医疗器械质量管理体系认证规则

Medical Device Quality Management System Certification Rules

编　制 Prepared By	审　核 Reviewed by	批　准 Approved by
李飞 2024.10.08	钱存章 2024.10.08	周延冲 2024.10.08

文件修改履历 Revision list

版本号 Version No	修改内容 Revision	生效日期 Effective Date	修改人 Prepared by	审批人 Approved by	备注 Remarks
A0	新版发布 Initial release	2018.11.28	夏劼清	周延冲	
B0	文件格式调整，进行升级换版 File format adjustment, version update	2022.10.25	姜苇苇	钱存章/周延冲	
B1	在CNAS第一次监督审核后文件重新整理、调整文件编号 After the first supervised audit of CNAS, rearrange the document and adjust the document number	2024.09.15	姜苇苇	周延冲	
C0	按国际专业代码新方案:IAF MD 9 New scheme by international professional code:IAF MD 9	2024.10.08	李飞	钱存章/周延冲	

目　　录

1 适用范围

1 scope

1.1 本规则用于规范苏州莱标标准认证有限公司（下称本机构或认证机构）对申请认证和获证的各类组织按照 GB/T 42061-2022 / ISO13485:2016《医疗器械 质量管理体系 用于法规的要求》标准 建立医疗器械质量管理体系的认证活动。

1.1 These rules are used to regulate the certification activities of Suzhou Lai biao Standard Certification Co., Ltd. (hereinafter referred to as the agency or the certification body) to establish the medical device quality management system in accordance with the GB / T 42061-2022 / ISO13485:2016 "Medical Device Quality Management System for Regulations" standards.

1.2 本规则旨在结合认证认可相关法律法规、国家认监委《质量管理体系认证规则》、国家及行业技术标准，对医疗器械质量管理体系认证实施过程作出具体规定，强化本机构对认证过程的 管理和责任。

1.2 The purpose of this rule is to make specific provisions on the implementation process of medical device quality management system certification in combination with the relevant laws and regulations of the state Accreditation Administration, the Quality Management System Certification Rules, national and industrial technical standards, and strengthen the management and responsibility of the agency for the certification process.

1.3 本规则是本机构从事医疗器械质量管理体系认证活动的基本要求，开展医疗器械质量管理体系认证活动时应当遵守本规则。

1.3 These Rules are the basic requirements for the institution to engage in the certification activities of medical device quality management system, and these Rules shall be observed when carrying out the certification activities of medical device quality management system.

2 基本条件要求

2.Basic requirements

2.1 本机构获得国家认监委批准、取得从事质量管理体系认证的资质方可开展医疗器械质量

管理体系认证。

2.1 Only the approval of the CNCA and the qualification of quality management system certification can carry out the medical device quality management system certification.

2.2 建立可满足 GB/T 27021《合格评定 管理体系审核认证机构要求》的内部管理体系，以使从事的医疗器械质量管理体系认证活动符合法律法规及技术标准的规定。

2.2 Establish an internal management system that can meet the GB / T 27021 Requirements of the Conformity Assessment Management System Audit and Certification Authority, so as to make the medical device quality management system certification activities comply with the provisions of laws, regulations and technical standards.

2.3 建立内部制约、监督和责任机制，实现受理、培训（包括相关增值服务）、审核和作出认证决定等环节的相互分开。

2.3 Establish internal restriction, supervision and responsibility mechanism to realize the separation of acceptance, training (including related value-added services), audit and certification decisions.

3 对认证人员的要求

3.Requirements for certified personnel

3.1 认证管理人员包括机构主要业务主管负责人、合同评审员、审核方案策划人员、人员能力评价人员、审核实施人员和认证决定人员等；

3.1 Certification management personnel include the head of the main business supervisor of the organization, contract reviewers, audit program planners, personnel ability evaluation personnel, audit implementation personnel and certification decision personnel, etc.;

3.1.1 应通过 GB/T 42061-2022 / ISO13485:2016《医疗器械 质量管理体系 用于法规的要求》标准基础知识及相关医疗器械法律法规的培训，并经考试合格。

3.1.1 Pass GB / T 42061-2022 / ISO13485:2016 Basic knowledge of Medical Device Quality Management System for Regulatory requirements and related medical device laws and regulations, and pass the examination.

3.1.1 应通过机构组织的与管理体系标准、医疗器械行业法律法规等相关的课题的培训且经过考评合格。

3.1.1 It shall pass the training of the topics related to the management system standards and the laws and regulations of the medical device industry organized by the organization and pass the evaluation.

3.1.2 掌握相应管理岗位所涉及的知识和技能，经考评合格。

3.1.2 Master the knowledge and skills involved in the corresponding management position, and pass the evaluation.

3.2 审核员

3.2, Auditor

3.2.1 取得中国认证认可协会（CCAA）颁发的质量管理体系审核员注册资格。

3.2.1 Obtain the registration qualification of quality management system auditor issued by China Certification and Accreditation Association (CCAA).

3.2.2 教育经历：

3.2.2 Education Experience:

3.2.2.1 大学本科以上学历，或大专学历及相应专业中级以上技术职称（注：2016 年 6 月 30 日前获得 CCAA 质量管理体系注册资格的，满足大专或以上学历即可）。

3.2.2.1 Bachelor degree or above, or college degree or intermediate technical title or above in the corresponding major (Note: those who obtain the CCAA quality management system registration qualification before June 30,2016 can meet the college degree or above).

3.2.2.2 专业要求

3.2.2.2 Professional requirements

（1）实施附件 A 医疗器械业务分类表，应满足下列相适当的专业之一：

(1) The implementation of Annex A shall meet one of the following appropriate specialties:

--生物学或微生物学;

- -Biology or microbiology;

--化学或生物化学;

- -Chemical or biochemistry;

--计算机和软件技术;

- -Computer technology and software technology;

--电气、电子、机械或生物工程;

- -Electrical, electronic, mechanical, or bioengineering;

--人类生理学;

- -Human physiology;

--医学;

--medical science;

--药学;

--pharmacy;

--物理或生物物理学;

- -Physical or biophysics;

--材料学等。

- -Materials science, etc.

（2）实施 IAF MD9 附录 A 1.7：零部件和服务 审核的，对所学专业不作限制。

(2)Implement IAF MD9 Appendix A 1.7: Parts and service audit, no restrictions on the major.

3.2.2.3 通过 GB/T 42061-2022 / ISO13485:2016《医疗器械 质量管理体系 用于法规的要求》标准知识及相关医疗器械法律法规的培训，并经考试合格。

3.2.2.3 Pass the training of GB / T 42061-2022 / ISO13485:2016 Requirements of Medical Device Quality Management System for Regulations and related medical device laws and regulations, and passed the examination.

3.3 专业审核员

3.3 Professional auditor

即承担医疗器械质量管理体系专业支持的审核员，除满足 3.2 条款的要求外，还需要:

That is, the auditor undertaking the professional support of the medical device quality management system, in addition to meeting the requirements of Article 3.2, also needs to:

3.3.1 实施附件 A 医疗器械业务分类医疗器械“研发、制造”专业审核的专业审核员，应具备 4 年或以上从事医疗器械设计研发、生产制造、质量检测、质量监督、测试评价或临床试验等密切相关的工作经验，经考评合格。

3.3.1 The professional auditor who implements the professional audit of "R & D and manufacturing" of Annex A shall have at least 4 years of closely related working experience in medical device design, development, manufacturing, quality testing, quality supervision, test and evaluation or clinical trial, and pass the evaluation.

3.3.2 实施附件 A 医疗器械业务分类的“批发、零售”专业审核的专业审核员， 满足 3.3.1 条款的工作经历要求，或具有 4 年或以上医疗器械批发、零售专业工作经验，经考评合格。

3.3.2 Professional auditors who implement the "wholesale and retail" professional audit of Annex A medical device business classification, meet the work experience requirements of Article 3.3.1, or have at least 4 years of professional work experience in the wholesale and retail of medical devices, and pass the evaluation.

3.3.3 在特殊情况下，可以考虑较短的经验或在医疗器械或相关部门以外的领域的经验持续时间。在这种情况下，机构应保留相关的证明及记录。

3.3.3 In special circumstances, short experience or duration of experience outside of the medical device or related sector may be considered. In such case, the agency shall keep the relevant certificates and records.

3.3.4 在经认可的质量管理体系计划中以专业审核人员身份在技术专家专业引导下至少参加 4 次审核，共至少 20 天，其中至少 50%为 ISO13485，其余的在任何其他认可的质量管理体系计划中（这些质量管理体系审核经历涉及的产品和服务的代码应确认转换后与 MDQ 代码一致）。经考评合格后，可以给予附件 A 中对应的技术领域的代码。

3.3.4 Take the audit for at least 20 days, at least 50% ISO13485 and the rest in any other

approved quality management system plan (the codes of the products and services involved in the quality management system audit experience shall be consistent with the MDQ code after conversion). After passing the evaluation, the code of the corresponding technical field in the Annex A can be given.

3.4 技术专家

3.4 Technical experts

大专或以上学历，满足 3.3 条款所对应专业所需要的工作经验，经考评合格。

College degree or above, meet the work experience required by the corresponding major in clause 3.3, and pass the evaluation.

3.5 认证决定人员为经本机构授权、对认证结果作出决定的人员，其中负责专业支持的专业人员具备与专业审核员或技术专家相同的专业教育与工作经历条件，并经过考评合格。

3.5 审核组长

3.5 The certification decision personnel shall be the personnel authorized by the agency to make decisions on the certification results, and the professional personnel responsible for professional support shall have the same professional education and working experience conditions as the professional auditor or technical experts, and have passed the evaluation.

3.5 Audit team leader

除满足 3.2 和 3.3 条款的要求外，担任审核组长还需要满足以下条件：

In addition to the requirements of clauses 3.2 and 3.3, the following conditions:

3.5.1 经过机构考评决定后授予的初始审核组长。

3.5.1 The initial audit team leader awarded after the organization evaluation decision.

3.5.2 在初始审核组长的监督下担任审核组长角色，至少三次 ISO13485 审核经验，经过初始审核组长的评价合格后，方可担任审核组长。

3.5.2 Under the supervision of the initial audit team leader, play the role of the audit team leader, have at least three ISO13485 audit experience, and serve as the audit team leader only after passing the evaluation of the initial audit team leader.

4 初次认证程序

4. Initial certification procedures

4.1 受理认证申请

4.1 Accept the certification application

4.1.1 本机构向申请认证的组织（以下简称申请组织）至少公开以下信息：

4.1.1 The Agency shall disclose at least the following information to the organization applying for certification (hereinafter referred to as the application organization):

4.1.1.1 可开展认证业务的范围，以及获得认可的情况。

4.1.1.1 Scope of certification business and recognition.

4.1.1.2 本机构的授予、保持、扩大、更新、缩小、暂停或撤销认证及其证书等环节的制度规定。

4.1.1.2 Institutional provisions of the agency to grant, maintain, expand, update, shrink, suspend or revoke the certification and its certificates.

4.1.1.3 认证证书样式。

4.1.1.3 Certification certificate style.

4.1.1.4 对认证决定的投诉、申诉控制程序。

4.1.1.4 Control procedures of complaints and complaints for certification decisions.

4.1.1.5 分支机构和办事机构的名称、业务范围、地址等。

4.1.1.5 Name, business scope and address of branches and offices.

4.1.2 申请认证的组织应提交以下申请资料：

4.1.2 The organization applying for certification shall submit the following application materials:

4.1.2.1 认证申请书，包括申请组织的生产经营或服务活动等情况的说明。

4.1.2.1 Certification application form, including the production, operation or service activities of the application organization.

4.1.2.2 认证申请组织的法律地位证明文件的复印件，如企业营业执照、许可证和/或备案批件、3C 证书等相关证明文件。若医疗器械质量管理体系覆盖多场所活动，应附每个场所的法律地

位证明文件的复印件（适用时）。

4.1.2.2 Copies of the legal status certification documents of the certification application organization, such as the enterprise business license, license and / or record approval document, 3C certificate and other relevant certification documents. If the medical device quality management system covers multiple site activities, copies of the legal status documents of each site should be attached (when applicable).

4.1.2.3 医疗器械质量管理体系覆盖的活动所涉及法律法规要求的行政许可证明、资质证书、强制性认证证书等的复印件，其中：

4.1.2.3 Copies of the administrative license certificate, qualification certificate, compulsory certification certificate as required by laws and regulations involved in the activities covered by the medical device quality management system, including:

（1）当申请组织为医疗器械生产企业时：

(1) When applying for the organization as a medical device manufacturer:

--生产 I 类产品的，需提供备案证明；

- -For the production of Class I products, the record-filing certificate shall be provided;

--生产 II、III 类产品的，需提供医疗器械注册证及医疗器械生产许可证。

- -For producing class II and III products, the medical device registration certificate and the medical device production license shall be provided.

（注：采用出口目的国的相关标准生产、产品完全用于出口的医疗器械生产企业除外）

(Note: except for the medical device manufacturers that adopt the relevant standards of the export destination country and whose products are completely used for export)

（2）当申请组织为医疗器械经营企业时:

(2) When applying for the organization as a medical device trading enterprise:

--销售 II 类医疗器械产品的，需提供营业执照和相关资质；

- -For selling class II medical devices, the business license and relevant qualifications shall be provided;

--销售 III 类医疗器械产品的，提供医疗器械经营许可证。

- -Selling class III medical device products, to provide the medical device business license.

（3）多场所活动、活动分包情况，以及主要外购件及外协件清单（适用时）。

(3) Subcontracting of activities and activities in multiple places, as well as the list of main purchased parts and outsourcing parts (when applicable).

（4）医疗器械质量管理体系手册及必要的程序文件。

(4) Manual of quality management system of medical devices and necessary procedure documents.

（5）医疗器械质量管理体系覆盖的产品或服务的质量标准清单。

(5) List of quality standards of products or services covered by the medical device quality management system.

（6）医疗器械质量管理体系已有效运行 6 个月以上的证明材料。

(6) Certificate materials that the medical device quality management system has been effectively in operation for more than 6 months.

（7）其他与认证审核有关的必要文件。

(7) Other necessary documents related to the certification audit.

4.1.3 认证申请的审查确认本机构对申请组织提交的申请资料进行审查，并确认：

4.1.3 Review of Certification Application The agency shall review the application materials submitted by the application organization and confirm that:

4.1.3.1 申请资料齐全。

4.1.3.1 Application materials are complete.

4.1.3.2 申请组织从事的活动符合相关法律法规的规定。

4.1.3.2 The activities shall comply with the provisions of relevant laws and regulations.

4.1.3.3 申请组织为达到质量目标而建立了文件化的医疗器械质量管理体系。

4.1.3.3 The application organization has established a documented medical device quality

management system to achieve the quality objectives.

4.1.4 根据申请组织申请的认证范围、生产经营场所、员工人数、完成审核所需时间和其他影响认证活动的因素，综合确定是否有能力受理认证申请。

4.1.4 Ability to accept the certification application according to the certification scope, the production and business site, the number of employees, the time required to complete the audit and other factors that affect the certification activities.

4.1.5 对符合 4.1.3、4.1.4 要求的，本机构可决定受理认证申请；对不符合上述要求的，应通知申请组织补充和完善，或者不受理认证申请。

4.1.5 For those who meet the requirements of 4.1.3 and 4.1.4, the agency may decide to accept the certification application; for those that do not meet the above requirements, it shall notify the application organization to supplement and improve, or do not accept the certification application.

4.1.6 本机构应完整保存认证申请的审查确认工作记录，归入申请组织认证档案。

4.1.6 The agency shall fully keep the review and confirmation work records of the certification application, and put them into the certification files of the application organization.

4.1.7 签订认证合同在实施认证审核前，认证机构应与申请组织订立具有法律效力的书面认证合同，合同应至少包含以下内容：

4.1.7 Signing of Certification Contract Before the implementation of certification audit, the certification body shall enter into a legally effective written certification contract with the application organization. The contract shall contain at least the following contents:

4.1.7.1 申请组织获得认证后持续有效运行医疗器械质量管理体系的承诺。

4.1.7.1 Commitment of continuous and effective operation of the medical device quality management system after the application organization obtains the certification.

4.1.7.2 申请组织对遵守认证认可相关法律法规，协助认证监管部门的监督检查，对有关事项的询问和调查如实提供相关材料和信息的承诺。

4.1.7.2 The application organization promises to comply with the relevant laws and regulations of certification and accreditation, assist in the supervision and inspection of the certification supervision authorities, and truthfully provide relevant materials and information for the inquiry and investigation of relevant matters.

4.1.7.3 申请组织承诺获得认证后发生以下情况时，应及时向认证机构通报：

4.1.7.3 The application organization shall timely notify the certification body of the following situations after obtaining the certification:

（1）客户及相关方有重大投诉。

(1) Major complaints from the customer and related parties.

（2）生产的产品或服务被执法监管部门认定不符合法定要求。

(2) The products or services produced are determined by the law enforcement and supervision authorities to do not meet the legal requirements.

（3）发生产品或服务的质量安全事故。

(3) Quality and safety accidents of products or services occur.

（4）相关情况发生变更，包括：法律地位、生产经营状况、组织状态或所有权变更；取得的行政许可资格、强制性认证或其他资质证书变更；法定代表人、最高管理者、管理者代表变更；生产经营或服务的工作场所变更；医疗器械质量管理体系覆盖的活动范围变更；医疗器械质量管理体系和重要过程的重大变更等。

(4) Changes of relevant situations, including: change of legal status, production and operation status, organization status or ownership; change of administrative license qualification, compulsory certification or other qualification certificate; change of legal representative, top management and management representative; change of production and operation or service workplace; change of scope of activities covered by medical device quality management system; major changes in medical device quality management system and important process, etc.

（5）出现影响医疗器械质量管理体系运行的其他重要情况。

(5) Other important situations affecting the operation of the medical device quality management system occur.

4.1.7.4 申请组织承诺获得认证后正确使用认证证书、认证标志和有关信息；不擅自利用医疗器械质量管理体系认证证书和相关文字、符号误导公众认为其产品或服务通过认证。

4.1.7.4 The application organization promises to correctly use the certification certificate, certification marks and relevant information after obtaining the certification; do not use the medical device quality management system certification certificate and relevant words and symbols to mislead the public to think that its products or services have passed the certification.

4.1.7.5 拟认证的医疗器械质量管理体系覆盖的生产或服务的活动范围。

4.1.7.5 Scope of production or service activities covered by the medical device quality management system to be certified.

4.1.7.6 在认证审核及认证证书有效期内各次监督审核中，认证机构和申请组织各自应当承担的责任、权利和义务。

4.1.7.6 The responsibilities, rights and obligations of the certification institution and the application organization in the supervision and examination within the validity period of the certification certificate.

4.1.7.7 认证服务的费用、付费方式及违约条款。

4.1.7.7 Fees, payment methods and default terms of the certification services.

4.2 **制定审核计划**

4.2 Arrange the review plan

4.2.1 审核时间

4.2.1 Audit time

4.2.1.1 为确保认证审核的完整有效，本机构以附录 B 所规定的基准审核时间为基础，根据申请组织医疗器械质量管理体系覆盖的活动范围、特性、技术复杂程度、质量安全风险程度、认证要求和员工人数等情况，核算并拟定完成审核工作需要的时间。

4.2.1.1 In order to ensure the complete and effective certification audit, the organization takes the benchmark audit time specified in Appendix B, according to the coverage of the medical device quality management system, characteristics, technical complexity, quality and safety risks, certification requirements, and the accounting and planning the audit time.

增加审核时间的情况：

Increase of audit time:

（1）当需要审核一个以上主要技术领域时应增加审核时间，以满足与其他主要技术领域相关的任何额外要求，增加一个主要技术领域，增加的审核时间为：基准审核人日的 15%，增加两个及以上的主要技术领域时，每一个技术领域增加 5%的基准人日。

(1) when the need to review more than one main technical field should increase the audit time, to meet any additional requirements related to other major technical areas, increase a major technical areas, increase the audit time is: 15% of the benchmark audit day, increase two or more main technical areas, each technical field increased by 5% of the benchmark day.

（2）考虑医疗器械的复杂性：依据 IAF MD9 附录 A，按照风险等级，本机构识别出：

(2) Consider the complexity of medical devices: According to IAF MD9 Appendix A, the agency identifies the risk level:

Ⅲ类风险（高）：A.1.3 有源植入医疗器械：

Class risk (high): A.1.3 Active implanted medical devices:

Ⅱ类风险（中）：A.1.1 无源植入医疗器械/A.1.4 检测试剂：

Class risks (middle): A.1.1 Passive implanted medical device / A.1.4 Test reagent:

Ⅰ类风险（低）：有源/无源的手术器械/诊断器械等：

Class I risk (low): Active / passive surgical device / diagnostic device, etc.:

（3）当制造商无法提供足够的证据证明符合审核标准时，应为每个供应商/客户现场留出额外的时间来接受审核（当现场审核需要延伸到受审核方的供方或其客户现场时，需要增加时间，应为受审核方现场以外的审核场所单独预留时间、增加审核时间为最低有效人数规模的审核人日数标准的 50%），多场所：包括固定的和临时场所，应实施现场审核，非中心职能的分场所

的审核时间不低于基准人日数的 50%。

(3) When the manufacturer cannot provide sufficient evidence to meet the audit standards, additional time shall be allowed for each supplier / customer site to extend to the supplier or the client site, the time shall be increased for the audit site for the audit time of the minimum effective number standard). Multiple sites: including fixed and temporary site, the audit time of non-central sites shall be not less than 50% of the benchmark number of days.

减少审核时间的因素：

Factors to reduce audit time:

（1）组织的范围不包括制造，而是批发、零售、运输或设备维护等活动。减少的审核时间总共不超过基准人日的 20%；

(1) The scope of the organization does not include manufacturing, but rather wholesale, retail, transportation or equipment maintenance activities. The total reduced audit time does not exceed 20% of the base person-day;

（2）仅针对分销或运输服务的认证范围执行的审核时间，从 IAF MD9 附录 D（基准审核人日）总计减少不超过 50%。

(2) The audit time performed only for the certification scope of distribution or transportation services is in total reduced by no more than 50% from IAF MD9 Appendix D (baseline audit day).

4.2.1.2 整个审核时间中，现场审核时间不应少于 80%。

4.2.1.2 In the whole audit time, the on-site audit time shall not be less than 80%.

4.2.2 审核组

4.2.2 Audit team

4.2.2.1 审核组由医疗器械质量管理体系审核员组成，其中至少包括 1 名与医疗器械质量管理体系覆盖活动专业技术领域相同的专业审核员。当审核员具备专业能力时，此审核员可同时兼任审核员及专业审核员。当无专业审核员参与时，应选择具备专业能力的技术专家参加审核组。审核组中的审核员应承担审核责任。

4.2.2.1 The audit team shall be composed of medical device quality management system auditors, including at least one professional auditor with the same professional technical field covered by the medical device quality management system. When the auditor is professional, the auditor may serve as both auditor and professional auditor. When there is no professional auditor involved, the technical experts with professional ability should be selected to attend the audit team. The auditor in the audit team shall bear the responsibility for the audit.

4.2.2.2 技术专家主要负责提供认证审核的技术支持，不作为审核员实施审核，不计入审核时间，其在审核过程中的活动由审核组中的审核员承担责任。

4.2.2.2 Technical experts are mainly responsible for providing technical support for certification audit. They shall not audit as auditors and not included in the audit time. Their activities in the audit process shall be borne by the auditors in the audit team.

4.2.2.3 审核组可以有实习审核员，其要在审核员的指导下参与审核，不计入审核时间，在审核过程中的活动由审核组中的审核员承担责任。

4.2.2.3 The audit team may have intern auditors, who shall participate in the audit under the guidance of the auditor, which is not included in the audit time. The activities in the audit process shall be borne by the auditors in the audit team.

4.2.3 审核计划

4.2.3 Audit plan

4.2.3.1 审核组根据本机构委派，制定书面审核计划并组织实施。 审核计划至少包括以下内容：审核目的、审核范围、审核过程、审核涉及的部门和场所、审核时间、审核组成员（其中：审核员应标明注册证书号及专业代码；技术专家应标明专业代码、技术职称或职务，如果在职应注明其服务的单位）。

4.2.3.1 The audit team shall make a written audit plan and organize the implementation. The audit plan shall at least include the following contents: audit purpose, audit scope, audit process, departments and places involved in the audit, audit time and audit team members

(including the auditor shall indicate the registration certificate number and professional code; technical experts shall indicate the professional code, technical title or position, and indicate the service unit).

4.2.3.2 初次认证审核、监督、再认证审核应在申请组织申请认证的范围涉及到的各个场所现场进行。如果医疗器械质量管理体系包含在多个场所进行相同或相近的活动，且这些场所都处于该申 请组织授权和控制下，认证机构可以在审核中对这些场所进行抽样，但应制定合理的抽样方案以确保对各场所医疗器械质量管理体系的正确审核。如果不同场所的活动存在根本不同、或不同场 所存在可能对医疗器械质量管理产生显著影响的区域性因素，则不能采用抽样审核的方法，应当逐一到各现场进行审核。

4.2.3.2 The initial certification audit, supervision and re-certification audit shall be carried out on site in each place involved in the scope of the application organization applying for certification. If the medical device quality management system contains the same or similar activities in multiple sites, and these sites are under the authorization and control of the application organization, the certification body may sample the sites in the audit, but a reasonable sampling scheme shall be developed to ensure the correct review of the medical device quality management system in each site. If there are fundamentally different activities in different places, or regional factors in different places that may have a significant impact on the quality management of medical devices, the sampling audit method cannot be adopted, and shall be reviewed on each site one by one.

4.2.3.3 为使现场审核活动能够观察到产品生产或服务活动情况，现场审核应安排在认证范围覆盖的产品生产或服务活动正常运行时进行。

4.2.3.3 In order to observe the product production or service activities during the site audit activities, the site audit shall be arranged during the normal operation of the product production or service activities covered by the certification scope.

4.2.3.4 在审核活动开始前，审核组应将书面审核计划交申请组织确认。遇特殊情况临时变更计划时，应及时将变更情况书面通知受审核的申请组织，并协商一致。

4.2.3.4 Before the review activity begins, the review team shall submit the written review plan to the application organization for confirmation. In case of temporary change plan under special circumstances, the approved application organization shall be notified of the change in writing and agreed through consultation.

4.3 实施审核

4.3 Implementation audit

4.3.1 审核组应当全员完成审核计划的全部工作。除不可预见的特殊情况外，审核过程中不得更换审核计划确定的审核员（技术专家和实习审核员除外）。

4.3.1 All the audit team shall complete all the work of the audit plan. Except for unforeseen special circumstances, the auditors determined in the audit plan shall not be replaced during the audit process (except for technical experts and practice auditors).

4.3.2 审核组应当会同申请组织按照程序顺序召开首、末次会议。审核组应当提供首、末次会议签到表，参会人员应签到。

4.3.2 The examination and approval team shall hold the first and last meetings together with the application organization in the order of procedures. The audit team shall provide the attendance form for the first and last meeting, and the participants shall sign in.

4.3.3 审核过程及环节

4.3.3 Audit process and links

4.3.3.1 初次认证审核，分为第一、二阶段实施审核。

4.3.3.1 The initial certification audit is divided into the first and second stages of the audit.

4.3.3.2 第一阶段审核应至少覆盖以下内容：

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

（1）结合现场情况，确认申请组织实际情况与医疗器械质量管理体系文件描述的一致性，特别是体系文件中描述的产品或服务、部门设置和负责人、生产或服务过程等是否与申请组织的实际情况相一致。

(1) Confirm the consistency of the actual situation of the application organization and the

description of the medical device quality management system documents, especially whether the products or services, department setting and responsible person, production or service process described in the system documents are consistent with the actual situation of the application organization.

（2）结合现场情况，审核申请组织有关人员理解和实施 ISO 13485 标准要求的情况，评价医疗器械质量管理体系运行过程中是否实施了内部审核与管理评审，确认医疗器械质量管理体系是否已有效运行并且超过 6 个月。对医疗器械质量管理体系文件不符合现场实际、相关体系运行尚未超过 6 个月或者无法证明超过 6 个月的，应当及时终止审核。

(2) Based on the site situation, review the relevant personnel to understand and implement the ISO 13485 standard requirements of the application organization, evaluate whether the internal audit and management review have been carried out in the operation of the medical device quality management system, and confirm whether the medical device quality management system has been in effective operation and for more than 6 months. If the documents of the medical device quality management system do not conform to the actual site, the relevant system operation has not exceeded 6 months or cannot be proved for more than 6 months, the audit shall be terminated in time.

（3）确认申请组织建立的医疗器械质量管理体系覆盖的活动内容和范围、申请组织的员工人数、活动过程和场所，遵守相关法律法规及技术标准的情况。

(3) Confirm the content and scope of activities covered by the medical device quality management system established by the application organization, the number of employees of the application organization, the activity process and place, and the compliance with relevant laws, regulations and technical standards.

（4）结合医疗器械质量管理体系覆盖活动的特点识别对质量目标的实现具有重要影响的关键点，并结合其他因素，科学确定重要审核点。

(4) Identify the key points with an important impact on the realization of the quality objectives based on the characteristics of the coverage activities of the medical device quality

management system, and scientifically determine the important audit points based on other factors.

（5）与申请组织讨论确定第二阶段审核安排。

(5) Discuss with the application organization to determine the second-stage review arrangement.

4.3.3.3 在下列情况，第一阶段审核可以不在申请组织现场进行，本机构保持不在现场进行一阶段审核的理由的记录：

4.3.3.3 In the following circumstances, the first-stage audit may not be conducted on the site of the application organization, and the agency maintains a record of the reasons for not conducting the first-stage audit on the site:

（1）申请组织已获本认证机构颁发的其他认证证书，认证机构已对申请组织医疗器械质量管理体系有充分了解。

(1) The application organization has obtained other certification certificates issued by the certification body, and the certification body has a full understanding of the medical device quality management system of the application organization.

（2）认证机构有充足的理由证明申请组织作为医疗器械经营销售企业，其经营服务的技术特征明显、过程简单，通过对其提交文件和资料的审查可以达到第一阶段审核的目的和要求。

(2) The certification body has sufficient reasons to prove that the application organization, as a medical device sales enterprise, has obvious technical characteristics and simple process, and the purpose and requirements of the first stage of audit can be achieved through the examination of the submitted documents and materials.

（3）申请组织获得过其他经认可的认证机构颁发的有效的医疗器械质量管理体系认证证书，通过对其文件和资料的审查可以达到第一阶段审核的目的和要求。

(3) The application organization has obtained the valid medical device quality management system certification certificate issued by other recognized accredited institutions, and the purpose and requirements of the first stage audit can be achieved through the examination

of its documents and materials.

除以上情况之外，第一阶段审核应在申请组织的生产经营或服务现场进行。

In addition to the above situation, the first stage of the audit shall be carried out at the production, operation or service site of the application organization.

4.3.3.4 审核组应将第一阶段审核情况形成书面文件告知申请组织。对在第二阶段审核中可能被判定为不符合项的重要关键点，要及时提醒申请组织特别关注。

4.3.3.4 The audit team shall inform the application organization of the written document of the first stage audit. For the key points that may be judged as nonconformance in the second stage of audit, the application organization should be reminded to pay special attention.

4.3.3.5 第一阶段审核和第二阶段审核应安排适宜的间隔时间，使申请组织有充分的时间解决第一阶段中发现的问题。

4.3.3.5 Appropriate intervals shall be arranged for the first and second stage audit, so that the application organization can have sufficient time to solve the problems found in the first stage.

4.3.3.6 第二阶段审核应当在申请组织现场进行。重点是审核医疗器械质量管理体系符合 GB/T 42061-2022 / ISO13485:2016 标准要求和有效运行情况，应至少覆盖以下内容：

4.3.3.6 The second stage of the review shall be conducted at the site of the application organization. The focus is to review the medical device quality management system compliance with the GB / T 42061-2022 / ISO13485:2016 standard requirements and effective operation, and should at least cover the following contents:

（1）在第一阶段审核中识别的重要审核点的监视、测量、报告和评审记录的完整性和有效性。

(1) Integrity and validity of the monitoring, measurement, reporting and review records of the important audit points identified in the first stage of the audit.

（2）为实现总质量目标而建立的各层级质量目标是否具体、有针对性、可测量并且可实现。

(2) Whether the quality objectives at each level established to achieve the overall quality

objectives are specific, targeted, measurable and achievable.

（3）对医疗器械质量管理体系覆盖的过程和活动的管理及控制情况。

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

（4）申请组织实际工作记录是否真实。

(4) Whether the actual work records of the application organization are true.

（5）申请组织的内部审核和管理评审是否有效。

(5) Whether the internal audit and management review of the application organization are valid.

4.3.4 发生以下情况时，审核组应终止审核，并向认证机构报告。

4.3.4 In the following cases, the audit team shall terminate the audit and report to the certification authority.

4.3.4.1 申请组织对审核活动不予配合，审核活动无法进行。

4.3.4.1 The application organization shall not cooperate with the audit activities, and the audit activities cannot be carried out.

4.3.4.2 申请组织的医疗器械质量管理体系有重大缺陷，不符合 ISO 13485 标准的要求。

4.3.4.2 The medical device quality management system of the application organization has major defects and does not meet the requirements of ISO 13485 standard.

4.3.4.3 发现申请组织存在重大质量安全问题或有其他严重违法违规行为。

4.3.4.3 The application organization is found to have major quality and safety problems or other serious violations of laws and regulations.

4.3.4.4 其他导致审核程序无法完成的情况。

4.3.4.4 Other circumstances leading to incomplete audit procedures.

4.4 审核报告

4.4 Audit report

4.4.1 审核组对审核活动形成书面的审核报告，并由审核组长签字。审核报告应准确、简要、

清楚地描述审核活动的主要内容，至少包括以下内容：

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

4.4.1.1 申请组织的名称和地址。

4.4.1.1 Name and address of the application organization.

4.4.1.2 审核的申请组织活动范围和场所。

4.4.1.2 Scope and place of the reviewed application organization.

4.4.1.3 审核组组长、审核组成员及其个人注册信息。

4.4.1.3 Leader of audit team, members of audit team and their personal registration information.

4.4.1.4 审核活动的实施日期和地点。

4.4.1.4 Date and place of implementation of the audit activities.

4.4.1.5 叙述 从 4.3 条列明的程序及各项要求的审核工作情况，其中：对 4.3.3.6 条的各项审核要求应逐项就审核证据、审核发现和审核结论进行详细描述；对质量目标实现情况的评价，应同 时叙述测量方法。

4.4.1.5 For the procedures and requirements specified in Article 4.3, the audit requirements in Article 4.3.3.6 shall be described in detail for the evaluation of the achievement of quality objectives.

4.4.1.6 识别出的不符合项。不符合项的表述，应基于客观证据和审核依据，用写实的方法准确、具体、清晰描述，易于被申请组织理解。不得用概念化的、不确定的、含糊的表述不符合项。

4.4.1.6 Non-conformance items identified. The expression of non-conformities should be based on objective evidence and audit basis, and accurate by realistic method Specific, clear description, easy to be understood by the application organization. No conceptual, uncertain, or vague statements shall be used.

4.4.1.7 审核组对是否通过认证的意见建议。

4.4.1.7 Suggestions of the audit team on whether to pass the certification.

4.4.2 审核报告应随附必要的用于证明相关事实的证据或记录，包括文字或照片摄像等资料。

4.4.2 The audit report shall be accompanied by the necessary evidence or records used to prove the relevant facts, including text, photos and video materials.

4.4.3 本机构将审核报告提交申请组织，保留签收或提交的证据。

4.4.3 The organization shall submit the review report to the application organization and retain the evidence signed or submitted.

4.4.4 对终止审核的项目，审核组应将已开展的工作情况形成报告，本机构将此报告及终止审核的原因提交给申请组织，保留签收或提交的证据。

4.4.4 For the terminated projects, the audit team shall report the work carried out, and the agency shall submit the report and the reasons for the termination to the application organization, and retain the evidence signed or submitted.

4.5 不符合项的纠正和纠正措施及其结果的验证

4.5 Corrective and corrective measures of non-conformance items and verification of the results

4.5.1 对审核中发现的不符合项，本机构要求申请组织分析原因，并要求申请组织在规定期限内采取措施进行纠正。

4.5.1 For the non-conformance items found in the audit, the agency requires the application organization to analyze the causes, and requires the application organization to take measures to correct them within the prescribed time limit.

4.5.2 本机构对申请组织所采取的纠正和纠正措施及其结果的有效性进行验证。

4.5.2 The agency shall verify the effectiveness of the corrective and corrective measures taken by the application organization and its results.

4.5.3 对下次审核的审核方案调整的建议。

4.5.3 Suggestions for the adjustment of the audit plan for the next review.

4.6 认证决定

4.6 Certification decision

4.6.1 本机构认证决定人员在对审核报告、不符合项的纠正和纠正措施及其结果进行综合评价基础上，作出认证决定。

4.6.1 The certification personnel of the agency shall make a certification decision on the basis of comprehensive evaluation of the audit report, corrective and corrective measures of non-conformance and their results.

4.6.2 审核组成员不得参与对审核项目的认证决定。

4.6.2 Members of the audit team shall not participate in the certification decision of the audit project.

4.6.3 认证决定人员在作出认证决定前应确认如下情形：

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

4.6.3.1 审核报告符合本规则第 4.4 条要求，能够满足作出认证决定所需要的信息。

4.6.3.1 The audit report shall comply with the requirements of Article 4.4 of these Rules and can meet the information required to make the certification decision.

4.6.3.2 反映以下问题的不符合项，本机构已评审、接受并验证了纠正和纠正措施及其结果的有效性:

4.6.3.2 For non conformance reflecting the following problems, the agency has reviewed, accepted and verified the effectiveness of corrective and corrective measures and their results:

（1）未能满足医疗器械质量管理体系标准的要求。

(1) Failure to meet the requirements of the medical device quality management system standards.

（2）制定的质量目标不可测量、或测量方法不明确。

(2) The formulated quality target cannot be measured, or the measurement method is unclear.

（3）对实现质量目标具有重要影响的关键点的监视和测量未有效运行，或者对这些关键点的报 告或评审记录不完整或无效。

(3) The monitoring and measurement of key points that have an important impact on the realization of quality objectives are not run effectively, or the report or review records of these key points are incomplete or invalid.

（4）在持续改进医疗器械质量管理体系的有效性方面存在缺陷，实现质量目标有重大疑问。

(4) There are defects in the effectiveness of the continuous improvement of the medical device quality management system, and there are major doubts about the realization of the quality goals.

（5）当病人和/或用户根据产品标签使用投放到市场的医疗器械导致不合理的风险。

(5) unreasonable risks when patients and / or users use medical devices put to the market according to the product label.

（6）医疗器械产品存在显然不符合客户要求的技术参数和/或政府监管要求。

(6) The medical device products obviously do not meet the customer requirements of the technical parameters and / or government regulatory requirements.

4.6.3.3 本机构对其他不符合项已评审，并接受了申请组织计划采取的纠正和纠正措施。

4.6.3.3 The agency has reviewed other non-conformance items and accepted the corrective and corrective measures taken by the application organization.

4.6.4 在满足 4.6.3 条要求的基础上，对有充分的客观证据证明申请组织满足下列要求的， 本机构将评定该申请组织符合认证要求，向其颁发认证证书。

4.6.4 On the basis of meeting the requirements of Article 4.6.3, if there is sufficient objective evidence to prove that the application organization meets the following requirements, the agency will assess that the application organization meets the certification requirements and issue a certification certificate to it.

4.6.4.1 申请组织的医疗器械质量管理体系符合标准要求且运行有效。

4.6.4.1 The medical device quality management system of the application organization

meets the standard requirements and has effective operation.

4.6.4.2 认证范围覆盖的产品或服务符合相关法律法规要求。

4.6.4.2 The products or services covered by the certification scope shall meet the requirements of relevant laws and regulations.

4.6.4.3 申请组织按照认证合同规定履行了相关义务。

4.6.4.3 The application organization has performed the relevant obligations in accordance with the provisions of the certification contract.

4.6.5 申请组织不能满足上述要求的，评定该申请组织不符合认证要求，本机构以书面形式 告知申请组织并说明其未通过认证的原因。

4.6.5 If the application organization fails to meet the above requirements, the application organization shall be assessed as not meeting the certification requirements, and the agency shall inform the application organization in writing and explain the reasons for its failure to pass the certification.

4.6.6 本机构在颁发认证证书后按照规定的要求将相关信息报送国家认监委。 本机构的认证证书信息可在国家认监委网站“www.cnca.gov.cn”上查询。

4.6.6 After issuing the certification certificate, the agency shall submit the relevant information to the CNCA in accordance with the prescribed requirements. The certification certificate information of the agency can be found on the CNCA website.“www.cnca.gov.cn”

4.6.7 本机构不将申请组织是否获得认证与参与认证审核的审核员及其他人员的薪酬挂钩。

4.6.7 The Agency does not link the certification of the application organization to the remuneration of the auditors and other personnel involved in the certification audit.

5 监督审核程序

5. Supervise the audit procedures

5.1 本机构对医疗器械质量管理体系获证组织进行有效跟踪，监督获证组织通过认证的医疗器械质量管理体系持续符合要求。

5.1 The organization shall effectively track the medical device quality management system

certification organization, and supervise the certified medical device quality management system of the certified organization to continuously meet the requirements.

5.2 为确保达到 5.1 条要求，本机构根据获证组织的产品或服务的质量风险程度或其他特性，确定对获证组织的监督审核的频次。

5.2 In order to ensure meeting the requirements of Article 5.1, the agency determines the frequency of supervision and review of the licensed organization according to the quality risk degree or other characteristics of the products or services of the licensed organization.

5.2.1 作为最低要求，在初次认证的第二阶段审核后至少 12 个月内应进行一次监督审核。此后，每次监督审核的时间间隔不超过 12 个月。

5.2.1 As a minimum requirement, a supervisory audit shall be conducted within at least 12 months after the second phase of the initial certification audit. Thereafter, the time interval of each supervisory audit shall not exceed 12 months.

5.2.2 在达到监督审核期限而有证据表明获证组织暂不具备实施监督审核的条件时，可以适当延长监督审核期限，但最长间隔不能超过 15 个月。

5.2.2 When the supervision and audit period is reached and there is evidence that the certified organization does not have the conditions for implementing the supervision and audit temporarily, it can be appropriate When the supervision and audit period is extended, but the maximum interval should not exceed 15 months.

5.2.3 超过期限而未能实施监督审核的，应按 7.2 或 7.3 条处理。

5.2.3 Failure to implement supervision and audit after the deadline shall be handled according to Article 7.2 or 7.3.

5.3 监督审核的基准人日，按 4.2.1 条计算审核时间人日数的 50%。附录 B 和 C 分别确定了通用基准人日和仅考虑了医疗器械级别的基准人日。

5.3 For the base person day of supervision and audit, 50% of the person day of the audit time shall be calculated according to Article 4.2.1. Appendix B and C identify the generic baseline day and only the medical device level, respectively.

5.4 监督审核的审核组，应符合 4.2.2 条和 4.3.1 条的要求。

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

5.5 监督审核应在获证组织现场进行，且应满足第 4.2.3.3 条确定的条件。由于产品生产的 季节性原因，在每次监督审核时难以覆盖所有产品的，在认证证书有效期内的监督审核需覆盖认证范围内的所有产品。

5.5 The supervisory audit shall be conducted at the site of the certified organization and shall meet the conditions specified in Clause 4.2.3.3. Due to the seasonal reasons of product production, if it is difficult to cover all products in each supervision and audit, the supervision and audit within the validity period of the certification certificate shall cover all products within the certification scope.

5.6 每次监督审核时至少应审核以下内容：

5.6 The following contents shall be reviewed during each supervisory audit:

5.6.1 上次审核以来医疗器械质量管理体系覆盖的过程、活动及相互关系、体系过程运行的资源的变更、以及由这些变更引发的管理体系和过程策划的变更；

5.6.1 Changes in the process, activities and interrelationships covered by the medical device quality management system, the resources of the system process operation, and the changes of the management system and process planning caused by these changes;

5.6.2 按 4.3.3.2 条要求已识别的重要关键点是否按医疗器械质量管理体系的要求在正常和有效运行，包括产品实现策划的变更、采购过程、生产和服务提供过程、产品监测、不合格品控制、生产设备和监测设备控制，（无菌/清洁产品的）工作环境控制；

5.6.2 Whether the important key points identified according to Article 4.3.3.2 are in normal and effective operation according to the requirements of the medical device quality management system, including product implementation planning change, procurement process, production and service provision process, product monitoring, control of nonconforming products, production equipment and monitoring equipment control, and

(working environment control of sterile / clean products);

5.6.3 对上次审核中确定的不符合项采取的纠正和纠正措施是否继续有效。

5.6.3 Whether the corrective and corrective measures taken for the non-conformance items identified in the last audit remain effective.

5.6.4 医疗器械质量管理体系覆盖的活动涉及法律法规规定的，相关法律法规或技术标准是发生变化，是否持续符合相关规定。

5.6.4 If the activities covered by the medical device quality management system involve the provisions of laws and regulations, the relevant laws and regulations or technical standards have changed, and whether they continue to meet the relevant regulations.

5.6.5 总质量目标及各层级质量目标是否实现。目标没有实现的，获证组织在内部管理评审时是否及时调查并采取了改进措施。

5.6.5 Whether the overall quality objectives and the quality objectives of all levels are achieved. If the goal is not achieved, whether the certified organization timely investigates and takes improvement measures during the internal management review.

5.6.7 获证组织对认证标志的使用或对认证资格的引用是否符合相关的规定。

5.6.7 Whether the use of the certification mark or the reference to the certification qualification complies with the relevant provisions.

5.6.8 内部审核和管理评审是否规范和有效。

5.6.8 Whether the internal audit and management review are standardized and effective.

5.6.9 是否及时接受和处理投诉，包括对不良事件的报告及调查处置。

5.6.9 Whether to accept and handle complaints in time, including the reporting, investigation and disposal of adverse events.

5.6.10 针对内审发现的问题或投诉的问题，及时制定并实施了有效的持续改进。

5.6.10 The problems found in the internal audit or the complaints.

5.6.11 其他监督审核条款由具体项目的审核方案确定。

5.6.11 Other supervision and review clauses shall be determined by the review plan of

specific projects.

5.7 监督审核的审核报告，应按 5.6 条列明的审核要求逐项描述审核证据、审核发现和审核结论。审核组应提出是否继续保持认证证书的意见建议。

5.7 In the audit report of supervision and audit, the audit evidence, audit discovery and audit conclusion shall be described item by item according to the audit requirements listed in Article 5.6. The audit team shall make suggestions on whether to continue to maintain the certification certificate.

5.8 本机构根据监督审核报告及其他相关信息，作出继续保持或暂停、撤销认证证书的决定。

5.8 The agency shall, based on the supervision audit report and other relevant information, make decisions to maintain or suspend or revoke the certification certificate.

6 再认证程序

6 Re-certification program

6.1 认证证书期满前，若获证组织申请继续持有认证证书，认证机构应当实施再认证审核决 定是否延续认证证书。

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

6.2 认证机构应按 4.2.2 条要求组成审核组。按照 4.2.3 条要求并结合历次监督审核情况， 制定再认证计划并交审核组实施。审核组按照要求开展再认证审核。在质量管理体系及获证组织的内部和外部环境无重大变更时，再认证审核可省略第一阶段审 核，但审核时间应不少于按 4.2.1 条计算人日数的 80%。

6.2 The certification body shall form an audit team according to the requirements of Article 4.2.2. According to the requirements of Article 4.2.3 and the previous supervision and audit situation, formulate the re-certification plan and submit it to the audit team for implementation. The audit team shall carry out the re-certification audit according to the requirements. When there is no major change in the quality management system and the

internal and external environment of the certified organization, the first stage of the audit can be omitted, but the audit time shall not be less than 80% of the number of people and days calculated according to Article 4.2.1.

6.3 对再认证审核中发现的不符合项，应按 4.5 条要求实施纠正和纠正措施并进行验证，验证应在原证书有效期满前完成。

6.3 For the non-conformance items found in the re-certification audit, corrective actions and corrective measures shall be implemented and verified as required in Article 4.5, and the verification shall be completed before the expiration of the original certificate.

6.4 认证机构参照 4.6 条要求作出再认证决定。获证组织继续满足认证要求并履行认证合同义务的，向其换发认证证书。

6.4 The certification body shall make a reccertification decision according to the requirements of Article 4.6. If the certified organization continues to meet the certification requirements and fulfill the certification contract obligations, the certification certificate shall be issued to it.

7 暂停或撤销认证证书

7 suspend or revoke the certificate

7.1 认证机构应制定暂停、撤销认证证书或缩小认证范围的规定，并形成文件化的管理制度。

7.1 Certification bodies shall formulate regulations on suspending or revoking certification certificates or narrowing the scope of certification, and form a documented management system.

7.2 暂停证书

7.2 Suspend the certificate

7.2.1 获证组织有以下情形之一的，认证机构应在调查核实后的 5 个工作日内暂停其认证证书。

7.2.1 In any of the following circumstances of the certification organization, the certification body shall suspend its certification certificate within 5 working days after the investigation

and verification.

7.2.1.1 管理体系持续或严重不满足认证要求，包括对管理体系运行有效性要求的。

7.2.1.1 The management system continuously or seriously fails to meet the certification requirements, including the requirements for the effectiveness of the management system.

7.2.1.2 不承担、履行认证合同约定的责任和义务的。

7.2.1.2 Failure to assume or perform the responsibilities and obligations stipulated in the certification contract.

7.2.1.3 被有关执法监管部门责令停业整顿的。

7.2.1.3 Being ordered to suspend business for rectification by the relevant law enforcement and supervision department.

7.2.1.4 被地方认证监管部门发现体系运行存在问题，需要暂停证书的。

7.2.1.4 The operation of the system and needs to suspend the certificate.

7.2.1.5 持有的行政许可证明、资质证书、强制性认证证书等过期失效，重新提交的申请已被受理但尚未换证的。

7.2.1.5 The administrative license certificate, qualification certificate, compulsory certification certificate held expire and expire, and the resubmitted application has been accepted but has not been renewed.

7.2.1.6 主动请求暂停的。

7.2.1.6 Active request for suspension.

7.2.1.7 其他应当暂停认证证书的。

7.2.1.7 Other certification certificates that should be suspended.

7.2.2 认证证书暂停期不得超过 3 个月。但属于 7.2.1.5 项情形的暂停期可至相关单位作出许可决定之日。

7.2.2 The suspension period of the certification certificate shall not exceed 3 months. However, the suspension period under the circumstances of item 7.2.1.5 may be up to the date when the relevant unit makes the licensing decision.

7.2.3 认证机构暂停认证证书的信息，应明确暂停的起始日期和暂停期限，并声明在暂停期 间获证组织不得以任何方式使用认证证书、认证标识或引用认证信息。

7.2.3 The suspension information of the certification body shall specify the starting date and suspension period, and declare 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 撤销证书

7.3.1 获证组织有以下情形之一的，认证机构应在获得相关信息并调查核实后 5 个工作日内撤销其认证证书。

7.3.1 In any of the following circumstances of the certification organization, the certification body shall revoke its certification certificate within 5 working days after obtaining the relevant information and investigation and verification.

7.3.1.1 被注销或撤销法律地位证明文件的。

7.3.1.1 The legal status certificate is cancelled or revoked.

7.3.1.2 拒绝配合认证监管部门实施的监督检查，或者对有关事项的询问和调查提供了虚假材料或信息的。

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

7.3.1.3 出现重大的产品或服务等质量安全事故，经执法监管部门确认是获证组织违规造成的。

7.3.1.3 Major quality and safety accidents such as products or services are confirmed by the law enforcement and supervision department as caused by the violation of the certified organization.

7.3.1.4 有其他严重违反法律法规行为的。

7.3.1.4 Other acts in serious violation of laws and regulations.

7.3.1.5 暂停认证证书的期限已满但导致暂停的问题未得到解决或纠正的（包括持有的行政许可

证明、资质证书、强制性认证证书等已经过期失效但申请未获批准）。

7.3.1.5 The period of the suspension certificate has expired but the problems leading to the suspension have not been solved or corrected (including the administrative license certificate, qualification certificate, compulsory certification certificate, etc. have expired but the application has not been approved)

7.3.1.6 没有运行医疗器械质量管理体系或者已不具备运行条件的。

7.3.1.6 There is no quality management system for medical devices or no conditions for operation.

7.3.1.7 不按相关规定正确引用和宣传获得的认证信息，造成严重影响或后果，或者认证机构已要求其纠正但超过 6 个月仍未纠正的。

7.3.1.7 Failing to correctly quote and publicize the certification information obtained in accordance with relevant regulations, causing serious impact or consequences, or the certification body has required it to correct, but still failed to correct for more than 6 months.

7.3.1.8 其他应当撤销认证证书的。

7.3.1.8 Other certification certificates shall be revoked.

7.3.2 撤销认证证书后，认证机构应及时收回撤销的认证证书。若无法收回，认证机构应及 时在相关媒体和网站上公布或声明撤销决定。

7.3.2 After the cancellation of the certification certificate, the certification body shall withdraw the revoked certification certificate in time. If it cannot be recovered, the certification body shall promptly publish or declare the cancellation decision on the relevant media and website.

7.4 认证机构暂停或撤销认证证书应当在其网站上公布相关信息，同时按规定程序和要求报国家认监委。

7.4 The certification body shall suspend or revoke the certification certificate, publish the relevant information on its website, and report to the CNCA in accordance with the prescribed procedures and requirements.

7.5 本机构通过采取有效措施以避免各类无效的认证证书和认证标志被继续使用。

7.4 The certification body shall suspend or revoke the certification certificate, publish the relevant information on its website, and report to the CNCA in accordance with the prescribed procedures and requirements.

8 认证证书要求

8 Certification certificate requirements

8.1 认证证书应至少包含以下信息：

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

8.1.1 获证组织名称、地址和组织机构代码。该信息应与其法律地位证明文件的信息一致。

8.1.1 Name, address, and organization code of the certified organization. The information shall be consistent with the information supporting its legal status document.

8.1.2 医疗器械质量管理体系覆盖的生产经营或服务的地址和业务范围。若认证的医疗器械质量管理体系覆盖多场所，表述覆盖的相关场所的名称和地址信息，该信息应与相应的法律地位证明文件信息一致。

8.1.2 Address and business scope of the production, operation or service covered by the medical device quality management system. If the certified medical device quality management system covers multiple places, stating the name and address information of the relevant sites covered, the information should be consistent with the corresponding legal status certification documents.

8.1.3 医疗器械质量管理体系符合 ISO 13485 标准的表述。

8.1.3 Statement that the medical device quality management system meets the ISO 13485 standard.

8.1.4 证书编号。

8.1.4 Certificate No.

8.1.5 认证机构名称。

8.1.5 Name of the certification body.

8.1.6 证书签发日期及有效期的起止年月日。 对初次认证以来未中断过的再认证证书，可表述该获证组织初次获得认证证书的年月日。

8.1.6 Date of certificate issuance and the date of validity period. For the recertification certificate that has not been interrupted since the initial certification, the date of the certification organization for the first time.

8.1.7 相关的认可标识及认可注册号（适用时）。

8.1.7 Relevant approval mark and approval registration number (when applicable).

8.1.8 证书查询方式。除公布认证证书在本机构网站上的查询方式外，还在证书上注明：“本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询”，以便于社会监督。

8.1.8 Certificate query method. In addition to the publication of the certification certificate on the agency website, it is also noted on the certificate: " The information of this certificate can be found on the official website of the Certification and Accreditation Administration (www.cnca.gov. cn) " to facilitate social supervision.

8.2 认证证书有效期最长为 3 年。

8.2 The maximum validity period of the certification certificate is 3 years.

8.3 本机构建立证书信息披露制度。除向申请组织、认证监管部门等执法监管部门提供认证证书信息外，还应当根据社会相关方的请求向其提供证书信息，接受社会监督。

8.3 The agency establishes a certificate information disclosure system. In addition to providing the certification certificate information to the application organization, the certification supervision department and other law enforcement and supervision departments, it shall also provide the certificate information to the relevant parties at the request of the social parties and accept the social supervision.

9 与其他管理体系的结合审核

9 Review the combination with other management systems

9.1 对医疗器械质量管理体系和其他管理体系实施结合审核时，通用或共性要求应满足本规则

要求，审核报告中应清晰地体现 4.4 条要求，并易于识别。

9.1 For the combined review of the medical device quality management system and other management systems, the general or common requirements shall meet the requirements of these Rules, and the 4.4 requirements shall be clearly reflected in the audit report and easy to identify.

9.2 对医疗器械质量管理体系（ISO13485）与质量管理体系（ISO9001）结合审核时，总的审核时间人日数不得少于医疗器械质量管理体系所需审核时间 110%。

医疗器械质量管理体系与除质量管理体系（ISO9001）之外的管理体系认证结合审核时，结合 审核的审核时间人日数，不得少于多个单独体系所需审核时间之和的 80%。

9.2 For the combination of the medical device quality management system (ISO13485) and the quality management system (ISO9001), the total audit time shall not be less than 110% of the audit time required by the medical device quality management system.

When combining the medical device quality management system with the management system certification except the quality management system (ISO9001), the audit time number and days of the audit shall not be less than 80% of the sum of the audit time required by multiple separate systems.

10 受理转换认证证书

10 Accept the conversion of the certification certificate

10.1 我机构认真履行社会责任，严禁以牟利为目的受理认证转换。针对从其它机构转换至本机构的认证申请，均按初次审核的要求进行受理。

10.1 Our organization conscientiously performs its social responsibilities, and strictly forbids to accept certification conversion for the purpose of profit. Certification applications converted from other institutions to our institutions are accepted according to the requirements of the initial examination.

10.2 被执法监管部门责令停业整顿或列入“黑名单”的（如 7.2 条第［3］项）、被发证的认证机构撤销证书的（如 7.3 条），除非该组织进行彻底整改，导致暂停或撤销认证证书的情形

已消除，否则不受理其认证申请。

10.2 is ordered to suspend business for rectification or included in the "blacklist" (such as article 7.2 item [3]), the certification body revoked the certificate (such as article 7.3), unless the organization for thorough rectification, resulting in the suspension or cancellation of the certification certificate has been eliminated, otherwise the certification application.

11 受理组织的申诉

11 Accept complaints from the organization

获证组织对认证决定有异议时，本机构接受获证组织的申诉，并按规定的程序进行受理、并及时进行处理，在 60 日内将处理结果形成书面通知送交获证组织。书面通知应当告知获证组织，若认为认证机构未遵守认证相关法律法规或本规则并导致自身合法权益受到严重侵害的，可以直接向所在地认证监管部门或国家认监委投诉，也可以向相关认可机构投诉。

If the certified organization has any objection to the certification decision, the organization shall accept the appeal of the certified organization, accept and handle the prescribed procedures, and handle it in time, and send the processing result into a written notice to the certified organization within 60 days. The written notice shall inform the certified organization that if the certification body does not comply with the relevant laws and regulations or these rules and causes serious infringement of its legitimate rights and interests, it can directly complain to the local certification regulatory department or CNCA, or to the relevant accreditation institution.

12 认证记录的管理

12 Management of certification records

12.1 本机构建立认证记录保持制度，记录认证活动全过程并妥善保存。

12.1 The agency shall establish a certification record keeping system to record the whole process of certification activities and keep them properly, for example.

12.2 记录应当真实准确以证实认证活动得到有效实施。记录资料应当使用中文，保存时间至少应当与认证证书有效期一致。

12.2 Records shall be true and accurate to confirm that the certification activities have been effectively implemented. The recorded data shall be used in Chinese, and the storage time shall be at least consistent with the validity period of the certification certificate.

12.3 以电子文档方式保存记录的，应采用不可编辑的电子文档格式。

12.3 If records are kept by electronic documents, a non-editable electronic document format shall be adopted.

13 其他

13 Other

13.1 本规则内容提及 GB/T 42061 和 ISO13485 标准时均指认证活动发生时该标准的有效版本（换版过渡期给与一定时间的过渡时间）。认证活动及认证证书中描述该标准号时，应采用当时有效版本的完整标准号。

13.1 The GB / T 42061 and ISO13485 standards both refer to the valid version of the standard at the time of the certification activity (the transition period gives a certain period of time). The standard number shall be described in the certification activities and the then valid version.

13.2 本规则所提及的各类证明文件的复印件应是在原件上复印的，并经复印件提供者签章（签字）认可其与原件一致。

13.2 Copies of all kinds of supporting documents mentioned in these rules shall be copied on the original, and the copy provider shall be consistent with the original.

13.3 认证机构可采取必要措施帮助组织开展医疗器械质量管理体系及相关技术标准的宣贯培训，促使组织的全体员工正确理解和执行医疗器械质量管理体系标准。

13.3 Certification bodies can take necessary measures to help organize the publicity and implementation training of medical device quality management system and related technical standards, so as to encourage all employees of the organization to correctly understand and implement the medical device quality management system standards.

附件 A 医疗器械业务分类

Annex A. Business classification of medical devices

MD 9 Code MD9 码	MD9 Group Description MD9 分组描述
Appendix A 1.1 Non-Active medical devices **附录 A 1.1 无源医疗器械**	
Appendix A 1.1.1 General non-active, non-implantable medical devices **附录 A 1.1.1 一般无源，非植入式医疗器械**	
9A.1.1.1.1	Non-active devices for anesthesia, emergency, and intensive care 用于麻醉、急诊和重症监护的无源器械
9A.1.1.1.2	Non-active devices for injection, infusion, transfusion, and dialysis 用于注射、输液、输血和透析的无源器械
9A.1.1.1.3	Non-active orthopedic and rehabilitation devices 矫形和康复装置无源器械
9A.1.1.1.4	Non-active medical devices with measuring function 具有测量功能的无源医疗器械
9A.1.1.1.5	Non-active ophthalmologic devices 眼科无源器械
9A.1.1.1.6	Non-active instruments 无源设备
9A.1.1.1.7	Contraceptive medical devices 避孕医疗器械
9A.1.1.1.8	Non-active medical devices for disinfecting, cleaning, rinsing 用于消毒、清洁、冲洗的无源医疗器械
9A.1.1.1.9	Non-active devices for in vitro fertilization (IVF) and assisted reproductive

	technologies (ART) 体外受精(IVF)和辅助生殖技术(ART)的无源器械
9A.1.1.1.10	Non-active medical devices for ingestion 吸入式无源医疗器械
	Appendix A 1.1.2 Non-active, implantable medical devices 附录 A 1.1.2 无源植入物
9A.1.1.2.1	Non-active cardiovascular implants 无源心血管植入物
9A.1.1.2.2	Non-active orthopedic implants 无源骨科整形植入物
9A.1.1.2.3	Non-active functional implants 无源功能性植入物
9A.1.1.2.4	Non-active soft tissue implants 无源软组织植入物
Appendix A 1.1.3 Devices for wound care 附录 A 1.1.3 伤口护理器械	
9A.1.1.3.1	Bandages and wound dressings 绷带和伤口敷料
9A.1.1.3.2	Suture material and clamps 缝合材料和夹子
9A.1.1.3.3	Other medical devices for wound care 其他用于伤口护理的医疗器械
A.1.1.4 Non-active dental devices and accessories A.1.1.4 无源牙科器械及配件	
9A.1.1.4.1	Non-active dental devices/equipment and instruments 无源牙科器械/设备和仪器
9A.1.1.4.2	Dental materials 牙科材料
9A.1.1.4.3	Dental implants 种植牙
A.1.1.5 Non-active medical devices other than specified above	

A.1.1.5 除上述规定外的无源医疗器械	
9A.1.1.5.0	Clothing / Personal Protective Equipment (PPE) 衣物/个人防护设备(PPE)： • Masks 口罩 • Robes 防护服 • EMS personnel clothing EMS 急救服务人员衣物 • Gowns, coveralls and lab coats 隔离衣、工装服、实验服 • Gloves 手套 • Caps 工作帽 • Hygiene products 卫生用品 • Disposable / single-use PPE items 一次性/单次使用 PPE 物品
9A.1.1.5.1	Non-active medical devices other than specified above 除上述规定外的无源医疗器械
A.1.2 Active (Non-Implantable) medical devices A.1.2 有源医疗器械（非植入性）	
A.1.2.1 General active medical devices A.1.2.1 一般有源医疗器械	
9A.1.2.1.1	Devices for extra-corporal circulation, infusion and haemopheresis 体外循环，输液和血液穿刺的器械
9A.1.2.1.2	Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anesthesia 呼吸器械，包括用于氧气疗法，吸入麻醉的高压舱的器械
9A.1.2.1.3	Devices for stimulation or inhibition 刺激或抑制器械
9A.1.2.1.4	Active surgical devices 有源手术器械
9A.1.2.1.5	Active ophthalmologic devices 有源眼科器械
9A.1.2.1.6	Active dental devices 有源牙科器械
9A.1.2.1.7	Active devices for disinfection and sterilization 用于消毒和杀菌的有源器械
9A.1.2.1.8	Active rehabilitation devices and active prostheses 有源康复设备和假肢
9A.1.2.1.9	Active devices for patient positioning and transport 用于患者定位和运输的有源器械
9A.1.2.1.10	Active devices for in vitro fertilization (IVF) and assisted reproductive technologies

	(ART) 体外受精（IVF）和辅助生殖技术（ART）的有源器械
9A.1.2.1.11	Software, including software design for medical devices 软件，包括为医疗设备设计的软件
9A.1.2.1.12	Medical gas supply systems and parts thereof 医用气体供应系统及其零件
A.1.2.2 Devices for imaging　　A.1.2.2 成像设备	
9A.1.2.2.1	Devices utilizing ionizing radiation 使用电离辐射的设备
9A.1.2.2.2	Devices utilizing non-ionizing radiation 使用非电离辐射的设备
A.1.2.3 Monitoring devices　　A.1.2.3 监控设备	
9A.1.2.3.1	Monitoring devices of non-vital physiological parameters 非重要生理参数的监测设备
9A.1.2.3.2	Monitoring devices of vital physiological parameters 重要生理参数的监测设备
A1.2.4 Devices for radiation therapy and　thermo therapy　A1.2.4 放射治疗和热疗设备	
9A.1.2.4.1	Devices utilising ionizing radiation 利用电离辐射的设备
9A.1.2.4.2	Devices utilising non-ionizing radiation 利用非电离辐射的设备
9A.1.2.4.3	Devices for hyperthermia / hypothermia 热疗/低温治疗设备
9A.1.2.4.4	Devices for (extracorporal) shock-wave therapy(lithotripsy) 用于(体外)冲击波治疗（碎石术）的设备
A.1.2.5 Active (non-implantable) medical devices other than specified above. A.1.2.5 除上述规定外的有源（非植入）医疗器械	
9A.1.2.5.0	Active (non-implantable) medical devices other than specified above.除上述规定外的有源（非植入）医疗器械
A.1.3Active implantable medical devices A.1.3 有源植入式医疗器械	
9A.1.3.1.1	Active implantable medical devices for stimulation/inhibition 用于刺激/抑制的有源植入式医疗器械
9A.1.3.1.2	Active implantable medical devices delivering drugs or other substances 输送药物或其他物质的有源植入式医疗器械

9A.1.3.1.3	Active implantable medical devices substituting or replacing organ functions 替代或者替代器官功能的有源植入式医疗器械
9A.1.3.2.0	Implantable medical devices other than specified above 以上规定以外的植入式医疗器械
A.1.4 In Vitro Diagnostic Medical Devices (IVD) A.1.4 体外诊断医疗器械（IVD）	
9A.1.4.1.0	Reagents and reagent products, calibrators and control materials for: 试剂和试剂产品，校准器和对照材料，用于: - Clinical Chemistry 临床化学 - Biochemistry (Immunology) 免疫化学（免疫学） - Hematology / Hemostats / Immunological 血液学/止血/免疫血液学 - Microbiology 微生物学 - Infectious Immunology 传染性免疫学 - Histology / Cytology 组织学/细胞学 - Genetic Testing 基因检测
9A.1.4.2.0	In Vitro Diagnostic (IVD) Instruments and software 体外诊断（IVD）器械和软件
9A.1.4.3.0	In Vitro Diagnostic (IVD) medical devices other than specified 除上述规定外的体外诊断（IVD）医疗器械
A.1.5 Sterilization methods for medical devices A.1.5 医疗器械的灭菌方法	
9A.1.5.1.0	Ethylene oxide gas sterilization (EOG) 环氧乙烷气体灭菌方法
9A.1.5.2.0	Moist heat 湿热
9A.1.5.3.0	Aseptic processing 无菌加工操作
9A.1.5.4.0	Radiation sterilization (e.g.,gamma, x-ray, electron beam) 辐射灭菌（例如伽马射线、X 射线、电子束）

9A.1.5.5.0	**Low temperature steam and formaldehyde sterilization** **低温蒸汽和甲醛杀菌**
9A.1.5.6.0	**Thermionic sterilization with dry heat** **干热热灭菌**
9A.1.5.7.0	**Sterilization with hydrogen peroxide** **用过氧化氢灭菌**
9A.1.5.8.0	**Sterilization method other than specified above** **上述规定以外的灭菌方法**
A.1.6 Devices Incorporating / Utilizing Specific Substances / Technologies **A.1.6 采用/利用特定物质/技术的设备**	
9A.1.6.1.1	**Medical devices incorporating medicinal substances** **含有药用物的医疗器械**
9A.1.6.1.2	**Medical devices utilizing tissues of animal origin** **利用动物源性组织的医疗器械**
9A.1.6.1.3	**Medical devices incorporating derivates of human blood** **含有人体血液衍生物的医疗器械**
9A.1.6.1.4	**Medical devices utilizing micromechanics** **利用微观力学的医疗器械**
9A.1.6.1.5	**Medical devices utilizing nanomaterials** **利用纳米材料的医疗器械**
9A.1.6.1.6	**Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed** **使用生物活性涂层和/或材料，全部或主要被吸收的医疗器械**
9A.1.6.1.7	**Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above.** **包含或利用上述规定以外的物质/技术/元素的其他医疗器械**
A.1.7 Parts or Services　A.1.7 零件和服务	
A.1.7.1 Raw Materials　A.1.7.1 原料	
9A.1.7.1.1	**Raw materials - Raw Metals 原料 - 金属**
9A.1.7.1.2	**Raw materials – Plastics 原料 - 塑料**
9A.1.7.1.3	**Raw materials – Wood 原料 - 木材**

9A.1.7.1.4	Raw materials – Ceramic 原料 - 陶瓷
A.1.7.2 Components A.1.7.2 组件	
9A.1.7.2.1	Components - Electrical Components 组件 - 电器元件
9A.1.7.2.2	Components – Fasteners 组件 - 紧固件
9A.1.7.2.3	Components - Shaped raw materials 组件 - 成型原材料
9A.1.7.2.4	Components - Machined raw materials 组件 - 机加工原材料
9A.1.7.2.5	Components - Molded plastic 组件 - 模塑材料
A.1.7.3 Subassemblies A.1.7.3 子组件	
9A.1.7.3.1	Subassemblies - Electronic subassemblies made to drawing and / or work instruction 子组件 - 根据图纸和/或工作说明书生成的电子子组件
9A.1.7.3.2	Subassemblies - Mechanical subassemblies made to drawing and / or work instruction 子组件 - 根据图纸和/或工作说明书生成的机械子组件
A.1.7.4 Calibration services* A.1.7.4 校准服务	
9A.1.7.4.0	Verification/confirmation services for measuring instruments, tools, or test fixtures 测量仪器、工具或测试夹具的验证/确认服务
A.1.7.5 Distribution services A.1.7.5 分销服务	
9A.1.7.5.0	Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices 仅提供医疗器械储存和交付的分销商，而不是医疗器械的“合法制造商”
A.1.7.6 Maintenance Services A.1.7.6 维修服务	
9A.1.7.6.1	Maintenance services - Electrical or mechanical repair services 维修服务 - 电气或机械维修服务
9A.1.7.6.2	Maintenance services - Facility cleaning and maintenance services 维修服务 - 设施清洁和维护服务
9A.1.7.6.3	Maintenance services - Uniform cleaning 维修服务 - 防静电工作服的统一清洁和测试服

	务
A.1.7.7 Transportation services　A.1.7.7 运输服务	
9A.1.7.7.1	Trucking, shipping, air transportation service in general 一般卡车运输、航运、空运服务
A.1.7.8 Other Services　A.1.7.8 其他服务	
9A.1.7.8.1	Other services - Consulting services related to medical devices 其他服务 - 与医疗设备有关的咨询服务
9A.1.7.8.2	Other services - Packaging services 其他服务 - 包装服务

附录 B ：13485 管理体系认证审核基准人日

Appendix B: 13485 Management system certification audit benchmark person day

有效人数	初审基准人天		监督（天）	再认证（天）
	（1＋2）阶段(天）	非现场时间（天）		
1-5	3	0	1.5	2.5
6-10	4	0.5	2	3.5
11-15	4.5	0.5	2.5	4
16-25	5	0.5	2.5	4
26-45	6	1	3	5
46-65	7	1	3.5	6
66-85	8	1	4	6.5
86-125	10	1	5	8
126-175	11	1	5.5	9
176-275	12	1	6	10
276-425	13	1	6.5	11
426-625	14	1	7	11.5
626-875	15	1.5	7.5	12
876-1175	16	1.5	8	13
1176-1550	17	1.5	8.5	14
1551-2025	18	1.5	9	14.5
2026-2675	19	1.5	9.5	15.5
2676-3450	20	1.5	10	16
3451-4350	21	1.5	10.5	17
4351-5450	22	1.5	11	18
5451-6800	23	1.5	11.5	18.5
6801-8500	24	1.5	12	19.5
8501-10700	25	1.5	12.5	20
＞10700	遵循上述递进规律 Follow the above			

Appendix B: 13485 Management system certification audit benchmark person day

Effective number	Initial audit — benchmark person day		supervise（day）	Re-certification（day）
	Stage 1＋Stage 2	Off-site time（day）		
1-5	3	0	1.5	2.5
6-10	4	0.5	2	3.5
11-15	4.5	0.5	2.5	4
16-25	5	0.5	2.5	4
26-45	6	1	3	5
46-65	7	1	3.5	6
66-85	8	1	4	6.5
86-125	10	1	5	8
126-175	11	1	5.5	9
176-275	12	1	6	10
276-425	13	1	6.5	11
426-625	14	1	7	11.5
626-875	15	1.5	7.5	12
876-1175	16	1.5	8	13
1176-1550	17	1.5	8.5	14
1551-2025	18	1.5	9	14.5
2026-2675	19	1.5	9.5	15.5
2676-3450	20	1.5	10	16
3451-4350	21	1.5	10.5	17
4351-5450	22	1.5	11	18
5451-6800	23	1.5	11.5	18.5
6801-8500	24	1.5	12	19.5
8501-10700	25	1.5	12.5	20
＞10700	Follow the above			

附录 C：仅考虑了医疗器械级别的 13485 管理体系认证 审核基准人日

有效人数	审核时间（天） 第 1 阶段＋第 2 阶段			有效人数	审核时间（天） 第 1 阶段＋第 2 阶段		
	I 级医疗	II 级医	III 级 医		I 级医疗	II 级医	III 级 医
1-5	2.5	3	3	626-875	12	13.5	15
6-10	3.5	4	4	876-1175	13	14.5	16
11-15	4	4.5	4.5	1176-1550	14	15.5	17
16-25	4	4.5	5	1551-2025	14.5	16.5	18
26-45	5	5.5	6	2026-2675	15.5	17.5	19
46-65	6	6.5	7	2676-3450	16	18	20
66-85	6.5	7.5	8	3451-4350	17	19	21
86-125	8	9	10	4351-5450	18	20	22
126-175	9	10	11	5451-6800	18.5	21	23
176-275	10	11	12	6801-8500	19.5	22	24
276-425	10.5	12	13	8501-10700	20	22.5	25
426-625	11.5	13	14	>10700	遵循上述递进规律		

Appendix C: Only the baseline person day of the implementation audit of the certification of 13485 medical device management system considering the level of medical devices

Effective number	Audit Time (days) Stage 1＋Stage 2			Effective	Audit Time (days) Stage 1＋Stage 2		
	I level	II level	III level		I level	II level	III level
1-5	2.5	3	3	626-875	12	13.5	15
6-10	3.5	4	4	876-1175	13	14.5	16
11-15	4	4.5	4.5	1176-1550	14	15.5	17
16-25	4	4.5	5	1551-2025	14.5	16.5	18
26-45	5	5.5	6	2026-2675	15.5	17.5	19
46-65	6	6.5	7	2676-3450	16	18	20
66-85	6.5	7.5	8	3451-4350	17	19	21
86-125	8	9	10	4351-5450	18	20	22
126-175	9	10	11	5451-6800	18.5	21	23
176-275	10	11	12	6801-8500	19.5	22	24
276-425	10.5	12	13	8501-10700	20	22.5	25
426-625	11.5	13	14	>10700	Follow the above		

注 1:有效人数，包括认证范围内涉及的所有全职人员，原则上以组织的社会保险登记证所附名册等信息为准。

Note 1. The valid number, including all full-time personnel involved in the certification scope, shall in principle be subject to the information attached to the social insurance registration

certificate of the organization.

注 2:对非固定人员（包括季节性人员、临时人员和分包商人员）和兼职人员的有效人数核定， 可根据其实际工作小时数予以适当减少或换算成等效的全职人员数。

Note 2:The effective number of non-permanent personnel (including seasonal, temporary and subcontractors) and part-time personnel may be appropriately reduced or converted to the equivalent number of full-time personnel according to the actual working hours.

注 3：以下无

Note 3:The following is no