Production Supervision and Administration of Medical Devices  
(State Food and Drug Administration Order No. 7)  

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State Food and Drug Administration Order  

No. 7  

"Production Supervision and Administration of Medical Devices" was June 27, 2014 by the State Food and Drug Administration executive meeting examined and approved, are hereby promulgated and shall be from October 1, 2014. 

Secretary Zhang Yong,  
30 July 2014  

Production Supervision and Administration of Medical Devices  

Chapter I  

In order to strengthen the supervision and management of medical device manufacturing, medical device manufacturing behavioral norms, to ensure that medical devices are safe and effective, according to the "Medical Devices Regulations" formulated.  

The second article in the territory of People's Republic of China engaged in medical equipment production activities and supervision and management, shall comply with these measures.  

Article State Food and Drug Administration is responsible for the national medical device manufacturing supervision and management. Above the county level food and drug administration department is responsible for the administrative regions of medical equipment production supervision and management.  

Higher food and drug administration department is responsible for directing and supervising subordinate food and drug administration departments to carry out the supervision and management of medical device manufacturing.  

Article State Food and Drug Administration medical device manufacturers to develop and oversee the implementation of quality management practices.  

Article food and drug administration department shall promptly publish medical device manufacturing license and registration information. Applicants can check the progress of the approval and approval of the results; public inspection approval results.  

Article VI of the medical device manufacturer should be responsible for the quality of the production of medical devices. Commissioned production, commissioned by the commissioning party is responsible for the production of medical devices quality.
Chapter II production license and record management

Article VII engaged in the production of medical devices, shall meet the following conditions:
(a) the production of medical devices to the production site, environmental conditions, production
equipment, and professional and technical personnel;
(b) for the production of medical equipment for quality testing institution or full-time inspectors
and inspection equipment;
(c) to ensure that medical device quality management system;
(d) the ability to service and production of medical devices compatible;
(v) compliance with product development, manufacturing process documents required Claim.

Article VIII start the second class, third class medical device manufacturers, it shall apply for
production licenses to the provinces, autonomous regions and municipalities directly under the food
and drug supervision and management departments, and submit the following information:
(a) the business license, organization code certificate copy pieces;
(b) the applicant holds a certificate of registration by the production of medical equipment and
product technology requirements copies;
(c) legal representative, responsible person a copy of proof of identity;
(d) production, quality and technical director of identity, education, job title certificate;
(five) production management, quality inspection posts practitioners qualifications, titles list;
supporting documents (six) production site, with special production requirements should also be
submitted facilities, environmental copying documents pieces;
(seven) main production equipment and testing equipment catalog;
(eight) quality manual and procedures;
nine) flow chart;
(ten) Attn authorization certificate;
(11) other supporting information.

Article IX provinces, autonomous regions and municipalities directly under the food and drug
administration department after receiving the application shall be made in accordance with the
following conditions were treated:
(a) apply for matters within its terms of reference, the application materials are complete and meet
the statutory form, shall accept the application;
(b) the application materials are incomplete or do not meet the statutory form, on the spot or
within five working days, inform the applicant needs correction entirety, fails to inform, from the date of
receipt of application materials shall be accepted;
(c) The application information can be corrected on the spot errors exist, the applicant shall be
allowed on the spot corrections;
(4) Application matter does not belong to the purview of the department, shall immediately make a
decision of rejection, and inform the applicant of the application to the relevant authorities .

Provinces, autonomous regions and municipalities food and drug supervision and management
departments to accept or not accept medical equipment production license application, it shall issue a
notice to accept or not admissible.

From Article 10 provinces, autonomous regions and municipalities food and drug administration
department shall accept the 30 working days for review of application materials and conduct on-site
verification in accordance with the Medical Device Good Manufacturing Practice requirements. On-site
verification should be based on the situation, to avoid duplication of verification. Require rectification,
the rectification time is not included in the audit timeframe.

Comply with the conditions, according to a written decision to grant permission, and in 10 working
days issue a "medical device manufacturing license"; do not meet the requirements, the written decision of disapproval, and explain the reasons.

Article XI opened the first class medical device manufacturer, shall apply to the food and drug administration departments and municipal districts of the first class seat medical equipment production record, held by the record companies to submit production of medical equipment registration certificate copy parts and the way the information specified in Article VIII (except for the second).

Food and drug administration departments shall submit the spot of the enterprise carried out to check the integrity of data, compliance with the conditions to be filed, sent first class medical equipment production record certificate.

Article XII of the medical device manufacturing license applications involve significant direct relationship between the applicant and the interests of others, food and drug administration departments shall inform the applicant, interested parties in accordance with the relevant laws and regulations and the State Food and Drug Administration for the enjoyment right to apply for a hearing; in the medical device manufacturing license review, the Food and Drug administration considered significant licensing matters involving the public interest, should be announced to the public, and hold a hearing.

Article XIII "medical equipment production license" is valid for five years, specifying the license number, business name, legal representative, responsible person, residence, address production, production range, the issuing authority, date of issue and effective duration and other matters.

"Medical equipment production license" attached to the medical device manufacturing product registration form, specifying product name, registration number and other information.

Article XIV increased production of products, medical equipment manufacturing enterprises shall apply to the issuing authorities to submit information specified in Article VIII of this approach involves changing the content.

Application to increase production of the product does not belong to the scope of the original production, the original issuing department shall conduct an audit in accordance with the provisions of Article 10 and to conduct on-site verification of compliance with the conditions change, "medical equipment production license," stated production range , and published information in the medical device manufacturing product registration table.

Apply to increase the production of the products are original range, and with the production process and production conditions of the original permit requirements produce products similar to the original issuing department shall conduct an audit of the claims data, comply with the conditions in the medical device manufacturing product registration form in published product information; Production and production conditions of the original permit substantive requirements for the production of different products, it should be reviewed in accordance with the provisions of Article 10 and to conduct on-site verification of compliance with the conditions in the medical device manufacturing product registration tables published product information.

ARTICLE 15 address non-textual changes, should apply to the issuing authority for medical device manufacturing license changes and submit the information specified in Article VIII of this approach involves changing the content. Original issuing department shall audit in accordance with the provisions of Article 10 and to carry out on-site inspections, made the decision not to grant a change or changes in 30 working days. Medical device manufacturers across provinces, autonomous regions and municipalities to set up production sites, medical equipment production license shall apply separately.

Article 16 An enterprise name, legal representative, responsible person, residence address textual changes or production changes, medical equipment manufacturing enterprises shall, within 30 working
days after the change, the original issuing department for "medical equipment production license"
"Change registration and submit supporting information relevant departments. Original issuing
department shall promptly process the change. Changes to the data are incomplete or do not meet the
prescribed form of review, shall inform all the content requires a correction.

Article XVII "medical equipment production license" expiry continuation, medical equipment
manufacturing enterprises shall before the expiry of six months, the original issuing department,
"medical equipment production license" continues to apply.

Original issuing department shall follow the provisions of the Article 10 review of the renewal
application, conduct on-site verification, if necessary, before the expiry of the "medical equipment
production license" is valid decision on whether to grant continuity. Comply with the conditions of grant
continue. Does not meet the prescribed conditions, shall order rectification; after rectification still meet
the specified conditions, is not renewed, and a written explanation. Late decided not to be deemed as
granting continue.

Article XVIII of separation, consolidation and subsisting medical device manufacturer, in accordance
with these Regulations shall apply for permission to change; due to corporate separation, merger and
dissolution of the medical device manufacturer, shall apply for cancellation of "medical device
manufacturing license"; due business division, merger and the newly established medical device
manufacturer shall apply for "medical equipment production license."

Article XIX, "medical equipment production license" loss statement posted on the missing, medical
device manufacturers in the original issuing department shall immediately specified media. Missing from
the date of publication of the statement after the expiry of one month, apply to the issuing authority for
a replacement. Timely replacement of the original issuing department, "medical equipment production
license."

Diershitiao change, replacement of "medical device manufacturing license" number and expiration
date unchanged. Continuation of "medical device manufacturing license" No. unchanged.

Twenty-one of the first class of medical device manufacturers to change the contents of the record
evidence, it should change the record.

Registration certificate is lost, medical equipment manufacturing enterprises should promptly apply
to the filing department for replacement procedures.

Article 22 medical device manufacturers due to illegal production of food and drug administration
has been filed but not yet closed the investigation department, or receive administrative punishment
decision but not yet fulfilled, food and drug supervision and administration department shall suspend
the license until the case is disposed of.

Twenty-three medical device manufacturers have laws and regulations should be canceled
circumstances, or validity under corporate initiative but canceled, provinces, autonomous regions and
municipalities Food and Drug administration it shall cancel its "medical equipment production license"
"and to be published on the website.

Twenty-four provinces, autonomous regions and municipalities food and drug supervision and
management departments should establish a "medical device manufacturing license" issuance, renewal,
modification, replacement, revocation and cancellation of licenses and other files.

Food and drug supervision and management departments and municipal districts shall establish a
first class medical equipment production record information file.

Article 25 Any unit or individual shall forge, alter, buy or lease, lend, "medical equipment
production license" and medical equipment production record certificate.
Chapter III commissioned the production management

Twenty-six commissioned the production of medical devices should be commissioned by the commissioning party's domestic production of medical equipment registrant or filing person. Which commissioned the production of innovative medical devices are not in accordance with the special approval process within the medical device approval, the commissioning party shall obtain commissioned the production of medical equipment production license or apply for a first class medical equipment production record.

Commissioned the production of medical devices trustees should be entrusted with the production of medical devices to obtain the appropriate license or production range of production handled first class medical equipment production record of domestic manufacturing enterprises. Trustees entrusted with negative mass production of medical equipment corresponding responsibility.

Article 27 of the Principal shall provide contract manufacturing of medical devices quality management system documents registered or filed and technical requirements to the trustees, the production conditions, technical level and quality management to assess the ability of the trustees, trustees confirmed has entrusted the production conditions and capabilities, and the production process and quality control guidance and supervision.

Article 28 The trustees shall, in accordance medical device manufacturing quality management standards, mandatory standards, technical requirements and commissioned production contract production, and save all documents and records entrusted production.

Article 29 of the principal and trustees should entrust production contract signed, specifying the rights, obligations and responsibilities.

Article 30 commissioned the production of the second class, third class medical devices, the client commissioned the production of the record shall go to the provinces, autonomous regions and municipalities food and drug supervision and management departments; commissioned the production of the first class of medical devices, the commissioning party shall apply to the food and drug supervision and management departments and municipal districts for commission seat production record. Comply with the conditions, food and drug administration department shall issue a certificate filed commissioned the production of medical devices.

When filing shall submit the following information:
(a) commissioned the production of medical devices registration certificate or a copy of the record evidence;
(b) the principal and trustees business license and organization code certificate;
(c) the trustees "medical equipment production license "or first class medical equipment production record certificate copy;
(four) commissioned the production of a copy of the contract;
(five) Attn attorney.
"Medical Device Manufacturing License" or first class medical device manufacturers commissioned the production of a copy of the record evidence does not belong to innovative medical devices in accordance with the approval of the special approval process for medical devices territory shall also submit the commissioning party; are particularly innovative medical device approval in accordance with the program within the medical device approval, shall be submitted for approval of innovative medical devices in particular supporting information.

Article 31 entrusted the production of the second category, Class III medical devices, the trustees should approach the relevant formalities in accordance with the provisions of Article 14, which contains information entrusted the production of medical device manufacturing product registration table.
Entrusted with the production of the first class of medical devices, the trustees shall be in accordance with the provisions of Article 21, apply to the department for filing the first class of medical equipment production record changes.

Article 32 trustees handle increased production and product information entrusted or first class medical device manufacturers to change when the record, in addition to the information submitted in line with the provisions of these Measures, should also submit the following information:
(a) the principal and the trustees of the business license, organization code certificate;
(b) the trustees' medical equipment production license "or first class medical equipment production record certificate copy;
(c) Principal commissioned the production of medical devices registration certificate copy;
(four) commissioned production copy of the contract;
(five) commissioned the production of medical devices to be adopted instructions and labels proofs;
(vi) a statement of the Principal trustees approved quality management system;
(seven) Principal commissioned the production of medical devices on the quality, sales and after-sales The self-service obligations assurance statement.
"Medical Device Manufacturing License" or first class medical device manufacturers filing a copy of the certificate does not belong to the Trustee in accordance with the production of innovative medical devices within the special approval process for approval of medical devices, shall also submit the commissioning party; are particularly innovative medical device approval in accordance with the program within the medical device approval, shall be submitted for approval of innovative medical devices in particular supporting information.

Article 33 of the trustees' medical equipment production license "production product registration form and the first class medical device manufacturers in the registration certificate shall be entrusted with the production of products marked" fiduciary production "and the fiduciary production deadlines.

Article 34 of the instructions commissioned the production of medical devices, in addition to the label shall comply with the relevant provisions, the trustees should also indicate the business name, residence, address the production, manufacture or production license number registration certificate number.

Article 35 Upon termination of contract manufacturing, principal and trustees should be reported promptly to the municipal food and drug administration departments of the provinces, autonomous regions, municipalities or districts.

Article 36 in the same period of the commissioning party can use the same medical products commissioned a medical device manufacturer (except absolute holding companies) for production.

Article 37 of the implantable medical device having a high risk of not entrust the production of specific directory formulated by the State Food and Drug Administration, adjusted and published.

Chapter IV production quality management

Article 38 The medical device manufacturer should be managed in accordance with the production quality medical equipment specifications, establish and maintain an effective quality management system running.

Article 39 of the medical device manufacturer of medical devices should be carried out laws, regulations, rules, standards, knowledge, training, and establish a training file.

Production jobs operator shall have appropriate theoretical knowledge and practical skills.
Article 40 of the medical device manufacturer in accordance with the registration or filing shall be the technical requirements of production to ensure the factory's compliance with mandatory standards and medical devices registered or filed technical requirements. Medical equipment factory should have passed the test along with compliance certification document.

41 medical device manufacturers should periodically in accordance with the Medical Device Good Manufacturing Practice requirements of the quality management system to conduct a comprehensive self-examination, and by the end of the annual municipal food to the provinces, autonomous regions, municipalities or districts The drug regulatory departments to submit annual self reports.

Production conditions Article 42 medical device manufacturer changes, no longer meets the medical device quality management system requirements, medical device manufacturers should take immediate corrective measures; may affect medical devices safe and effective, it should immediately stop production activities and to the county level food and drug administration department.

Article 43 of the Medical Devices continuous production for more than one year and no similar products in production, re-production, medical device manufacturers must report in writing in advance of municipal food and drug supervision and management departments of the provinces, autonomous regions, municipalities or districts, after verification of compliance with the requirements behind the resume production.

Article 44 does not have the medical equipment manufacturer original production license conditions or inconsistent with the record information, and can not get in touch, or for the record by the original issuing department of publicity after the cancellation of the law, "medical equipment production license" or at production record information in a class of medical devices to be marked, to the public.

Article 45 of the medical device manufacturer should be produced in licensed or record production sites, production equipment, process equipment and testing instruments and other facilities and equipment maintenance to ensure their normal operation.

Article 46 The medical device manufacturer shall strengthen procurement management, the establishment of supplier audit system, evaluation of suppliers to ensure that purchased product meets the statutory requirements.

Article 47 of the medical device manufacturer should purchase of raw materials, production, testing and other processes for recording. Records shall be true, accurate, complete and comply with traceability requirements.

Article 48 The State encourages enterprises to adopt advanced medical equipment manufacturing technology to establish information management systems.

Article 49 of the medical device manufacturer of medical devices produced major quality accidents should be reported within 24 hours of the provinces, autonomous regions and municipalities directly under the food and drug supervision and management departments, provinces, autonomous regions, municipalities directly under the food and drug administration department shall immediately report State Food and Drug Supervision Administration.

Chapter V Supervision and Administration

Article 50 of the Food and Drug administration in accordance with the risk management principles for medical device manufacturers to implement classification management.
Article 51 provinces, autonomous regions and municipalities directly under the food and drug administration departments shall supervise the preparation of medical device manufacturers inspection plan of the administrative regions, to determine the focus of medical device regulation, inspection frequency and coverage, and supervise their implementation.

Article 52 of the supervision and inspection of medical device manufacturing medical device manufacturers should check the implementation of the laws, regulations, rules, norms, standards and other requirements, the matters specified in Article 53 of the focus check "Medical Devices Regulations."

Article 53 of the Food and Drug Administration supervision and examination sector organizations, should develop inspection programs, inspection standards clear, accurate records of on-site inspection, the inspection results in writing inform the inspection business. Require rectification, rectification content should be clear and rectification period, and implement follow-up examination.

Article 54 of the Food and Drug administration departments shall strengthen the random testing of medical devices.

The provincial food and drug administration department shall promptly publish a notice under medical device quality random inspection conclusions.

Article 55 complaint or other information display as well as daily supervision and inspection found that there may be security risks of medical equipment products manufacturing enterprises, there are records of misconduct or medical device manufacturers, food and drug supervision and management departments can implement flight inspection.

Article 56 of the following circumstances, the food and drug administration departments of the medical device manufacturer's legal representative or person in charge of the responsibility for corporate interviews:
- the presence of (a) the production of serious safety hazards;
- (b) Production products due to quality problems or complaints reported by several media exposure;
- (c) for the bad credit credit rating companies;
- (d) Food and Drug administration considers necessary to carry out the responsibility to interview other circumstances.

Article 57 of the local food and drug administration departments at all levels shall establish the administrative areas of medical device manufacturers regulatory files. Regulatory file should include the medical device manufacturer product registration and filing, licensing and record production, commissioned production, supervision and inspection, sampling and testing, monitoring of adverse events, product recalls, bad behavior and complaint records and other information.

Article 58 The State Food and Drug Administration medical device manufacturers to establish a unified information platform for the supervision and management, local food and drug administration departments at all levels should strengthen the information technology, to ensure that the information convergence.

Article 59 local food and drug administration departments at all levels should be based on the records of medical device manufacturers supervision and management of medical equipment manufacturing enterprises credit evaluation, establish credit files. For businesses with bad credit records, inspection frequency should be increased.

Of "blacklisted" companies, implemented in accordance with the relevant provisions of the State Food and Drug Administration's.
Article 60 individuals and organizations find medical device manufacturers for illegal production activities, the right to food and drug supervision and management departments to report, food and drug supervision and administration department shall verify and deal with. Be verified, shall be rewarded according to relevant regulations.

Chapter VI Legal Liability

Article 61 of the following circumstances, in accordance with Article 63 of the "Medical Devices Regulations" provides penalties:
(a) the production of medical equipment without obtaining the registration certificate of the second class, third class medical devices;
(b) engage in unauthorized II and Class III medical devices production activities;
(iii) production beyond the scope of production or product and medical device manufacturers produce products stated in the registration form is inconsistent second class, third class medical instruments
(four) in unauthorized production sites producing the second category, Class III medical devices;
(five) II and Class III medical devices produced after the commission terminated fiduciary trustees continue to produce the product.

Article 62, "medical equipment production license" after the expiry, the law did not apply for renewal, still continue to engage in the production of medical devices, shall be punished in accordance with Article 63 of the "Medical Devices Regulations" requirement.

Article 63 provides false information or by other fraudulent means to obtain "medical equipment production license", in accordance with the first paragraph of Article 64 of the "Medical Devices Regulations" punishment.

Provide false information when filing; Article 64 engaged in production activities first class medical device failing to be filed with the Food and Drug administration, according to "Medical Devices Regulations," the first paragraph of Article 65 shall be punished, in accordance with the provisions of Article 65, paragraph 2 of the "Medical Devices Regulations" punishment.

Article 65 forged, altered, sold, leased, lent "medical equipment production license", in accordance with the provisions of the second paragraph of Article 64 "Supervision and Regulation of Medical Devices" punishment.

Forged, altered, sold, leased, lent medical equipment production record certificate by the Food and Drug Administration or above the county department shall order correction, a fine of 10,000 yuan.

Article 66 of the following circumstances, in accordance with Article 66 of the "Medical Devices Regulations" provides penalties:
(a) production does not meet the mandatory standards or does not comply with the registration or filing of the technical requirements of; medical devices
(two) medical device manufacturers are not in accordance with the registration, filing products and technical requirements of production, or not established quality management system in accordance with the provisions of these Measures and maintain effective operation;
(c) commission does not have the conditions stipulated The production on the production of medical devices or not the behavior of the trustees to manage.

Production conditions Article 67 medical device manufacturer changes, no longer meets the medical device quality management system requirements, this approach is not in accordance with the provisions of rectification, to stop production of the report, in accordance with the sixty-seventh "Supervision and Regulation of Medical Devices" provisions of the punishment.
Article 68 of the medical device manufacturer failing to submit the corporate quality management system operation self report to the municipal food and drug administration departments provinces, autonomous regions, municipalities or districts, according to the "Supervision and Regulation of Medical Devices" Article 68 shall be punished.

Article 69 of the following circumstances, above the county level food and drug supervision and management departments to give a warning, ordered to make corrections, and may impose a fine of 30,000 yuan:
(a) medical equipment factory inspection is not conducted in accordance with the provisions;
(b) is not accompanied by a qualified medical instrument factory documents as prescribed;
(c) does not apply for the "medical equipment production license" change of registration in accordance with the provisions of Article XVI of the way;
(d) is not in accordance with the regulations commissioned to produce the record procedures;
(e) medical products and no more than one year of continuous discontinuation of similar products in the industry, without the municipal food and drug administration department to verify the location of the provinces, autonomous regions, municipalities or districts that meet the requirements to resume production;
(six) to supervise and inspect the food and drug supervision and management departments to conceal the situation, providing false information or refuse to provide a true reflection of its activities information.

There are circumstances listed above, serious or harmful consequences, constitutes a breach of the relevant provisions "Supervision and Regulation of Medical Devices", in accordance with the provisions of "Supervision and Regulation of Medical Devices" punishment.

Chapter VII Supplementary Provisions

Article 70 The production and export of medical devices must ensure that the production of medical equipment to meet the requirements of the importing country (region), and product-related information filed with the municipal seat of the Food and Drug administration districts.

Production companies to accept overseas enterprises listed overseas sales commissioned the production of medical devices, medical equipment shall obtain third-party certification of quality management system, or similar products within the production license or registration.

71 "medical equipment production license" and the first class medical device manufacturers to develop a unified format of filing the certificate by the State Food and Drug Administration.
"Medical Device Manufacturing License" provinces, autonomous regions and municipalities Food and Drug administration printed.

The presentation of "medical equipment production license" number is: X XXXXXXXX Food and Drug Administration firearms production number. Where:
X represents the first license department referred to the provinces, autonomous regions and municipalities; second to five X represents a 4-digit year license;
sixth to nine X represents a 4-digit license serial number.

The presentation of the first class of medical equipment production record certificate for the record number: XX SFDA production equipment XXXXXXXX number. Where:
X represents the first record department referred to the location of the provinces, autonomous regions and municipalities;
short second X represents the location of the record department of the municipal districts administrative regions;
third to record six X represents a 4-digit year;
first seven to ten X filed on behalf of four-digit serial number.
Article 72 These Measures shall go into effect October 1, 2014. July 20, 2004 announced the "Production Supervision and Administration of Medical Devices" (former State Food and Drug Administration Order No. 12) shall be repealed simultaneously.