

管理体系认证的授予、拒绝、保持、 扩大、更新、缩小、暂停、恢复和撤销/注销管理

Management system certification Registration granting, refusing, maintaining, expanding, renewing, reducing, suspending, restoring and withdrawing/deregistering management

1 目的

Purpose

本文件规定了北京国医械华光认证有限公司在进行质量、环境、职业健康安全、信息安全管理体系及医疗器械质量管理体系认证活动中，对于管理体系认证的授予、拒绝、保持、扩大、更新、缩小、暂停、恢复和撤销/注销的管理。

This document specifies the management of granting, refusing, maintaining, expanding, renewing, reducing, suspending, restoring and withdrawing/cancelling the management system certification by Beijing Hua Guang Certification of Medical Devices Co, Ltd.

2 管理体系认证注册的授予或更新（再认证）

Granting or renewing of management system certification registration (recertification)

——通过现场审核证实申请认证组织按标准要求建立的管理体系符合认证准则要求，并且能够得到有效实施和保持；

Through the on-site audit to confirm that the management system established by the organization applying for certification in accordance with the requirements of the standard meets the requirements of the certification criteria, and can be effectively implemented and maintained.

——审核过程符合管理体系认证程序要求，现场审核开具的不符合全部得到有效的关闭，现场审核满足管理体系标准的要求、制订的相关目标可测量及测量方法明确；管理体系目标关键点有效监测、管理体系有效性持续改进。

Audit process in line with the requirements of the management system certification procedure, all non-conformities issued by the on-site audit are effectively closed, on-site audits to meet the requirements of the management system standards, the relevant objectives can be measured and the measurement methods are clear, effective monitoring of the key points of the management system, continuous improvement of the

effectiveness of the management system.

——产品实物质量符合规定要求；

The physical quality of the product meets the specified requirements.

——认证范围覆盖的活动、产品和服务，符合相关法律法规要求，未发生重大事故和严重违法行为。

The activities, products and services covered by the certification scope meet the requirements of relevant laws and regulations without major accidents and serious violations.

注：1) 获证组织应在认证有效期（三年）满前四个月提出再认证申请。

2) 管理体系认证覆盖范围应在认证合同中予以明确，并符合以上要求。

3) 对于管理体系覆盖范围为医疗器械产品的，在认证合同中应依据“医疗器械注册证”明确到产品的规格型号，符合以上要求的方可授予认证注册，其认证证书描述范围依据“医疗器械注册证”中产品名称，可适当时进行归纳，但不可产生如扩大认证覆盖范围等歧义。审核报告中应明确描述管理体系认证覆盖的医疗器械产品名称和规格型号（或注册证号/备案证号）。

Note: 1) The certified organization shall apply for re-certification four months before the expiry of the certification period (three years).

2) Management system certification coverage should be specified in the certification contract, and in line with the above requirements.

3) For the management system covering medical device products, in the certification contract, the specification and model of the product should be clearly stated in accordance with the "Medical Device Registration Certificate", those who meet the above requirements may be granted certified registration. The coverage description of its certification certificate is based on the product name in the "Medical Device Registration Certificate", which can be summarized when appropriate, but can't produce ambiguity in the coverage of the certification, such as expansion. The audit report should clearly describe the name and specification model of the medical device product covered by the management system certification (or the registration certificate number/filing certificate number).

3 管理体系认证注册的拒绝

Refusing Management System Certification Registration

- 1) 在现场审核过程中当发生以下情况时，审核组向 CMD 报告，经机构同意后终止审核。

When the following situations occur during the on-site audit, the audit team shall report to CMD and terminate the audit with the consent of the organization

- a) 受审核方对审核活动不予配合，审核活动无法进行。

When the auditee does not cooperate with the audit activities and the audit activities cannot be carried out.

- b) 受审核方实际情况与申请材料有重大不一致。

The actual situation of the auditee is significantly inconsistent with the application materials.

- c) 其他导致审核程序无法完成的情况，如当可获得的审核证据显示审核目的无法实现，或显示存在紧急和重大的风险（例如安全风险）时。

Other situations where the audit process cannot be completed, such as when the available audit evidence indicates that the audit objective cannot be achieved, or indicates that there is an urgent and significant risk (such as a security risk)

- 2) 在审定过程中，经确认申请组织存在以下情况的，该申请组织不予认证注册。

In the process of review and approval, if it is confirmed that the applicant organization has the following circumstances, the applicant organization will not be certified for registration.

- a) 初次、再认证现场审核开具的严重不符合，申请组织未在规定的时限内完成整改并跟踪有效的，对于轻微不符合（观察项），未在规定的时限内实施纠正并提交纠正措施的计划并审查和接受的。

For major nonconformities issued in the initial and recertifications on-site audit, the applicant organization fails to complete rectification and follow up effectively within the prescribed time limit. For minor nonconformities (observation items), the applicant organization fails to implement rectification and submit a corrective action plan within the prescribed time limit for review and acceptance.

- b) 受审核方的管理体系存在有重大缺陷，不符合标准要求且运行无效。

The auditee's management system has significant deficiencies, does not meet the requirements of the standard and does not operate effectively

- c) 认证范围覆盖的活动、产品或服务，不符合相关法律法规要求，发现受审核方存在重大安全问题或有其他与产品和服务质量相关严重违法违规行为。

The activities, products or services covered by the certification do not meet the requirements of relevant laws and regulations, and the auditee is found to have major safety problems or other serious violations related to the quality of products and services.

4 管理体系认证注册的保持

Maintaining Management System Certification Registration

- 通过监督审核证实获证组织的管理体系持续符合认证准则的要求，并能有效运行，管理评审、内部审核和纠正和预防措施实施有效。

To verify through surveillance audit confirms that the management system of the certified organization continues to meet the requirements of the certification criteria and operates effectively, and that management reviews, internal audits and corrective and preventive actions are implemented effectively.

- 监督审核过程符合管理体系认证程序的规定，现场审核开具的不符合全部得到有效的关闭，且上次审核的不符合项的纠正措施经验证有效；

The surveillance audit process in accordance with the provisions of the management system certification procedure, all non-conformities issued in the on-site audit have been effectively closed, and the corrective actions for the nonconformities in the last audit have been validated.

- 上次审核以来管理体系覆盖活动及运行体系的资源是否有变更；

Whether the activities covered by the management system and the resources of the operation system have changed since the last audit.

- 重要关键点(参照一阶段审核内容)按照管理体系的要求正常和有效运行；

Key points (refer to the contents of the stage 1 audit) operate normally and effectively in accordance with the requirements of the management system.

- 总目标和各层级目标均已实施；

Overall objectives and objectives at all levels have been implemented.

- 认证证书和标志使用正确；

Certification certificates and marks are used correctly.

——内审核管理评审规范和有效；

Internal audit, management reviews are standardized and effective.

——及时接受和处理投诉；

Receiving and handling complaints in a timely manner.

——产品实物质量符合规定要求；

The physical quality of the product meets the specified requirements.

——符合有关法律法规要求。

Complies with the requirements of relevant laws and regulations.

5 管理体系特殊审核

Management systems special audits

5.1 认证范围的扩大

Expanding scope

5.1.1 获证组织可因以下原因以书面形式向 CMD 提出扩大管理体系认证范围的申请：

The certificated organization may apply to CMD in writing for expanding the scope of management system certification for the following reasons:

a) 获证组织的管理体系发生了重大变化，如成立了分支机构并将其覆盖在管理体系认证范围内；

Significant changes in the management system of the certified organization, such as the establishment of branch offices and covering them in the scope of management system certification.

b) 获证组织管理体系所覆盖的产品范围增加。

The range of products covered by the certified organization management system has increased.

5.1.2 当获证组织管理体系有上述情况变化时，应提前向审核策划组提出扩大管理体系认证范围的申请并提交相应材料。

When the management system of the certified organization has the above changes, the application for expanding the scope of management system certification should be submitted to the CMD Audit Planning Group in advance and the corresponding materials should be

submitted.

5.1.3 CMD 考虑认证范围扩大所涉及的场所、审核依据标准、过程、产品复杂程度等因素，确定变更认证范围的途径；如需现场审核则应明确扩大需要的审核时间，并与该获证组织补充签署认证协议。认证范围扩大的审核可与监督审核一起进行，也可单独进行。

CMD considers the sites (involved in the scope expanding), audit criteria, process and product complexity and other factors to determine the way to change the scope of certification. If an on-site audit is required, the required audit time should be clarified and a supplementary certification agreement should be signed with the certified organization. The audit of the expanding scope may be conducted in conjunction with the surveillance or separately.

5.2 提前较短时间通知的审核

Short-notice audits

在下列情况之一的，CMD 可能需要在提前较短时间通知获证客户后或不通知获证客户就其进行审核（如，突击审核）。

In any of the following cases, CMD may be required to conduct an audit of the certified client with or without notice to the certified client (e.g. surprise audit).

a) 调查投诉；

To investigate complaints.

b) 对客户的变更做出回应；

In response to changes.

c) 对被暂停的客户进行追踪；

As follow up on suspended clients.

d) 发生了与环境或 OHS 有关的严重事件，如严重事故或严重违法行为进行调查；

To investigate the occurrence of serious incidents related to the environment or OHS, such as serious accidents or serious violations.

e) 认证范围内的医疗器械产品表明质量管理体系可能存在重大缺陷；

A medical device product within the scope of certification indicates a possible material defect in the quality management system.

f) 为CMD获知的重要安全和性能相关信息；

Important security and performance-related information that CMD learns.

- g) 已按法规要求提交或CMD获知的重大变更，可能对客户满足法规要求的决定有影响时；

When a material change has been submitted (or has been known to CMD) in accordance with regulatory requirements that may affect the client's decision to meet regulatory requirements.

- h) 当相关的法律要求或相关监管机构的要求时；

When required by relevant law or relevant regulatory authority.

- i) CMD 对获证客户纠正措施的实施或满足标准和法规要求等有合理的担忧时。

When CMD has legitimate concerns about the implementation of corrective actions by a certified client or meeting standards and regulatory requirements.

6 管理体系认证注册的暂停及恢复

Suspending and restoring Management System Certification Registration

6.1 有下列情况之一的，CMD 应在调查核实后的 5 个工作日内暂停其认证证书：

CMD shall suspend its certification certificate within 5 working days after investigation and verification in case of any of the following circumstances:

- a) 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。

Continuous or serious failure of the management system to meet the certification requirements, including the effectiveness of the management system operation requirements.

- b) 不承担、履行认证合同约定的责任和义务的：

— 不能在规定期限内接受 CMD 监督审核和再认证审核的；

— 获证组织未按期缴纳费用且经指出后未予纠正的；

Failure to assume and fulfill the responsibilities and obligations agreed upon in the certification contract.

— Fail to accept CMD surveillance audit and recertification audit within the specified period.

— If the certified organization fails to pay the fee on time and fails to correct it after being pointed out.

- c) 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；
If the local certification regulatory authorities finds that there are problems with the operation of the system, the certificate needs to be suspended.
- d) 被有关执法监管部门责令停业整顿的；
Being ordered by the relevant law enforcement and supervision department to suspend business for rectification.
- e) 监管机构参与调查的环境或 OHS 的严重事故或严重违法（行为）的；
Serious incidents or serious violations of the environment or OHS that are investigated by regulatory bodies.
- f) 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；
Holding administrative licenses, qualification certificates, mandatory certificates, etc. expired, resubmitted applications have been accepted but have not yet been renewed.
- g) 获证组织主动请求暂停的；
The certified organization requests suspension voluntarily.
- h) 在国家、省市产品监督抽查活动中获证组织不能保持产品实物质量符合规定要求且不能按规定期限采取有效措施的；
In the national, provincial and municipal product supervision and random inspection activities, the certified organization fails to keep the physical quality of the product in line with the prescribed requirements and fails to take effective measures within the prescribed time limit.
- i) 不能在规定期限内对 CMD 监督审核中提出的不符合项采取有效的纠正和纠正措施的；
Failing to take effective correction and corrective measures for the nonconformities proposed in the CMD surveillance audit within the specified period.
- j) 顾客对获证组织质量管理体系覆盖的产品提出严重质量问题并经查实造成危害的；
The customer raises serious quality problems to the products covered by the certified organization quality management system and it is verified to have caused harm.
- k) 获证组织对管理体系认证证书和认证标志的使用不符合 CMD 规定的；

The use of the certification certificate and certification mark of the management system by the certified organization does not comply with the provisions of CMD.

1) 发现其它违反管理体系认证规则的情况。

Other violations of management system certification rules are found.

被暂停认证注册的组织在接到暂停通知后，应立即停止认证证书的使用。暂停信息将在 CMD 网站上予以公布。认证证书暂停期不得超过 6 个月。但属于上述第 e) 项情形的暂停期可至相关单位作出许可决定之日。

The organization whose certification registration has been suspended shall immediately stop using the certification certificate after receiving the notice of suspension. The suspension information will be published on the CMD website. The suspension period of certification certificate shall not exceed 6 months. However, the suspension period in the case of item e) above can be up to the date when the permit decision is made by relevant authority.

6.2 被暂停认证注册的组织在暂停期内使用证书造成任何后果，应全部由被暂停认证注册的组织负责。

Any consequences arising from the use of the certificate by the suspended organization during the period of suspension shall be the sole responsibility of the suspended organization.

6.3 被暂停认证注册的组织应在暂停期限内解决造成暂停问题，并在暂停期满前提出恢复认证资格的申请。一般情况下，应安排一次现场审核后，CMD 再做出是否能够恢复认证资格的决定。属于 d) 项情形的，需取得执法监管部门恢复生产的通告或监管部门出具的其它证明性文件才能进行证书的暂停恢复，可免除现场审核。

The organization whose certification registration has been suspended shall solve the problem that caused the suspension within the suspension period, and apply for resumption of certification qualification before the expiration of the suspension period. In general, CMD shall arrange an on-site audit before planning on whether the certification qualification can be restored. In the case of item d), it is necessary to obtain a notice of resumption of production from the law enforcement and regulatory authorities or other supporting documents issued by the regulatory authorities to restore the certificate, and on-site audit can be exempted.

7 管理体系认证注册的撤销或缩小

Withdrawing or reducing the scope of the certification

7.1 有下列情况之一的，CMD 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或缩小认证范围：

In any of the following cases, CMD shall withdraw or reduce the scope of certification within 5 working days after obtaining relevant information and investigating and verifying:

- a) 被注销或撤销法律地位证明文件的；

The certificate of legal status has been cancelled or withdrawn.

- b) 被国家市场监督管理总局列入质量信用严重失信企业名单；

Listed by the SAMR on “The list of seriously discredited enterprises in quality and credit”.

- c) 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；

Refuse to cooperate with the certification regulatory authorities to implement the supervision and inspection, or on matters related to inquiries and investigations provided false materials or information.

- d) 拒绝接受国家产品质量监督抽查的；

Refusing to accept the national product quality supervision and sampling.

- e) 出现重大的产品或服务等质量安全事故，、E 和 OHS 严重事故或严重违法行为，经执法监管部门确认是获证组织违规造成的；

The occurrence of major product or service quality and safety accidents, and OHS serious accidents or serious violations, which are confirmed by the law enforcement and supervision authorities to be caused by the violation of the certificated organization.

- f) 有其他严重违法违反法律法规行为的；

Any other serious violations of laws and regulations.

- g) 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）；

Suspension of certification has expired but the issues that led to the suspension have not been resolved or corrected (including the holding of administrative licenses,

certificates of qualification, mandatory certification certificates and other certificates have expired but the application has not been approved).

- h) 没有运行管理体系或者已不具备运行条件的；

Does not operate a management system or no operation conditions.

- i) 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 2 个月仍未纠正的；

Failure to properly cite and publicize the certification information obtained in accordance with the relevant provisions, resulting in serious impact or consequences, or the certification body has been requested to rectify the situation but has not done so for more than two months.

- j) 发现 CMD 与获证组织之间正式协议中规定要求的其它构成撤销管理体系认证资格情况。

Other circumstances required in the formal agreement between CMD and the certified organization which constitute withdrawing of the certification of the management system.

- k) 认证范围的缩小应与认证标准的要求一致。若由于缩小而导致不能符合认证标准要求的，应做撤消处理。CMD 将对是否需要全部撤消或缩小认证范围做出决定。

The reduction of the scope of certification should be consistent with the requirements of the certification standard. If it cannot meet the requirements of the certification standard due to reduction, it should be withdrawn. CMD makes a decision on whether the certification needs to be withdrawn or reduced.

7.2 被撤销认证注册的组织应交回所有认证文件；对于缩小认证范围的需变更证书。撤销或缩小信息将在 CMD 网站上予以公布，同时按规定程序和要求报国家认监委。

The organization whose certification registration is withdrawn shall return all the certification documents. If the certification scope is reduced, the certificate must be changed. withdrawal or reduction of information will be published on the CMD website and reported to the CNCA in accordance with the prescribed procedures and requirements.

7.3 被撤消认证注册的组织不得继续使用认证证书或进行有关宣传，若继续使用认证

证书或进行有关宣传而造成的任何后果，应全部由被撤消认证注册的组织负责。

The organization whose certification registration has been withdrawn shall not continue to use the certification certificate or carry out related publicity, and any consequences caused by the continued use of the certification certificate or carry out related publicity shall be solely the responsibility of the organization whose certification registration has been withdrawn.

7.4 原则上，被撤销理体系认证资格的组织一年后方可重新提出管理体系认证申请。

In principle, an organization whose management system certification qualification has been withdrawn may re-apply for management system certification one year later.

8 管理体系认证注册的注销

Deregistering Management System Certification Registration

8.1 认证注销是指获证组织由于某种原因主动提出不继续保持管理体系认证注册的资格。

Certification deregistration means that the certified organization, for some reason, voluntarily offers not to continue to maintain the qualification of management system certification registration.

8.2 注销认证注册的组织应交回所有认证文件。注销信息将在 CMD 网站上予以公布。

An organization deregistering a certification registration shall return all certification documents. Deregistration information will be posted on the CMD website.

8.3 已注销认证注册的组织不得继续使用认证证书或进行有关宣传，若继续使用认证证书或进行有关宣传而造成的任何后果，应全部由已注销认证注册的组织负责。

An organization that has deregistered its certification registration shall not continue to use the certification certificate or conduct related publicity, and the organization that has deregistered its certification registration shall be solely responsible for any consequences caused by its continued use of the certification certificate or related publicity.