**管理体系再认证工作通知及确认单**

**Management System Re-Certification**

**Notification and Confirmation Form**

**尊敬的体系负责人**

**Dear System Responsible Person：**

您好Greetings！

贵公司 管理体系认证证书有效期截止日XXXX年XX月XX日**，**应于XXXX年XX月接受再认证现场审核。为确保证书的有效衔接，请务必于XXXX年XX月XX日前将如下信息反馈（直接填写在此通知，先需提供word版进行双方核对，确认后提供PDF版（盖章件），必要时提供相关证明文件。

The validity period of your company's management system certification certificate will expire on XXXX Year XX Month XX Day, and the on-site re-certification audit should be conducted in XXXX Year XX Month. To ensure the effective transition of the certificate, please be sure to provide the following information by XXXX Year XX Month XX Day (filled directly in this notification, a Word version must be provided for mutual verification first, and after confirmation, a PDF version (stamped document) should be provided, along with relevant supporting documents if necessary).

**北京国医械华光认证有限公司**

Beijing Hua Guang Certification of Medical Devices Co. Ltd.

**XXXX年Year XX月Month XX日Day**

本组织自愿申请 管理体系再认证。已详细阅读了北京国医械华光认证有限公司提供的认证规范（公开文件）。本组织承诺，遵守北京国医械华光认证有限公司认证规范（公开文件）的规定和认可机构的要求，认真履行有关认证的义务，并对以下申请及认证过程中所出示材料的真实性负责。

This organization voluntarily applies for management system re-certification. I have thoroughly read the certification specifications (public document) provided by Beijing Hua Guang Certification of Medical Devices Co. Ltd. Our organization commits to comply with the certification specifications (public document) of Beijing Hua Guang Certification of Medical Devices Co. Ltd. and the requirements of the accreditation body, to diligently fulfill the obligations related to certification, and to be responsible for the authenticity of the materials presented during the application and certification process.

**一、基本信息：**（以下信息适用的请填写，不适用的请划掉）

**Basic Information:** (Please fill in applicable information; cross out what is not applicable)

1、统一信用代码Unified Social Credit Code（营业执照统一社会信用代码Unified Social Credit Code of Business License）：

2、组织名称Organization Name（企业名称Company Name）：

3、组织电话Organization Phone Number：

4、组织邮箱Organization Email：

5、法人代表Legal Representative：

6、注册资本Registered Capital：

7、住所Address：

8、生产地址Production Address（生产许可证登记地址Address Registered on manufacturing License）：

9、通讯地址Correspondence Address：

10、经营场所Business Location（经营企业填写filled by the sales enterprise）

11、库房地址Warehouse Address（经营企业填写filled by the sales enterprise）：

**二、附加信息Additional Information：**

1、联系人姓名、电话、邮箱Contact Person's Name, Phone, Email：

、 、

2、管理者代表姓名、电话、邮箱Management Representative's Name, Phone, Email：

、 、

3、最高管理者姓名、电话Top Management's Name, Phone: 、

4、人员总数Total Number of Personnel：

各体系覆盖人数Number of Personnel Covered by Each System：

GB/T 19001： 人Persons；

GB/T 42061： 人Persons（不带标Unmarked）；

ISO 13485 人Persons（带标Marked）；

GB/T 24001： 人Persons；

GB/T 45001： 人Persons；

ISO/IEC 27001：人Persons

**（体系覆盖人数为本次覆盖产品相关工作人员，财务除外（仅质量适用）；提供数据需准确。）**

(The number of personnel covered by the system refers to the relevant staff for the products covered this time, excluding finance (applicable only to quality); the data provided must be accurate.)

5、希望审核时间Desired audit time： （每月第一周不安排审核Audits are not scheduled for the first week of each month）

周一至周五Monday to Friday：□

周六Saturday：□

周日Sunday：□

工作时间Working hours：上午Morning ： 至 to ： ;

下午Afternoon ： 至to ：

6、管理体系认证标准（请在对应“□”内勾选）：

Management system certification standards (please check the corresponding “□”):

□GB/T 19001-2016 idt ISO 9001:2015 □GB/T 42061-2022 idt ISO 13485:2016

□GB/T 24001-2016 idt ISO 14001:2015 □GB/T 45001-2020 idt ISO 45001:2018

□ISO/IEC 27001:2022

申请组织法人代表Applicant Legal representative（签字signature）

申请组织Applying organization（盖章Seal） 年Year 月Month 日Day

北京国医械华光认证有限公司

Beijing Hua Guang Certification of Medical Devices Co., Ltd.

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**再认证覆盖范围确认表**

**Re-Certification Scope Confirmation Form**

**本次审核覆盖范围Scope of this Audit：**

适用性声明版本（ISMS适用）：

Applicability Statement Version (ISMS Applicable):

产品注册证号请标注在产品名称后，并确保注册证在有效期内。

Please indicate the product registration certificate number after the product name, and ensure that the registration certificate is valid.

以上内容为最近一次审核的审核结论，请确认

The above content is the audit conclusion from the most recent audit, please confirm：

□本次认证范围与上述审核范围一致，无变化

The certification scope this time is consistent with the above audit scope, with

no changes.

□本次审核范围与上述范围相比，有无如下变化：

Compared to the above scope, are there any changes in the audit scope this time:

1）变更Changes：  
2）新增Additions：  
3）缩小Reductions：

**变化情况应包括：**

**The changes should include:**

* 营业执照住所、生产许可证生产地址、受托方生产许可证生产地址；经营许可证经营场所、库房地址、经营范围；产品注册证产品名称、规格型号、注册证号；

Business license address, production license production address, entrusted party production license production address; Sales business license operating location, warehouse address, Sales business scope; product registration certificate product name, specifications and models, registration certificate number ;

* 对于ISMS认证，还应关注适用性声明版本、 ISMS保密性和/或敏感性声明（附件1）、ISMS管理体系范围企业信息化建设说明（附件2）的变更。如没有变更，不需要重复提供。

For ISMS certification, attention should also be paid to changes in the applicability statement version, ISMS confidentiality and/or sensitivity statement (Attachment 1), and changes in the ISMS management system scope enterprise information construction description (Attachment 2). If there are no changes, there is no need to provide it again.

**请您确保上述内容填写的准确性，我们将依据上述内容确定审核范围并进行合同签订。**

Please ensure the accuracy of the information provided above, as we will determine the scope of the audit and proceed with the contract signing based on this information.

**申请组织声明：**

**Application Organization Declaration:**

本组织自愿申请认证范围确认或变更。本组织声明，已了解认证范围变更的有关规定，并对申请及变更审核中所出示材料的真实性负责。

Our organization voluntarily applie for confirmation or change of the certification scope. We declare that it understands the relevant regulations regarding changes to the certification scope and is responsible for the authenticity of the materials presented during the application and change audit.

**申请组织代表（签字）/申请组织（盖章）**

**Representative of the applicant (signature)/Applicant (seal）：**

年Year 月Month 日Day

**附件annex 1：**

**ISMS保密性和/或敏感性声明**

**ISMS Confidentiality and/or Sensitivity Declaration**

**1、不允许接触信息Information not allowed to be accessed：**

1）是否存在包含保密性和/或敏感性信息而导致不能提供给审核组核查的ISMS文件和记录?

Are there any ISMS documents and records containing confidential and/or sensitive information that cannot be provided for review by the audit team?

□否No; □是Yes。

涉及的资料Related materials：

2）对于认证机构的其他安全要求

Other security requirements of the certification body

□无No； □有Yes。

具体要求Specific requirements：

**2.信息安全声明Information Security Statement：**

公司所提供的与信息相关的管理活动，从未因公司的原因导致客户的信息泄漏，或对客户的信息安全造成任何形式的威胁。

The management activities related to information provided by the company have never caused any leakage of customer information or posed any form of threat to the security of customer information due to the company's reasons.

公司确认符合工信部联协[2010]394 号文《关于加强信息安全管理体系认证安全管理的通知》的要求，以及有关主管部门/监管部门对信息安全管理体系认证的管理要求(如工信部 2011年第 21 号公告《工业和信息化部加强政府部门信息技术外包服务安全管理》等相关规定。

The company confirms compliance with the requirements of the Ministry of Industry and Information Technology's joint document [2010]394 titled '*Notice on Strengthening the Security Management of Information Security Management System Certification*,' as well as the management requirements for information security management system certification set forth by relevant authorities/regulatory bodies (such as the Ministry of Industry and Information Technology's Announcement No. 21 of 2011 *'Strengthening the Security Management of Information Technology Outsourcing Services in Government Departments*' and other related regulations).

本公司对上述声明的真实性负责。

Our company is responsible for the authenticity of the above statement.

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声明代表Declaration Representative (签字Signature)：

(公章Official Seal)

年Year 月Month 日Day

**附件annex 2：**

**ISMS管理体系范围企业信息化建设说明**

**Description of enterprise information construction**

**within the scope of ISMS management system**

1. **网站建设说明**

**Website Construction Description**

**2、机房数量及所在物理位置**

**Number of Computer Rooms and Their Physical Locations**

**3、服务器数量及用途说明**

**Number of Servers and Description of Their Uses**

|  |  |  |  |
| --- | --- | --- | --- |
| 序号  Serial No. | 服务器名称  Server Name | 用途  Purpose | 数量  Quantity |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

**4、网络设备的架设和设置情况说明**

**Description of the Setup and Configuration of Network Devices**

|  |  |  |  |
| --- | --- | --- | --- |
| 序号  Serial No. | 网络设备名称  Network Device Name | 型号  Model | 数量  Quantity |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |

**5、使用的信息系统**

**Information Systems in Use**

|  |  |  |
| --- | --- | --- |
| 序号  Serial No. | 信息系统名称  Information System Name | 信息系统作用  Function of the Information System |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |
| 6 |  |  |