1. Scope

These rules are used to regulate the certification body to carry out medical device quality management system certification activities in China.

2. Certification criteria

GB/T 42061-2022/ISO 13485:2016 "Medical devices – Quality management system – Requirements for use in regulations" standard is the basis for certification.

3. Basic requirements for certification auditors

3.1 The certification auditor shall obtain the QMS registration qualification issued by the Certification Personnel Registration Agency (CCAA) determined by the CNCA, participate in the medical device quality management system training organized by the company and pass the assessment.

3.2 certification personnel shall comply with the relevant laws and regulations of the profession, and bear the corresponding legal responsibility for the authenticity of the certification audit activities and related certification audit records and certification audit reports.

4. Initial certification process

4.1 Accept certification applications

4.1.1 The certification body shall disclose at least the following information

to the applicant organization:

(1) The scope of certification business that can be carried out.

(2) The full content of these Rules.

(3) certification work procedures;

(4) Certification basis;

(5) Certification certificate style.

(6) Provisions on the application and complaint of the certification process.

4.1.2 The certification body shall require the applicant organization to submit at least the following information:

(1) Application for certification, the application shall include a description of the scope and activities of the production, operation or service activities for which the certification is applied.

(2) Certificate of legal person qualification (industrial and commercial business license, certificate of legal person of public institution or registration certificate of legal person of social group);

(3) Obtain administrative license documents, qualification certificates, compulsory certification certificates, etc. (when applicable) stipulated by relevant laws and regulations;

(4) The business activities engaged in comply with the requirements of the relevant laws, regulations, medical device quality standards and relevant specifications of the People's Republic of China;

(5) A description of the business activities involved in the scope of medical

device quality management system certification;

(6) A documented medical device quality management system has been established and implemented in accordance with the certification basis and relevant requirements;

(7) The system has been in effective operation for more than 3 months, and the internal audit and management review have been completed.

(4) Documented information on the management system (if applicable).

4.1.3 The certification body shall review the application materials submitted by the applicant organization, and comprehensively determine whether it has the ability to accept the certification application according to the scope and place of the application for certification, the number of employees, the time required to complete the audit and other factors affecting the certification activities.

The certification body shall not accept the certification application of the applicant organization that has been ordered by the law enforcement and regulatory department to suspend business for rectification or has been included in the "list of enterprises with serious violations" in the national enterprise credit information publicity system.

4.1.4 For those who meet the requirements of 4.1.2 and 4.1.3, the certification body may decide to accept the certification application; If the above requirements are not met, the certification body shall notify the applicant organization to supplement and improve, or not accept the certification application.

4.1.5 Sign the certification contract

Before the implementation of the certification audit, the certification body shall enter into a legally effective written certification contract with the applicant organization, which shall contain at least the following contents:

(1) The commitment of the applicant organization to continue to effectively operate the medical device quality management system after obtaining certification.

(2) The applicant organization is committed to complying with the relevant laws and regulations on certification and accreditation, assisting the supervision and inspection of the certification supervision department, and truthfully providing relevant materials and information for inquiries and investigations on relevant matters.

(3) The applicant organization shall notify the certification body in a timely manner if the following situations occur after the applicant organization undertakes to obtain certification:

(1) There are major complaints from customers and related parties.

(2) The products produced or sold or the services provided are determined to be unqualified by the quality or market supervision departments.

(3) The occurrence of quality and safety accidents of products and services.

(4) Changes in relevant circumstances, including: changes in legal status, production and operation status, organizational status or ownership; Changes in administrative licensing qualifications, compulsory certifications or other

qualification certificates obtained; Change of legal representative and top management; changes in workplaces for production, operation or services; Changes in the scope of activities covered by the medical device quality management system; major changes in the quality management system and important processes of medical devices, etc.

(5) Other important situations that affect the operation of the management system.

(4) The applicant organization promises to correctly use the certification certificate, certification mark and related information after obtaining the certification, and does not use the management system certification certificate and related words and symbols to mislead the public to believe that its products or services have passed the certification.

(5) The scope of production or service activities covered by the management system to be certified.

(6) During the implementation process of the certification audit and the validity period of the certification certificate, the certification body and the applicant organization shall bear their respective responsibilities, rights and obligations.

(7) The fee, payment method and breach of contract clause of the certification service.

4.2 Audit planning

4.2.1 Review time

The certification body shall calculate and determine the auditor days according to factors such as the size, characteristics, business complexity, scope of the medical device quality management system, certification requirements and the risks it bears to ensure the adequacy and effectiveness of the audit.

4.2.2 Audit Group

4.2.2.1 Determine the audit team

(1) Certification auditors must obtain the qualification of quality management system auditor registration.

(2) The audit team shall be composed of auditors who have obtained the qualification of quality management system auditor registration and passed the company's training and assessment, and at least one of them is a formal auditor. Technical experts can be supplemented when necessary to enhance the technical capacity of the audit team.

(3) Technical experts with specific knowledge of medical devices can become members of the audit team. Technical experts shall work under the supervision of auditors and may advise auditors on technical adequacy matters in the auditee's management system, but technical experts cannot act as auditors.

4.2.3 Audit plan

4.2.3.1 The certification body shall develop a written audit plan for each audit. The audit plan should include at least the following: audit purpose, audit criteria, audit scope, date and location of the on-site audit, duration of the on-site audit, and members of the audit team (wherein: the auditor should indicate the

registration number of the certified person; The technical expert should indicate the professional code, work unit and professional and technical title).

4.2.3.2 If the coverage of the medical device quality management system includes the same or similar activities in multiple sites, and these sites are all under the authorization and control of the applicant organization, the certification body may sample these sites in the audit, but shall carry out sampling in accordance with the relevant requirements to ensure that the audit of the sample is representative of all sites included in the medical device quality management system. If there are obvious differences in the activities of different sites, or there are regional factors that may have a significant impact on quality management between different sites, the method of sampling audit cannot be adopted, and the audit should be conducted on each site one by one.

4.2.3.3 Before the start of the audit activities, the audit team shall submit the audit plan to the applicant organization for confirmation, and in case of temporary changes in the plan under special circumstances, the applicant organization shall be notified of the change in a timely manner and reach a consensus.

4.3 Implementation Audit

4.3.1 The audit team shall complete the audit work in accordance with the arrangement of the audit plan. Except in unforeseen special circumstances, the auditors identified in the audit plan shall not be replaced during the audit process.

4.3.2 The audit team shall convene the first and last meetings in conjunction with the applicant organization in the order of procedure, and the management of the applicant organization (including, if applicable, the responsible personnel of the function or process to be reviewed) shall attend the meeting. Participants should sign in, and the audit team should keep the sign-in sheet for the first and last meetings. When requested by the applicant organization, the members of the review team shall present their identification documents to the applicant organization.

4.3.3 Review process and links

4.3.3.1 The initial certification audit is divided into the first and second stages of the audit. The interval between the first and second stage on-site audits should be no less than 0.5 days and not more than 60 days. In the event of a public health event, travel restrictions, natural disasters and other restrictive circumstances that prevent the auditor from reaching the auditee's premises to conduct the audit, the certification body may arrange a remote audit.

4.3.3.2 The first stage of the audit shall cover at least the following:

(1) Confirm the consistency between the actual situation of the applicant organization and the description of the documented information of the medical device quality management system, especially whether the products and services, department settings, responsibilities and authority, production or service processes described in the documented information of the system are consistent with the actual situation of the applicant organization.

(2) Review the understanding and implementation of the requirements of the GB/T 42061-2022/ISO 13485:2016 standard by the applicant organization, evaluate whether internal audit and management review have been implemented during the operation of the medical device quality management system, and confirm whether the medical device quality management system has been in operation for more than 3 months.

(3) Confirm the content and scope of activities covered by the medical device quality management system established by the applicant organization, the effective number of people, processes and places covered by the system, and the compliance with applicable laws, regulations and mandatory standards.

(4) Identify key points that have an important impact on the realization of quality objectives in combination with the characteristics of products and services covered by the medical device quality management system, and scientifically determine the important audit points in combination with other factors.

(5) Discuss with the applicant organization to determine the second stage of the review arrangement. If the written information of the medical device quality management system does not conform to the actual on-site situation, the relevant system has not been in operation for more than 3 months or cannot be proved to be more than 3 months, and other conditions for the second-stage audit are not met, the second-stage audit should not be implemented.

4.3.3.3 The audit team shall inform the applicant organization of the first

stage of the review in writing. For the important key points that may be judged to be non-conformities in the second stage of the review, the applicant organization should be reminded to pay special attention in a timely manner.

4.3.3.4 The second stage of review shall be conducted at the site of the application organization. The focus is on reviewing the compliance of the medical device quality management system with the requirements and effective operation of the GB/T 42061-2022/ISO 13485:2016 standard, which should cover at least the following:

and (1) the effectiveness of process controls at the important audit points identified in the first stage of the audit.

(2) Establish whether the quality objectives are specifically applicable, measurable, communicated and monitored in relevant functions, levels and processes in order to achieve the quality policy.

(3) The management and control of the processes and activities covered by the medical device quality management system.

(4) Whether the actual work records of the applicant organization are true. Evidence of doubtful authenticity found in the audit should be recorded and taken into account when making audit conclusions and certification decisions.

(5) Whether the internal audit and management review of the applicant organization are effective.

4.3.4 In the event of any of the following situations, the audit team shall report to the certification body and terminate the audit with the consent of the

certification body.

(1) The auditee does not cooperate with the audit activities, and the audit activities cannot be carried out.

(2) There are major inconsistencies between the actual situation of the auditee and the application materials.

(3) Other circumstances that make it impossible to complete the audit process.

4.4 Audit report

4.4.1 The audit team shall form a written audit report on the audit activities, which shall be signed by the leader of the audit team. The audit report should accurately, concisely and clearly describe the main elements of the audit activities, including at least the following:

(1) The name and address of the applicant organization.

(2) Apply for the scope and place of the organization's activities.

and (3) the type, criteria and purpose of the audit.

(4) The leader of the audit team, the members of the audit team and their personal registration information.

(5) The date and place of implementation of the audit activities, including fixed sites and temporary sites; A description of deviations from the audit plan, including an objective statement of the audit risks and uncertainties affecting the audit conclusions.

(6) Describe the procedures and requirements listed in Article 4.3 for the

audit work, wherein: for 4.3.3The audit requirements of Article 4 shall describe or cite the audit evidence, audit findings and audit conclusions item by item; Evaluate the achievement of quality objectives and processes and quality performance.

and (7) identified non-conformities.

(8) The opinions and suggestions of the audit team on whether to pass the certification.

4.4.2 The certification body shall retain evidence to substantiate the relevant information in the audit report.

4.4.3 The certification body shall submit the audit report to the applicant organization within 30 working days after making the certification decision, and retain the evidence of receipt or submission.

4.4.4 For the termination of the audit project, the audit team shall form a report on the work carried out, and the certification body shall submit the report and the reasons for the termination of the audit to the applicant organization, and retain the evidence of receipt or submission.

4.5 Correction of non-conformities and verification of corrective actions and their results

4.5.1 For the non-conformities found in the audit, the certification body shall be required to apply for an organizational analysis of the reasons and propose corrective and corrective measures. In the case of serious non-conformity, the applicant organization shall be required to take corrective and corrective

measures within a period of up to 6 months. The certification body shall verify the validity of the corrective and corrective actions taken by the applicant organization and their results. If the corrective and corrective actions implemented for a serious non-conformity are not verified within 6 months after the end of Phase II, they shall be dealt with in accordance with Article 4.6.5, or in accordance with 4.3.34. The second phase of the review was re-implemented.

4.6 Certification Decisions

4.6.1 The certification body shall make a certification decision on the basis of a comprehensive evaluation of the audit report, the correction and corrective actions of the non-conformities and their results.

4.6.2 The certification decision personnel shall be the personnel under the management and control of the certification body, and the members of the audit team shall not participate in the certification decision of the audit project.

4.6.3 The certification body shall confirm the following circumstances before making a certification decision:

(1) The audit report meets the requirements of Article 4.4 of these rules, and the audit report and other information provided by the audit team can meet the information required for making certification decisions.

(2) Non-conformities that reflect the following problems, the certification body has reviewed, accepted and verified the effectiveness of the correction and corrective action.

(1) There are deficiencies in the effectiveness of the continuous

improvement of the medical device quality management system, and there are major doubts about the achievement of quality objectives.

(2) The quality objectives set are not measurable, or the measurement method is not clear.

(3) Monitoring and measurement of critical points that have a significant impact on the achievement of quality objectives are not operating effectively, or the reporting or review records of these critical points are incomplete or invalid.

(4) Other serious non-conformities.

(3) The certification body has reviewed other general non-conformities and accepted the corrective and corrective measures planned by the applicant organization.

4.6.4 On the basis of meeting the requirements of Article 4.6.3, if the certification body has sufficient objective evidence to prove that the applicant organization meets the following requirements, the applicant organization shall be assessed to meet the certification requirements and issued a certification certificate to it.

(1) The medical device quality management system of the applicant organization meets the requirements of the standard and is operating effectively.

(2) The products and services covered by the certification comply with the requirements of relevant laws and regulations.

(3) The applicant organization has fulfilled the relevant obligations in accordance with the provisions of the certification contract.

4.6.5 If the applicant organization cannot meet the above requirements or has the following circumstances, the applicant organization shall be assessed as not meeting the certification requirements, and the applicant organization shall be notified in writing and explain the reasons for its failure to pass the certification.

(1) The auditee's medical device quality management system has major defects and does not meet the requirements of the GB/T 42061-2022/ISO 13485:2016 standard.

(2) It is found that the auditee has major quality and safety problems or other serious violations of laws and regulations related to the quality of products and services.

4.6.6 After the certification body issues the certification certificate, it shall, within 30 working days, submit the relevant information of the certification results to the CNCA in accordance with the prescribed requirements.

5. Surveillance audit process

5.1 The certification body shall effectively track the organization (hereinafter referred to as the certified organization) that holds the medical device quality management system certification certificate issued by it, and supervise the continuous operation of the medical device quality management system by the certified organization and meet the certification requirements.

5.2 In order to ensure that the requirements of Article 5.1 are met, the

certification body shall determine the frequency of supervision and audit of the certified organization according to the degree of quality risk or other characteristics of the products and services of the certified organization.

5.2.1 As a minimum requirement, the first surveillance audit after the initial certification shall be conducted within 12 months from the date of issuance of the certification certificate. Thereafter, surveillance audits shall be conducted at least once every calendar year (except for the year in which recertification is due) and the interval between surveillance audits shall not exceed 15 months.

5.2.2 If the supervision and audit is not carried out beyond the time limit, it shall be dealt with in accordance with Article 7.2 or 7.3.

5.2.3 When the products of the certified enterprise are found to be unqualified in the national supervision and random inspection, the certification body shall supervise and audit the enterprise within 30 days from the notification issued by the random inspection unit.

5.3 The time of supervision and audit shall not be less than 1/3 of the number of person-days of the audit time calculated in accordance with Article 4.2.1.

5.4 The audit team that supervises the audit shall meet the requirements of Article 4.2.2 and 4.3.1.

5.5 The surveillance audit shall be conducted at the site of the certified organization and shall meet the conditions determined in clause 4.2.3.3. Due to market, seasonality and other reasons, it is difficult to cover all products and

services during each supervision and audit, and the supervision and audit within the validity period of the certification certificate shall cover all products and services within the scope of certification.

5.6 At least the following should be reviewed during the supervision and audit:

(1) Since the last audit, the activities covered by the medical device quality management system and the important changes affecting the system and whether there are changes in the resources of the operating system.

(2) Whether the important key points that have been identified in accordance with the requirements of Article 4.3.3.2 (4) are operating normally and effectively in accordance with the requirements of the medical device quality management system.

and (3) whether the corrective and corrective actions taken for the non-conformities identified in the previous audit continue to be valid.

(4) Whether the activities covered by the medical device quality management system involve the provisions of laws and regulations, and whether they continue to comply with the relevant regulations.

(5) Whether the quality objectives and quality performance meet the determined value of the medical device quality management system. If not, whether the certified organization operates an internal audit mechanism identifies the causes, and whether the management review mechanism identifies and implements improvement measures.

(6) Whether the use of the certification mark or the citation of the certification qualification of the certified organization complies with the "Certification and Accreditation Regulations" and other relevant regulations.

(7) Whether the internal audit and management review are standardized and effective.

(8) Whether complaints are accepted and handled in a timely manner.

(9) In response to the problems or complaints found in the operation of the system, effective improvement measures have been formulated and implemented in a timely manner.

5.7 For non-conformities found in the supervision audit, the certification body shall require the certified organization to analyze the reasons, specify a time limit to require the certified organization to complete the corrective and corrective measures and provide evidence of the effectiveness of the corrective and corrective measures.

The certification body shall use appropriate methods to verify the effect of the certification organization's disposal of non-conformities in a timely manner.

5.8 The audit report of the supervision and audit shall describe or cite the audit evidence, audit findings and audit conclusions in accordance with the audit requirements listed in Article 5.6.

5.9 The certification body shall make a decision to continue to maintain or suspend or revoke the certification certificate according to the supervision audit report and other relevant information.

6. Recertification process

6.1 Before the expiration of the certification certificate, if the certified organization applies to continue to hold the certification certificate, the certification body shall implement a recertification audit and decide whether to renew the certification certificate.

6.2 The certification body shall form an audit team in accordance with the requirements of 4.2.2 and 4.3.1. In accordance with the requirements of Article 4.2.3 and combined with the previous supervision and audit, the recertification audit plan shall be formulated and submitted to the audit team for implementation.

When there are no major changes in the medical device quality management system and the internal and external environment of the certified organization, the first stage of the recertification audit can be omitted, but the audit time should not be less than 2/3 of the number of person-days calculated in accordance with Article 4.2.1.

6.3 For serious non-conformities found in the recertification audit, the certification body shall specify a time limit to require the certified organization to implement corrective and corrective measures, and complete the verification of corrective and corrective measures before the expiration of the original certification certificate.

6.4 The certification body shall make a recertification decision in accordance with the requirements of Article 4.6. If the certified organization continues to

meet the certification requirements and fulfill the obligations of the certification contract, the certification certificate shall be renewed.

6.5 If the recertification activities are completed and the certificate is renewed before the expiration date of the current certification certificate, the termination date of the new certification certificate may be based on the termination date of the current certification certificate. The date of issuance on the new certificate should be no earlier than the date of the recertification decision.

If, prior to the termination date of the current certificate, the certification body fails to complete the recertification audit or the corrective and corrective actions implemented for serious non-conformities fail to be verified, the certification body shall not be recertified and the validity of the original certification certificate shall not be extended.

After the expiration of the current certification certificate, the certification body can resume the certification if it is able to complete the outstanding recertification activities within 6 months, otherwise at least one Phase 2 audit should be conducted before the certification can be restored. The effective date of the certification certificate should be no earlier than the date of the recertification decision, and the termination date should be based on the previous certification cycle.

7. Suspension and withdrawal of certification certificate

7.1 The certification body shall formulate a management system for suspending or revoking the certification certificate or narrowing the scope of certification, and the regulations and management system shall meet the relevant requirements of these rules. The suspension and revocation of the certification certificate by the certification body shall be in accordance with its management system, and the certification certificate shall not be suspended or revoked at will.

7.2 Suspension of Certificates

7.2.1 If the certified organization has any of the following circumstances, the certification body shall suspend its certification certificate within 5 working days after investigation and verification.

(1) The medical device quality management system continues or seriously does not meet the certification requirements, including the requirements for the effectiveness of the operation of the medical device quality management system.

(2) Failure to assume or perform the responsibilities and obligations agreed in the certification contract.

(3) Being ordered by the relevant law enforcement and regulatory departments to suspend business for rectification.

(4) The administrative license certificate, qualification certificate, compulsory certification certificate, etc. related to the scope of the medical device quality management system have expired and become invalid, and the resubmitted application has been accepted but has not been renewed.

(5) Actively requesting a suspension.

(6) Other certification certificates shall be suspended.

7.2.2 The suspension period of the certification certificate shall not exceed 6 months. However, the suspension period in the case of subparagraph (4) of 7.2.1 may end on the date on which the relevant entity makes a licensing decision.

7.2.3 The certification body shall disclose the information of the suspension of the certification certificate in an appropriate manner, clarify the start date and suspension period of the suspension, and state that the certification organization shall not use the certification certificate, certification mark or reference certification information in any way during the suspension period.

7.3 Revocation of Certificates

7.3.1 If the certified organization has any of the following circumstances, the certification body shall revoke its certification certificate within 5 working days after obtaining the relevant information and investigating and verifying.

(1) The certificate of legal status has been cancelled or revoked.

(2) Included in the list of seriously untrustworthy enterprises by the relevant administrative law enforcement departments

(3) Refusing to cooperate with the supervision and inspection carried out by the certification regulatory department, or providing false materials or information for the inquiry and investigation of relevant matters.

(4) Refusal to accept the national product quality supervision and random inspection.

(5) There is a major quality and safety accident of products and services, which is confirmed by the law enforcement and supervision department to be caused by the violation of the certification organization.

(6) There are other serious violations of laws and regulations.

(7) The period of suspension of the certification certificate has expired but the problems that led to the suspension have not been solved or corrected (including the administrative license certificate, qualification certificate, compulsory certification certificate, etc. related to the scope of the medical device quality management system held have expired but the application has not been approved).

(8) There is no operation of the medical device quality management system or no longer has the operating conditions.

(9) Failure to correctly quote and publicize the obtained certification information in accordance with relevant regulations, causing serious impact or consequences, or the certification body has required it to correct but has not corrected it for more than 2 months.

(10) Other certification certificates shall be revoked.

7.3.2 After the revocation of the certification certificate, the certification body shall withdraw the revoked certification certificate in a timely manner. If it cannot be recovered, the certification body shall promptly publish or declare the revocation decision in the relevant media and website.

7.4 The certification body shall publish the relevant information on its

website to suspend or revoke the certification certificate, and at the same time report to the CNCA in accordance with the prescribed procedures and requirements.

7.5 certification body should take effective measures to avoid all kinds of invalid certification certificates and certification marks to be used continuously.

8. Certificate requirements

8.1 The certification certificate shall contain at least the following information:

(1) The name, address and unified social credit code (or organization code) of the certified organization. This information should be consistent with the information in their legal status documents.

(2) The address and business scope of production, operation or services covered by the medical device quality management system. If the certified medical device quality management system covers multiple sites, state the name and address information of the relevant sites covered.

(3) The medical device quality management system conforms to the statement of GB/T 42061-2022/ISO 13485:2016 standard.

(4) Certificate number.

(5) The name of the certification body.

(6) The date of the start and end of the validity period.

The certificate should indicate that the certified organization must be

regularly supervised and audited, and the certificate must be audited and qualified in order to continue to be valid.

(7) Relevant accreditation mark and accreditation registration number (if applicable).

(8) Certificate inquiry method. In addition to announcing the inquiry method of the certification certificate on the website of this institution, the certification body shall also indicate on the certificate: "The information of this certificate can be queried on the official website of the Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn)", so as to facilitate social supervision.

8.2 The initial certification certificate is valid for up to 3 years. The validity period of the recertified certification certificate shall not exceed the deadline of the most recent valid certification certificate plus 3 years.

8.3 The certification body shall establish a certificate information disclosure system. In addition to providing certification certificate information to the applicant organization, certification supervision departments and other law enforcement and regulatory departments, certificate information shall also be provided to relevant social parties at their request and subject to social supervision.

9. Transfer of certificate

9.1 The certification body shall fulfill its social responsibilities and strictly

prohibit the transfer of certification certificates for organizations that do not meet the GB/T 42061-2022/ISO 13485:2016 standard and cannot effectively implement the medical device quality management system for the purpose of profit.

9.2 The certification body accepting the organization's application to convert to the certification certificate of the organization should understand the reasons for the application for transfer in detail, and conduct on-site audit if necessary.

9.3 Conversion is limited to the current valid certificate. Certificates that have been suspended or are being suspended or revoked, as well as certificates that have expired, shall not be eligible for transfer.

9.4 If the certification body that is issued the certificate revokes the certificate, it shall not accept its certification application unless the organization has carried out a thorough rectification that has led to the suspension or revocation of the certification certificate.

10. Acceptance of complaints from organizations

When the applicant organization or the certified organization has any objection to the certification decision, the certification body shall accept the appeal and deal with it in a timely manner, and send a written notice of the result to the complainant within 60 days.

The written notice shall inform the complainant that if it believes that the certification body has not complied with the relevant laws and regulations of

certification or these rules and has caused serious infringement of its legitimate rights and interests, it can directly complain to the local certification regulatory authority or CNCA, or to the relevant accreditation body.

11. Management of certification records

11.1 The certification body shall establish a certification record keeping system, record the whole process of certification activities and keep it properly.

11.2 Records shall be true and accurate to confirm that the certification activities have been effectively carried out. The recorded materials shall be in Chinese, and the retention time shall be at least consistent with the validity period of the certification certificate.

11.3 If the records are kept in the form of electronic documents, they shall be in a non-editable electronic document format.

11.4 All written records signed by relevant personnel can be made into electronic documents for preservation and use, but the originals must be properly kept, and the retention time should be at least consistent with the validity period of the certification certificate.

12 Miscellaneous requirements

12.1 When the content of these rules refers to the GB/T 42061/ISO 13485 standard, it refers to the effective version of the standard at the time of certification activities. When the standard number is described in the certification activity and the certification certificate, the full standard number of

the current version in force shall be used.

12.2 The photocopies of the various types of supporting documents mentioned in these rules shall be copied on the original, and shall be signed by the auditor to confirm that they are consistent with the original.

12.3 The certification body can carry out publicity and training on the medical device quality management system and related technical standards, so as to promote all employees of the organization to correctly understand and implement the medical device quality management system standards.

12.4 This certification rule is interpreted by Lyard Standard Technical Services (Jiangsu) Co., Ltd. (GAIA).