

证书、标志的使用和管理规定

Provision on the use and administration of certificates and marks

1 目的

Purpose

为符合中国合格评定国家认可委员会（CNAS）、国际认可服务公司（IAS）的要求，使获证认证组织正确使用北京国医械华光认证有限公司（CMD）颁发的认证证书和CMD认证标识，并规范CMD对认证证书和CMD认证标识的管理，特制定本规定。

This provision is formulated to meet the requirements of China National Accreditation Service for Conformity Assessment (CNAS) and International Accreditation Service (IAS), enable certificated organizations to correctly use the certification certificate and CMD certification mark issued by Beijing Hua Guang Certification of Medical Devices Co., Ltd. (CMD), and standardize the management of CMD on certification certificate and CMD certification mark.

2 范围

Scope

本规定适用于带有CMD标志的认证证书和CMD认证标识的管理。

This provision is applicable to the management of certification certificate with CMD mark and CMD certification mark.

3 认证证书

Certification certificate

3.1 CMD 管理体系认证证书内容

Contents of CMD management system certification certificate

- a) 证书名称：“质量管理体系认证证书”、“环境管理体系认证证书”、“职业健康管理体系认证证书”、“信息安全管理证书”；

Name of certificate: "Certificate of Quality Management System Certification", "Certificate of Environmental Management System Certification", "Certificate of Occupational Health and Safety Management System Certification", "Certificate of Information Security Management System Certification".

- b) 获证组织名称、地址（对于医疗器械生产企业应注明注册地址和生产地址）、统一社会信用代码；

The name and address of the certificated organization (for medical device manufacturers, the domicile and production address should be indicated) and the unified social credit code.

- c) 依据的管理体系标准和/或其它标准类文件的编号与版次；

The number and version number of the management system standard and/or other standard document on which it is based.

- d) 管理体系认证所覆盖的范围，对多场所组织还应在证书上或附件中明确注明已获准认证的场所名称、地址、产品（服务）类别及涉及的过程；

The scope covered by the management system certification, and for multi-site organizations, the name, address, product (service) category and process involved in the certification should also be clearly indicated on the certificate or in an annex.

- e) 颁证日期、换证日期以及证书有效期的起止年月日。初次认证证书的有效期限最长为 3 年，再认证的认证证书有效期不超过最近一次有效认证证书截止期再加 3 年；
Date of issuance, date of renewal, and the beginning and ending date of the certificate validity period. Initial certification certificate is valid for a maximum of 3 years, the validity period of the re certificated certificate shall not exceed the deadline of the latest valid certificate plus 3 years.

- f) 认证注册号：认证证书编号作为认证注册号，对同一个组织实施的同一个体系认证，赋予一个认证证书编号；

Certification registration number: The certification certificate number serves as the certification registration number. The certification of the same system implemented by the same organization is assigned a certification certificate number.

- g) CMD 名称、地址与标徽、CMD 公章或总经理签字；

CMD name, address and mark, CMD official seal or signature of the General Manager.

- h) 对于 CNAS/IAS 认可的业务范围附加 CNAS/IAS 认可标识及认可注册号；

For CNAS accredited business scope, use CNAS accreditation mark and accreditation registration number.

- i) 在 CNAS/IAS 认可的业务范围内并经 CNAS/IAS 许可, 附加国际互认 IAF-MLA 标识。
Certification certificate within the scope of business accredited by CNAS, and with the permission of CNAS, use an International Mutual Accreditation (IAF-MLA) mark.
- j) 对于 IAS 认可的业务范围应包括获得认可服务描述和相应的 IAF 代码 (如 ID-1、MD-17 等中列出)、医疗器械技术领域 (ISO13485);

For IAS accredited business scope, include a description of the services and the appropriate IAF codes (as listed in ID-1, MD -17 etc), and medical device technical areas.

- k) “仅供出口”字样, 适用于仅供出口的质量管理体系认证证书;
The words "for export only" apply to the quality management system certification certificate for export only.
- l) 证书应注明: “获证组织必须定期接受监督审核并经审核合格此证书方继续有效”的提示信息;
The certificate should contain the message: "The certificated organization must be subject to periodic surveillance and audit, and the certificate will remain valid only if the organization passes the audit"
- m) 证书的查询方式, 认证机构除公布认证证书在本机构网站上的查询方式外, 还应当在证书上注明: “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。

Certificate query method: the certification body in addition to the publication of the certificate in the agency's website query, it should also be stated in the certificate: "This certificate information can be found on the official website of China National Certification and Accreditation Administration (www.cnca.gov.cn) to facilitate social monitoring.

3.2 CMD 产品认证证书内容

Content of CMD product certification certificate

- a) 证书名称: “产品认证证书”;

Name of certificate: "Certificate of product Certification".

- b) 获证组织名称、地址、统一社会信用代码（或组织机构代码）；

The name and address of the certificated organization and the unified social credit code.

- c) 依据的产品认证制度，相应产品所依据的法规、产品标准或其他引用文件、认证模式，包括：

The product certification system that the corresponding products are based on, the regulations, product standards or other reference documents, and certification modes, including:

- 1) 获准认证的产品，可以按产品的类型或范围划分；

certificated products may be classified by type or scope of product.

- 2) 通过认证的每个产品或每类产品认证所依据的标准或其它规范性文件；

The standard or other normative document on which each product or category of product is certificated.

- 3) 采用的认证制度；

The certification system adopted.

- d) 证书有效期的起止年月日。CMD 产品认证证书有效期为四年；

The beginning and ending date of the certificate validity period. CMD product certification is valid for four years.

- e) 认证注册号：认证证书编号作为认证注册号，对同一组织实施的同一个产品认证，赋予一个注册号；

Certification registration number: The certification certificate number serves as the certification registration number. The certification of the same system implemented by the same organization is assigned a certification certificate number.

- f) CMD 名称与标徽、CMD 公章或代表签字；

CMD name and mark, CMD official seal or signature of the representative.

- g) 对于 CNAS 认可的业务范围附加 CNAS 认可标识及认可注册号；

For CNAS accredited business scope, use CNAS accreditation mark and accreditation registration number.

- h) 证书应注明：“获证组织必须定期接受监督审核并经审核合格此证书方继续有效”的提示信息。

The certificate should contain the message: "The certificated organization must be subject to periodic surveillance and audit, and the certificate will remain valid only if the organization passes the audit".

- i) 证书的查询方式，认证机构除公布认证证书在本机构网站上的查询方式外，还应当在证书上注明：“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；

For the query of the certificate, the certification body shall not only publish the query method of the certification certificate on its website, but also indicate on the certificate: "The information of this certificate can be queried on the official website of China National Certification and Accreditation Administration (www.cnca.gov.cn)" to facilitate social surveillance.

3.3 CMD 服务认证证书内容

Content of CMD service certification certificate

- a) 证书名称：“XX 服务认证证书”，如售后服务、批发零售服务、修订服务等；

Name of certificate: "certificate of XX service Certification", such as after-sales service, wholesale and retail service, revision service, etc.

- b) 获证组织名称、地址及其服务提供场所的地址、统一社会信用代码（或组织机构代码）；

The name, domicile and the address of the place where their services are provided, and the unified social credit code.

- c) 获准认证的服务范围，可以按服务的类型或特性划分；

The certificated service scope can be divided according to the type or characteristics of services.

- d) 认证所依据的服务标准、技术规范或其他规范性文件；

Service standards, technical specifications or other normative documents on which the certification is based.

- e) 服务认证方案；

Service certification scheme.

- f) 证书有效期的起止年月日。CMD 服务认证证书有效期为三年；

The beginning and ending date of the certificate validity period. CMD service certification is valid for three years.

- g) 认证注册号：认证证书编号作为认证注册号，对同一组织实施的同一个服务认证，赋予一个注册号；

Certification registration number: The certification certificate number serves as the certification registration number. The certification of the same system implemented by the same organization is assigned a certification certificate number.

- h) CMD 名称与标徽、CMD 公章或代表签字；

CMD name and mark, CMD official seal or signature of the representative.

- i) 对于 CNAS 认可的业务范围附加 CNAS 认可标识及认可注册号。

For CNAS accredited business scope, use CNAS accreditation mark and accreditation registration number.

- a) 证书应注明：“获证组织必须定期接受监督审核并经审核合格此证书方继续有效”的提示信息。

The certificate should contain the message: "The certificated organization must be subject to periodic surveillance and audit, and the certificate will remain valid only if the organization passes the audit".

- b) 证书的查询方式，认证机构除公布认证证书在本机构网站上的查询方式外，还应当在证书上注明：“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；

For the query of the certificate, the certification body shall not only publish the query method of the certification certificate on its website, but also indicate on the certificate: "The information of this certificate can be queried on the official website of China National Certification and Accreditation Administration (www.cnca.gov.cn)" to facilitate social surveillance.

4 标识说明

Marks specification

4.1 管理体系认证书和产品认证证书中“CMD”标徽（见图 1）为北京国医械华光认证有限公司徽标。

The "CMD" mark in the management system certification and product certification certificate (see Figure 1) is the mark of Beijing Hua Guang Certification of Medical Devices Co., Ltd.

4.2 证书中包含认可标识，分为单一认可标识和国际互认联合认可标识。CMD 在其颁发的认证证书上使用“CNAS” / “IAS” 单一认可标识或者国际互认联合认可标识或“经中国合格评定国家认可委员会认可（Accredited by China National Accreditation Service for Conformity Assessment） / 经国际认可服务公司认可（Accredited by International Accreditation Service for Conformity Assessment,）”字样与认可注册号，表示该认证证书所覆盖的认证领域和业务范围已获得 CNAS/IAS 的认可。

The certificate contains an accreditation mark, which can be a single accreditation mark or a combined accreditation mark for International Mutual Accreditation. CMD uses the "CNAS"/" IAS "single accreditation mark or the International Mutual Accreditation combined accreditation mark on its certification certificates, or use the words “Accredited by China National Accreditation Service for Conformity Assessment/Accredited by International Accreditation Service for Conformity Assessment” and accreditation registration number, indicating that the certification area and business scope covered by the certification certificate has been accredited by CNAS/IAS.

4.3 CNAS 认可标识的使用不代表 CNAS/IAS 对机构出具的证书和报告结果负责，也不表示 CNAS/IAS 对获得认证的特定管理体系、产品、服务、人员或过程等进行了批准。

The use of the CNAS accreditation mark does not mean that CNAS/IAS is responsible for the certificates and reported results issued by the certification body, nor does it mean that CNAS/IAS has approved the certificated specific management system, product, service, person or process.

4.4 管理体系认证书中“IAF-MLA”标识为国际互认标识，表示在该认证领域 CNAS/IAS 已签署国际互认协议。

The "IAF-MLA" mark in the management system certificate is an international mutual accreditation mark, indicating that CNAS/IAS has signed the IAF Multilateral

Recognition Agreement in this area of certification.

4.5 获得 CMD 产品认证的组织，CMD 同时授权其使用“CMD”产品认证标识。“CMD”产品认证标识为（图 2）。CMD 产品认证实施规则中给出了产品认证的要求。

Organizations that obtain CMD product certification are also authorized by CMD to use the "CMD" product certification mark. The "CMD" product certification mark is as Figure 2. The requirements of product certification are given in *the CMD Product Certification Implementation Rules*.



图Figure 1



图Figure 2

5 认证证书和标志的使用要求

Requirements for the use of certificates and marks

5.1 获证组织应建立认证证书和认证标识使用制度以满足 CMD 的要求。

The certificated organization shall establish a certification certificate and certification mark use system to meet the requirements of CMD.

5.2 CMD 认证证书的查询方式可通过登陆 CMD 网站 <http://www.cmdc.com.cn>。

The CMD certification certificate can be queried by logging into the CMD website <http://www.cmdc.com.cn>

5.3 北京国医械华光认证有限公司的《管理体系认证证书》用于表明获证组织的管理体系符合相对应的管理体系标准的要求。

The Certificate of Management System Certification of Beijing Hua Guang Certification of Medical Devices Co., Ltd. is used to indicate that the management system of the certificated organization meets the requirements of the relevant management system standards.

5.4 北京国医械华光认证有限公司的《产品认证证书》用于表明获证组织生产的产品符合

证书上的相关标准和认证模式。

The "Product Certification Certificate" of Beijing Hua Guang Certification of Medical Devices Co., Ltd. is used to indicate that the products produced by the certificated organization comply with the relevant standards and certification modes on the certificate.

5.5 按照 CNAS-R01《认可标识使用和认可状态声明规则》、IAS/ADM/084《IAS 关于 IAF/IAS 和 ILAC/IAS 组合标志的政策》的规定，获证组织不得使用“IAF-MLA”国际互认标识。

In accordance with CNAS-R01 Rules for the Use of Accreditation Symbols and Reference to Accreditation, IAS/ADM/084 Policy on The Use of the ILAC/IAF/IAS Combined Marks, certificated organizations shall not use the "IAF-MLA" International mutual recognition mark.

5.6 对于获得管理体系认证的组织，获证客户在产品包装和宣传材料附带信息中声明客户的管理体系通过相应标准的管理体系认证。产品包装的判定标准是其可从产品上移除且不会导致产品分解、碎裂或损坏。有关的宣传材料的判定标准是可分开获得或易于分离，但不可用在产品上以免误导消费者以为该产品获得了产品认证，产品的型号标签和产品铭牌视为产品的组成部分；不可用于实验室检测、校准或检验的报告或证书。

For clients that have obtained management system certification, when the certified clients use any statement on product packaging or in accompanying information that the certificated client has a certificated management system, the statement shall in no way imply that the product is certificated by this means. Product packaging is considered as that which can be removed without the product disintegrating or being damaged. Accompanying information is considered as separately available or easily detachable. Type labels or identification plates are considered as part of the product. CMD certification marks are not permit to be applied by certificated clients to laboratory test, calibration or inspection reports or certificates.

5.7 对于获得产品认证的组织，产品认证证书、“CMD”标徽、“CMD”产品标识可用于获证组织的有关宣传材料上，“CMD”产品标识可用于产品上。

For clients that have obtained product certification, the product certification certificate, "CMD" mark and "CMD" product certification mark can be used on the relevant promotional materials of the certificated client, and the "CMD" product

certification mark can be used on the products.

5.8 获证组织在广告和有关宣传中，不得误用证书或使用会误导顾客的宣传语言，如夸大本体系认证覆盖的产品或地域范围，混淆产品认证和管理体系认证。

In advertising and related publicity, the certificated clients shall not misuse the certificates or use promotional language that will mislead customers, such as exaggerating the product or geographical scope covered by the certification system, confusing product certification and management system certification.

5.9 获证组织若在宣传材料上使用“CMD”标徽和“CMD”产品标识，标识必须完整，按比例放大缩小不得将其变形。“CMD”标徽可单独使用，获证组织可通过CMD网站下载“CMD”标徽的电子版本。获得产品认证的组织可向CMD购买“CMD”产品标识，加贴在产品表面或包装上，也可将“CMD”产品标识使用方案向CMD申请备案后，自行印刷在产品表面或包装上。

If the certificated organization uses the "CMD" mark and the "CMD" product certification mark on the promotional materials, the mark must be complete, and it must not be deformed when scaled up or down. The "CMD" mark can be used independently, and the certificated organization can download the electronic version of the "CMD" mark through the CMD website. The organization that has obtained the product certification can purchase the "CMD" product certification mark from CMD and paste it on the surface or package of the product, or print it on the surface or package of the product by itself after applying to CMD for the record.

5.10 获证组织在产品包装和宣传资料附带信息中声明其管理体系通过认证，应包含获证客户的名称、管理体系的类型（质量、环境、职业健康安全）和适用的标准、颁发证书的认证机构等信息；

The certificated organization declares in the product packaging and promotional materials that its management system is certificated, which shall include the name of the certificated client, the type of management system (quality, environment, occupational health and safety) and applicable standards, and the certification body

issuing the certificate.

5.11 认证证书和标识只能在证书的有效期内使用。注销和撤销认证注册资格的组织不得使用认证证书和相关标识。暂停认证注册资格的组织在暂停期间内不得使用认证证书和相关标识。

The certification certificate and mark can only be used within the validity period of the certificate, and the organization whose certification registration has been canceled shall not use the certification certificate and related mark. The organization whose certification registration is suspended shall not use the certification certificate and associated mark during the suspension period.

5.12 获证组织不得以任何方式转让、转借认证证书和标识。

The certificated organization shall not transfer or lend the certification certificate and mark in any way.

5.13 获证组织在使用管理体系认证证书时应与所提供的产品注册证一起使用。在产品注册证有效期内，体系证书中所覆盖的该产品是有效的。

The certificated organization shall use the management system certification certificate together with the product registration certificate. Only within the validity period of the product registration certificate, the product covered by the system certificate is valid.

6 认证证书和标志的管理

Management of certificates and marks

6.1 CMD 在对获证组织实施监督审核时，必须审核认证证书和标志的使用是否符合规定要求。

When CMD conducts surveillance and audit of the certificated organization, it must check whether the use of the certification certificate and the marks meets the specified requirements.

6.2 当获证组织违反使用规定的要求，经 CMD 调查核实后向违规组织下发不合格报告，要求限期采取纠正措施，并进行跟踪。在限期内未能纠正的，CMD 将根据有关要求，对违规组织暂停直至撤销相应的认证注册资格。

When the certificated organization violates the prescribed use requirements, CMD issues a nonconforming report to the offending organization after investigation and

verification, requiring corrective measures to be taken within a time limit and tracking. If the offending organization fails to correct it within the time limit, CMD will suspend or withdraw the corresponding certification registration qualification according to the relevant requirements.

6.3 当获证组织被 CMD 缩小、暂停、撤销/注销其管理体系认证或产品认证时，对于缩小范围的组织应当按照其实际获证范围进行宣传和使用“CMD”产品标识；对于暂停的组织，应按照 CMD 通知的要求，在暂停期间应停止使用该证书（产品认证包括认证标识），并向现有的和潜在的所有相关采购方告知其认证状态；对于撤销/注销组织，应停止一切涉及认证的宣传，停止使用认证证书及标识并退回认证证书。

When a certificated organization is reduced, suspended, withdrawn/cancelled its management system certification or product certification, the reduced organization shall publicize and use the "CMD" product mark in accordance with its actual certificated scope. The suspended organization shall, in accordance with the requirements of the CMD notice, cease to use the certificate (product certification including certification mark) during the suspension period and inform all relevant existing and potential purchasers of its certification status. For the withdrawn/cancelled organization, all publicity related to certification should be stopped, the use of certification certificates and marks should be stopped, and the certification should be returned.

6.4 认证证书的变更

Changes of certification certificate

6.4.1 一般性变更

General changes

6.4.1.1 一般性变更涉及的内容：

General changes include:

- a. 获准认证组织的名称、地址名称、邮编变更；

Changes of name, address and postcode of the certificated organization.

- b. 获准认证的产品名称或管理体系覆盖的产品名称的变更；

Changes of product name or changes in product names covered by the management system.

- c. 由于 CMD 认可领域或业务范围的变化而带来证书上 CNAS 标志的变化。

Changes in the CNAS mark on the certificate due to changes in CMD's accredited area or business scope.

6.4.1.2 对于 6.4.1.1 中 a 和 b 条款的变更, 获证组织应向 CMD 提出书面申请, 并提交相关的证明材料, 由专业管理人员对产品名称变化进行确认 (依据医疗器械产品注册证、相关标准、说明书等, 确认这种变化符合有关产品规定的要求), 由审核策划组和审核服务组对组织名称或地址名称的变更进行确认; 并报质量委员会审批后, 由质量委员会负责换发证书。

For the changes of clause a and b in 6.4.1.1, the certificated organization shall submit a written application to CMD and relevant supporting materials, and the professional management personnel shall confirm the change of product name (according to the medical device product registration certificate, relevant standards, instructions, etc., to confirm that the change meets the requirements of relevant product regulations), the audit planning group and the audit service group shall confirm the change of the organization name or address. After being reported to the Quality Committee for approval, the Quality Committee shall be responsible for renewing the certificate.

6.4.1.3 如果组织的注册地发生变化, 获证组织应提交相应的变更证明材料由审核策划组和审核服务组评审确认, 并报质量委员会审批后, 由质量委员会负责换发证书。

If the domicile of the organization changes, the certificated organization shall submit the corresponding supporting materials for review and confirmation by the audit planning group and the audit service group, and report to the quality committee for approval, and the quality committee is responsible for replacing the certificate.

6.4.1.4 对于 6.4.1.1 中 c 条款的变更, 由质量委员会负责与获证组织联系按规定换发证书。

For the change of clause c in 6.4.1.1, the Quality Committee shall be responsible for contacting the certificated organization to renew the certificate as required.

6.4.2 生产地变更

Change of production site

6.4.2.1 如果组织的生产地发生变化, 获证组织应提交相应的变更证明材料 (医疗器械生产企业许可证、医疗器械产品注册证), 由审核策划组及审核服务组评审确认, 并报质量

委员会审批后，由质量委员会负责换发证书。

If the production site of the organization changes, the certificated organization should submit the corresponding supporting materials (medical device production license, medical device product registration certificate) which will be reviewed and confirmed by the audit planning group and the audit service group, and reported to the quality committee for approval, and the quality committee is responsible for replacing the certificate.

6.4.2.2 如仅能提供变更后的医疗器械生产企业许可证，则组织还应提交生产场地的变更说明（说明变更原因、时间、场地描述及生产情况），同时还应提交组织生产地变更后所进行的内部管理体系审核材料。由专业管理人员对材料进行审核确认，并报质量委员会审批后，由质量委员会负责换发证书。如果生产场地的变化对产品的生产过程和质量、环境影响因素、职业健康危险源及危险因素产生影响，则审核策划组应根据专业技术管理人员确认的结果安排现场审核。

6.4.3 If only the changed medical device production license can be provided, the organization should also submit a change description of the production site (indicating the reason for the change, the time, the description of the site and the production situation), and should also submit the internal management system audit materials conducted after the change of the organization's production site. The professional technical management personnel will review and confirm the materials, and report to the quality committee for approval, and the quality committee will be responsible for replacing the certificate. If the change of the production site has an impact on the production process and quality of the product, environmental influencing factors, occupational health hazards and risk factors, the audit planning group shall arrange on-site audit according to the results confirmed by the professional technical management personnel.

6.4.4 对于涉及一般性变更以外的其它变更执行《管理体系认证注册的授予、拒绝、保持、扩大、更新、缩小、暂停、恢复和撤消/注销管理》及《产品认证实施规则》。

For changes other than general changes, implement the Provisions of *Management system certification Registration granting, refusing, maintaining, expanding, renewing, reducing, suspending, restoring and withdrawing/deregistering management*, and

Implementation Rules for Product Certification.