate, complete and traceable.

Article 48

The state encourages medical device manufacturers to employ advanced technology to establish complete information management system.

Article 49

In case that major quality accidents occur to the medical device manufactured, it shall be reported to the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government where the enterprise is located within 24 hours, and then the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall immediately report to CFDA.

Chapter V. Supervision and Administration

Article 50

The food and drug regulatory authority shall implement classification and grading management on the manufacturing of medical device products according to the principle of risk management.

Article 51

The food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall formulate supervision and inspection plan on medical device manufacturer within the administrative region, and explicitly determine the focus, inspection frequency and coverage of the inspection on relevant medical device manufacturers.

Article 52

The main contents of the supervision and inspection on medical device manufacturers are the specific situations of the medical device manufacturers in implementing relevant laws, regulations, rules, specifications and standards, etc. The focus of inspection shall be in compliance with Article 53 of the Regulations for the Supervision and Administration of Medical Devices.

Article 53

For supervision and inspection conducted by the food and drug regulatory authority, the inspection scheme shall be prepared, clearly defining inspection standard, and keeping a record of field inspection according to facts. Inspection results shall be informed to the enterprise inspected in written. In case that rectification is required, the rectification contents and time limit shall be clarified. Follow-up inspection shall be implemented.

Article 54

The food and drug regulatory authority shall strengthen sampling inspection on the medical devices.

The food and drug regulatory authorities at provincial level and above shall publish the medical device quality announcement according to the results of the sampling inspection.

Article 55

The food and drug regulatory authority can implement the unannounced inspection on the medical device manufacturer where may exist the problem of product safety or record of bad behavior found by the complaints and reporting or other information display as well as routine supervision and inspection.

Article 56

In any of the following circumstances, the food and drug regulatory authority shall make responsibility interview with the legal representatives or responsible persons of the medical device manufacturer:

1. If serious safety hazards exists within manufacture;
2. If its products are complained about or exposed by the media or repeatedly by the masses due to safety issues;
3. If the credit rating of enterprise is with bad credit record;
4. Other circumstances under which the food and drug regulatory authority shall also consider it necessary to conduct the interviews.

Article 57

The local food and drug regulatory authority shall establish the supervision and administration archive for the medical device manufacturers within the administrative region. Supervision and administration archive shall include the registration and filing for medical device products, certificate and filing for manufacture, commissioned manufacture, supervision and inspection, sampling inspection, adverse event monitoring, recall, record of bad behavior, complaints and reporting, and other contents.

Article 58

CFDA shall establish a unified information platform for the supervision and administration on medical device manufacture and the local food and drug regulatory authority at all levels shall

strengthen information construction and ensure the information link.

Article 59

The local food and drug regulatory authority at all levels shall conduct credit rating on medical device manufacturers, create credit file according to the relevant records of the supervision and administration on medical device manufacturers. For enterprises with bad credit record, the frequency of inspection shall be increased.

For the enterprises included in the “black list”, they shall be dealt with according to relevant regulations of CFDA.

Article 60

Any individual and organization finding any illegal manufacture activity of medical device manufacturer shall have the right to report to the food and drug regulatory authority. The food and drug regulatory authority shall timely verify and deal with the reporting. If the reporting is verified as true after investigation, the reporter will be rewarded according to relevant laws and regulations.

Chapter VI Legal Responsibilities

Article 61

In any of the following circumstances, punishment shall be imposed on the manufacturer according to Article 63 of the Regulations for the Supervision and Administration of Medical Devices:

1. Manufacturing the Class II and Class III medical devices without obtaining Registration Certificate for Medical Device ;
2. Engage in the activities of manufacturing the Class II and Class III medical devices without obtaining approval;
3. Manufacturing the Class II and Class III medical devices beyond the manufacturing range or inconsistent with the registration form for medical device products manufactured;
4. Manufacturing the Class II and Class III medical devices on disapproved manufacturing site.
5. The commissioned party continues the manufacturing of Class II and Class III medical devices after such commission terminated.

Article 62

For manufacturers with Manufacture Certificate for Medical Device expired but not renewed still engage in manufacturing of medical device, they shall be punished according to Article 63 of the Regulations for the Supervision and Administration of Medical Devices.

Article 63

In case of obtaining the Manufacture Certificate for Medical Device by providing spurious materials or adopting other cheating means, punishment shall be imposed according to Item I of Article 64 of the Regulations for the Supervision and Administration of Medical Devices.

Article 64

In case of engaged in the manufacture activities of Class I medical devices without filing with food and drug regulatory authority according to relevant regulations, punishment shall be imposed according to Item I of Article 65 of the Regulations for the Supervision and Administration of Medical Devices. In case of providing spurious materials for filing, punishment shall be imposed according to Item II of Article 65 of the Regulations for the Supervision and Administration of Medical Devices.

Article 65

In case of fabricating, altering, buying and selling, leasing or lending the Manufacture Certificate for Medical Device, punishment shall be imposed according to Item II of Article 64 of the Regulations for the Supervision and Administration of Medical Devices.

If fabricating, altering, buying and selling, leasing or lending the filing certificate for the manufacturing of medical devices, the local food and drug regulatory authority above county level shall order the enterprise to make rectification and impose a fine of less than RMB 10,000.

Article 66

In any of the following circumstances, the medical device manufacturer shall be punished according to Article 66 of the Regulations for the Supervision and Administration of Medical Devices:

1. Products manufactured not in compliance with the compulsory standards or product technical requirements registered or filed;
2. The medical device manufacturers fail to organize manufacture according to product technical requirements registered or filed, to establish quality management system and

maintain its effective operation according to the Provisions;

3. Commission the enterprise not meeting the conditions as specified in the Provisions to manufacture medical device or not conduct management on the manufacture behaviors of the commissioned party.

Article 67

In case that medical device manufacturer fails to rectify, stop manufacture and report according to the Provisions when the manufacturing conditions change and do not meet the requirements of the quality management system for the medical device any longer, punishment shall be imposed on the enterprises according to Article 67 of the Regulations for the Supervision and Administration of Medical Devices.

Article 68

In case that the self-inspection report on the operation of the quality management system of the enterprise is not submitted according to relevant regulations by the medical device manufacturer to the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government, punishment shall be imposed on the manufacturers based on Article 68 of the Regulations for the Supervision and Administration of Medical Devices.

Article 69

In any of the following circumstances, punishment shall be imposed on the manufacturers by the food and drug regulatory authority above county level by giving warning, ordering to make rectification within specified time, and imposing a fine of less than RMB 30,000:

1. The medical devices delivered aren't inspected according to relevant regulations;
2. The medical devices delivered aren't attached with the supporting documents of conformity according to relevant regulations;
3. Failure to handle the registration procedures for the change of Manufacture Certificate for Medical Device according to Article 16 of the Provisions;
4. Failure to handle the procedures for the filing for commissioned manufacture;
5. Re-organize manufacture of medical device product that has been stopped for more than one year as well as no similar product in manufacturing without being inspected by the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government where the enterprise is located or the food and drug regulatory authority of the municipality consisting of districts as meeting the requirements;

6. Cover up the truth of relevant situations, provide spurious documents or refuse to provide the true information on its activities to the food and drug regulatory authority in charge of supervision and inspection.

For the circumstances as listed in preceding clause with serious degree or causing harmful consequences, and being the violations to the Regulations for the Supervision and Administration of Medical Devices, punishment shall be imposed according to the Regulations for the Supervision and Administration of Medical Devices.

Chapter VII Supplementary Provisions

Article 70

The manufacturer of export medical devices shall ensure their import medical devices complying with the requirements of importing country (region), and shall file for relevant information on products to the food and drug regulatory authority of the municipality consisting of districts where the enterprise is located.

For the manufacturer accepting the commissioning manufacture of medical devices to be marketed overseas, it shall obtain the third party certification for medical device quality management system or manufacture filing or certificate for similar product within the territory of the People's Republic of China.

Article 71

The format and numbering rules for Manufacture Certificate for Medical Device and Filing Certificate for Class I Medical Device Manufacture shall be uniformly formulated by CFDA.

Manufacture Certificate for Medical Device shall be printed by the food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government.

The numbers of Manufacture Certificate for Medical Device shall be arranged in the following form: × SYJX Manufacture Certificate No. ×××××××. Among which:

The first × shall be the abbreviation of the provinces, autonomous regions and municipalities directly under the central government where the approval department is located; The second × to the fifth × shall be the year of approval;

The second × to the fifth × shall be the serial number of approval;

The numbers of Filing Certificate for Class I Medical Device Manufacture shall be arranged in the following form: ×× SYJX Filing Certificate No. ×××××××. Among which:

The first × shall be the abbreviation of the provinces, autonomous regions and municipalities directly under the central government where the filing department is located;

The second × shall be abbreviation of the municipality consisting of districts where the filing department is located;

The third × to the sixth × shall be the year of filing;

The seventh × to the tenth × shall be the serial number of filing;

Article 72

The Provisions shall come into force from October 1, 2014. The Provisions for Supervision of Medical Device Manufacture (The former CFDA Decree No. 12) published on July 20, 2004 shall be simultaneously annulled.