

**质量管理体系认证申 请 书**

**Quality Management System Certification**

**Application Form**

**申 请 组 织**：

**Applicant**:

**申 请 日 期：**

**Date：**

**北京国医械华光认证有限公司**

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

**质量管理体系认证申请条件及申报材料**

**Conditions and Application Materials for**

**Quality Management System Certification**

**一、申请质量管理体系认证注册条件:**

**I. Conditions for Applying for Quality Management System Certification Registration:**

1. 申请组织应持有营业执照或证明其法律地位的文件；

The applying organization should hold a business license or documents proving its legal status;

1. 已取得产品注册证、生产许可证或其它资质证明（国家或部门法规有要求时）；

A product registration certificate, production license, or other qualification certificates should be obtained (when required by national or departmental regulations);

1. 申请认证的质量管理体系覆盖的产品应符合有关国家标准、行业标准或注册产品的技术要求。

The products covered by the quality management system applying for certification should comply with relevant national standards, industry standards, or technical requirements of registered products.

1. 申请组织应建立符合拟申请认证标准的质量管理体系，企业质量管理体系运行时间不少于3个月；对从事医疗器械生产、经营企业还应符合GB/T42061-2022标准的要求；

The applying organization shall establish a quality management system that complies with the certification standards being applied for, and the enterprise's quality management system must have been in operation for no less than 3 months; Organizations engaged in the production and operation of medical devices must also comply with the requirements of the GB/T42061-2022 standard;

1. 申请组织至少进行过一次全面内部审核及一次管理评审。

The applying organization must have conducted at least one comprehensive internal audit and one management review.

1. 在提出认证申请前的一年内，申请组织的产品无重大顾客投诉及质量事故。

Within one year prior to submitting the certification application, the applying organization has had no major customer complaints or quality incidents regarding its products.

**二、质量管理体系认证申请材料要求(提供电子版)：**

**Requirements for Quality Management System Certification Application Materials (provide**

**electronic version):**

1. 申请组织授权代表签署的质量管理体系认证申请书及两个个附件，**申请书word版、PDF版（盖公司章）各一份；**

The quality management system certification application form signed by the authorized representative of the applying organization and two attachments, one copy each of the application form in Word and PDF formats (with company seal);

1. 申请组织企业法人营业执照副本复印件；

A copy of the business license of the applying organization;

1. 申请组织其它资质证明（国家或部门法规有要求时）；如，计量许可、特种设备许可等证明文件（适用时）； 安装清单（适用时）；

Other qualification certificates of the applying organization (when required by national or departmental regulations); such as, measurement licenses, special equipment licenses, and other supporting documents (if applicable); installation list (if applicable);

1. 申请组织体系运行**3个月**以上的**质量手册（全文），程序文件（全文）**；**（手册内容及职能分配表内容需包含本次认证标准的相应条款）**

**Quality manual (full text) and procedure documents (full text) of the applying organization that have been in operation for 3 months or more; (The content of the manual and the functional allocation table must include the relevant clauses of the certification standard this time)**

1. 申请组织体系运行**3个月**以上的管理评审报告、内审报告**（一年内）**；

Management review reports and internal audit reports of the applying organization that have been in operation for **3 months** or more **(within one year)**;

1. 组织申请认证覆盖的范围所适用的法规清单（企业外来文件清单）；

A list of applicable regulations covering the scope of the organization's certification application (list of external documents for the enterprise);

1. 组织申请覆盖的产品或服务所涉及的国家标准、行业标准清单；

A list of national standards and industry standards related to the products or services covered by the applying organization;

1. 组织申请产品生产工艺流程图（包含特殊过程、关键过程说明；每个产品单独提供）；

A flowchart of the production process for the products applied for by the organization (including descriptions of special processes and key processes; to be provided separately for each product);

1. 组织申请覆盖产品的说明书；（每个产品单独提供，文件名称以产品名称命名）；

The instruction manual for the products covered by the application from the organization; (to be provided separately for each product, with the document name named after the product name);

1. 申请组织医疗器械**生产许可证及副本**复印件（登陆省局网上办事大厅，提供新增产品的注册登记信息的截图）；一类医疗器械生产企业须提供**第一类医疗器械生产备案凭证**；经营企业提供经营许可证和二类备案凭证**复印件**；如申请产品为非医疗器械产品，应提供**生产场地租赁协议**。

The applying organization must provide a production license for medical devices and a copy (visit the provincial bureau's online service hall and provide a screenshot of the registration information for the newly added products); Class I medical device manufacturers must provide Class I medical device production filing certificate ; operating enterprises must provide a business license and a copy of the Class II filing certificate ; If the applied product is a non-medical device, a production site lease agreement must be provided.

1. 申请覆盖的医疗器械产品，提供上述资料外，还须提供医疗器械产品**注册证**复印件(如有附页、变更页

需一并提供）；一类医疗器械生产企业须提供第一类医疗器械备案凭证复印件和**第一类医疗器械备案信息表**复印件（如有附页、变更页 需一并提供）；

For the medical devices covered by the application, in addition to the above materials,

a copy of the medical device **registration certificate** must be provided (if there are

annexes or change pages, they must be provided together); Class I medical device

manufacturers must provide a copy of the Class I medical device filing voucher and

a **copy of the Class I medical device filing information form** (if there are annexes or

change pages, they must be provided together);

1. 申请组织申请认证**产品覆盖范围清单word版、PDF版（盖公司章）各一份；**覆盖范围清单PDF版可与

申请书盖章扫描在一起

The applying organization must submit a list of products covered by the certification in

both Word and PDF formats (with company seal) each in one copy; the PDF version of the

coverage list can be scanned together with the stamped application form.

13.申请覆盖部分过程的医疗器械产品：

Application for medical device products covering part of the process:

1. 尚未取得医疗器械产品注册证的：提供上述1、2、4、5、6、7、12外，还需提供：

For those that have not yet obtained a medical device product registration certificate: In addition to providing the above 1, 2, 4, 5, 6, 7, 12, it is also necessary to provide:

1. 产品技术要求（或备案标准）和风险管理报告；

Product technical requirements (or filing standards) and risk management report;

1. 产品注册检测报告；产品说明书；产品流程图；

Product registration testing report; product specification; product flowchart;

1. 符合相应规定的临床评价报告或临床试验资料和豁免临床的说明;

Clinical evaluation report or clinical trial data that complies with relevant regulations and explanation for exemption from clinical trials;

1. 与已取得医疗器械注册证的同类产品的比较说明（适用时）；

Comparison explanation with similar products that have obtained medical device

registration certificates (if applicable);

1. 尚未取得生产许可证的：提供上述1、2、3、4、5、6、7、8、9、11、12；

For those that have not yet obtained a production license: provide the above 1, 2, 3, 4,

5, 6, 7, 8, 9, 11, 12;

1. 委托生产的企业提供上述1、2、3、4、5、6、7、8、9、12外，还需提供：

In addition to providing the above items 1, 2, 3, 4, 5, 6, 7, 8, 9, and 12, the entrusted

manufacturing enterprise must also provide:

* 1. 医疗器械委托生产授权书或委托生产协议（盖章版）。

Medical device entrusted manufacturing authorization letter or entrusted

manufacturing agreement (stamped version).

* 1. 有特殊环境要求的产品（无菌、植入、IVD等）第三方“环境检测报告”复印件。

For products with special environmental requirements (sterile, implantable, IVD,

etc.), a copy of the third-party 'Environmental Testing Report' is required.

1. 申请覆盖的产品不在国内销售仅供出口时，还需提供：

If the products covered by the application are not sold domestically and are for export only, the following must also be provided:

* 1. 出口国或地区的适用的产品标准和法规清单（必要时提供法规）；

A list of applicable product standards and regulations for the exporting country or region (regulations should be provided if necessary);

* 1. 符合相关法规要求的型式检验报告；产品说明书；

Type test report that meets relevant regulatory requirements; product specification;

* 1. 产品出口国或地区代理销售协议/销售合同/订单/或CE 认证协议；

Sales agreement/sales contract/order/or CE certification agreement for the country or region of product export;

备注：如果有委托加工合同或协议(注：若为部件和组件的OEM方式可省略b、c条；若为整机的OEM方式可省略b条；若能提供CFDA产品出口批准文件可省略c条)；

Note: If there is a commissioned processing contract or agreement (Note: If it is an OEM method for parts and components, items b and c can be omitted; if it is an OEM method for complete machines, item b can be omitted; if CFDA product export approval documents can be provided, item c can be omitted);

1. 未纳入《医疗器械分类目录》的产品，若申请GB/T42061-2022体系认证，受理范围暂适用如下产品：医疗器械专用配套组件或配套件、医疗器械原料或半成品、包装材料，康复保健产品，医疗器械相关过程的提供；提供上述1、2、3、4、5、6、7、8、9、12外，还需提供：

Products not included in the 'Medical Device Classification Catalog', if applying for GB/T42061-2022 system certification, the acceptance scope currently applies to the following products: dedicated supporting components or kits for medical devices, raw materials or semi-finished products for medical devices, packaging materials, rehabilitation and health care products, and the provision of processes related to medical devices; In addition to providing the above items 1, 2, 3, 4, 5, 6, 7, 8, 9, and 12, the following must also be provided:

1. 独立产品提供备案的产品标准和产品说明书；医疗器械原料或半成品、专用配套组件或配套件提供医疗器械相关过程提供技术要求文件

Independent products must provide the product standards and product specifications for filing; raw materials or semi-finished products, specialized supporting components or kits provide technical requirement documents related to the medical device process;

1. 医疗器械无菌包装应提供符合相应级别的环境检测报告（一年之内）；

The sterile packaging of medical devices must provide an environmental testing report that meets

the corresponding level (within one year);

1. 独立产品提供产品型式检验报告；医疗器械原料或半成品、专用配套组件或配套件提供相

应的产品销售合同或订单。

Independent products must provide product type inspection reports; raw materials or semi-finished products, specialized supporting components or kits must provide corresponding product sales contracts or orders.

1. 租赁协议（租房合同）或地址情况说明。

Lease Agreement (Rental Contract) or Address Situation Statement.

1. 注册人制企业，还需提供：双方盖章的委托协议，以及双方的资质文件；

For registered enterprises, it is also necessary to provide: a stamped power of attorney agreement from both parties, as well as both parties' qualification documents;

**三、填写说明：**

**Instructions for Filling Out:**

1. 申请方的单位名称、地址应写全称和英文名称。请仔细校对产品名称、地址等内容**(与资质文件一致）；如涉及覆盖多个场所，请填写附件二；注：不涉及覆盖多个场所的不需要填写此附件**；通讯地址为合同、证书、CMD认证通讯等文件的邮寄地址；**如有资质文件未包含的地址需覆盖，需提供地址情况说明（盖章版）。**

The applicant's unit name and address should be written in full, including the English name. Please carefully check the product name, address, and other content **(consistent with the qualification documents); if it involves multi-sites, please fill out Attachment 2; note: if it does not involve multi-sites, this attachment does not need to be filled out** ; the correspondence address is the mailing address for contracts, certificates, CMD certification correspondence, and other documents; **if there are addresses not covered by the qualification documents that need to be included, a address situation statement (stamped version) must be provided.**

1. 申请组织应确保提交信息的真实性，如申报信息与实际情况不符（产品、场地、人数等），可能导致审核失效，由此造成的后果由申请组织承担。

The applying organization must ensure the authenticity of the submitted information. If the declared information does not match the actual situation (such as products, location, number of people, etc.), it may lead to the invalidation of the review, and the consequences arising therefrom shall be borne by the applying organization.

1. 申请表中所列内容以及三个附件（如涉及），**均应全部完整真实填写**；虚线框中内容（注册资本、统一社会信用代码、企业类型、法人代表）以营业执照信息为准；

The contents listed in the application form and the three attachments (if applicable) must be filled out completely and truthfully; The content in the dashed box (registered capital, unified social credit code, enterprise type, legal representative) shall be based on the information from the business license;

1. 所有文件按上述要求 以压缩包形式提供，**文件压缩包整体控制在100M 以内**，过大文件请提前压缩处理；提交文件中如有涉及保密无法提供的，需提供情况说明（盖章版）；

All documents must be provided in a compressed package as per the above requirements, **with the overall size of the compressed package controlled within 100M** ; please compress larger files in advance; If there are confidential documents that cannot be provided in the submitted files, a statement of circumstances (stamped version) must be provided;

1. 联系方式公司地址：北京国医械华光认证有限公司地址：北京市东城区安定门外大街甲88号中联大厦第五层； 邮编：100011 电话：（010）62351993（总机）； 传真：（010）62013872；联系电话：初次认证受理、合同电话（010）62358380；财务电话:（010）62368699；监督审核、再认证审核（受理、合同）电话：（010）64257855、（010）62379330；公司网址：<http://www.cmdc.com.cn>

资料回复邮箱：cmd-sc@cmdc.com.cn

Contact information Company address: Beijing Hua Guang Certification of Medical Devices Co., Ltd.

Address: 88 Jia, Andingmen Outer Street, Dongcheng District, Beijing, 5th Floor, Zhonglian Building; Postal code: 100011 Phone: (010) 62351993 (Switchboard); Fax: (010) 62013872; Contact phone: Initial certification acceptance, contract phone (010) 62358380; Finance phone: (010) 62368699; Supervision audit, re-certification audit (acceptance, contract) phone: (010) 64257855, (010) 62379330; Company website:<http://www.cmdc.com.cn> Email: cmd-sc@cmdc.com.cn

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **申请方基本情况**  **Basic information of the applicant** | | | | | | | | |
| 企业名称  Company name | | 中文：  Chinese: | | | | | | |
| 英文：  English: | | | | | | |
| 住 所  Address  （注册地址）  (Registered address) | | 中文：  Chinese: | | | | | | |
| 英文：  English: | | | | | | |
| 生产地址  Production address  （经营企业填经营场所）  ( Operating Enterprise fills in the operating location) | | 中文：  Chinese: | | | | | | |
| 英文：  English: | | | | | | |
| 通讯地址  Mailing Address | |  | | | | | | |
| 邮政编码  Postal Code | |  | | | 最高管理者  Top Management | |  | |
| 注册资本  Registered Capital | |  | | | 统一社会信用代码  Unified Social Credit Code | |  | |
| 企业类型  Enterprise Type | |  | | | 法人代表  Legal Representative | |  | |
| **管理者代表**  **Management Representative** | |  | | | 管理者代表手机号  Management Representative Mobile Number | |  | |
| 管理者代表邮箱  Management Representative Email | |  | |
| **联 系 人**  **Contact Person** | |  | | | 联系人手机号  Contact Person Mobile Number | |  | |
| 联系人邮箱  Contact Person Email | |  | |
| 联系人电话(座机)  Contact Person Phone (Landline) | |  | | | 传 真  Fax | |  | |
| 备用联系邮箱  Backup Contact Email | |  | | |  | | | |
| 质量管理体系认证标准  Quality Management System  Certification Standards | | □ GB/T 19001-2016 idt ISO 9001:2015  □ GB/T 42061-2022 idt ISO 13485:2016  □ 其他Other | | | | | | |
| 质量管理体系认证咨询情况  Consultation Status for Quality Management System Certification | | * + - 无None     - 有Yes 咨询机构：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   Consulting Agency:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| 申请类别  Application Category | | * + - 初次认证Initial Certification □ 再认证Recertification | | | | | | |
| 审核涉及的语言  Languages Involved in the Audit | | * + - 中Chinese □ 英English □ 其他Other | | | | | | |
| 质量手册当前运行版本时间Current running quality manual version time： ；  版本号Version Number：  □是否满足三个月的运行时间Whether the system runs for more than three months | | | | | | | | |
| 希望审核的时间Expected audit time： 年year 月month | | | | | | | | |
|  | | | |  | | | | |
| **质量体系覆盖的范围Scope Covered by the Quality System (填写附件一Fill out Attachment 1)**  **注Note:**   1. 注册证文件以序号+产品名称命名，序号需与 《覆盖范围清单》序号一致，以便核对。   The registration certificate document should be named with the serial number + product name, and the serial number must match the serial number in the 'Coverage List' for verification.  ②《覆盖范围清单》中的医疗器械产品填写产品名称、证号须与资质完全相同，相同名称产品序号相连。  The product name and certificate number for medical devices listed in the 'Coverage List' must be exactly the same as the qualifications, and products with the same name should be connected by serial numbers.  ③**非医疗产品**规格型号以产品技术文件为准，需填写规格型号；**未获证产品**无需填写型号以产品技术要求为准；**医疗器械已取证产品**无需填写型号，填写证号即可。  For non-medical products, specifications and models should be based on the product technical documents, and specifications and models must be filled in; for uncertified products, models do not need to be filled in, and should be based on product technical requirements; For certified medical devices, models do not need to be filled in, only the certificate number is required. | | | | | | | | |
| 企业占地面积Enterprise land area： ㎡；  建筑面积Building area： ㎡；  使用面积Usable area： ㎡  洁净房面积Cleanroom area（如有if applicable）：□30万级Claass300000 ㎡  □10万级Claass100000 ㎡ □万级Claass10000 ㎡  **（涉及本次认证产品的related to the products certified this time）** | | | | | | | | |
| **体系覆盖总人数Total number of personnel covered by the system：**  检验员人数Number of inspectors： 内审员人数Number of internal auditors： | | | | | | | | |
| 名单  List | 姓名  Name | | 职务  Position | 学历  Education | | 职称  Title | | 备注  Remarks |
| 生产负责人  Production Manager |  | |  |  | |  | |  |
| 质量负责人  Quality Manager |  | |  |  | |  | |  |
| 技术负责人  Technical Manager |  | |  |  | |  | |  |
| 检验员  Inspector |  | |  |  | |  | |  |
|  |  | |  |  | |  | |  |
| 主要生产设备：  Main production equipment: | | | | | | | | |
| 主要检验设备：  Main inspection equipment: | | | | | | | | |
| 工作时间Working hours：  上午Morning 至to ；下午Afternoon 至to ；  正常休息日Normal rest days：  □一Monday □二Tuesday □三Wednesday □四Thursday □五Friday □六Saturday □日Sunday | | | | | | | | |
| 生产运作状况最恰当的描述The most appropriate description of production operation status：  □连续作业Continuous operation □周期性作业Periodic operation | | | | | | | | |
| 各类产品生产批量情况：  Production batch situation of various products: | | | | | | | | |
| 申请认证组织外包信息Outsourcing information for certification application:  是否有外包Is there outsourcing:：□否No □是Yes  外包过程Outsourcing process： | | | | | | | | |
| 近两年来，国家、省市监管部门对产品监督抽查情况：  In the past two years, the national and provincial regulatory authorities' product supervision and sampling inspection situation:    近两年来，国家、省市监管部门对企业体系考核情况：  In the past two years, the national and provincial regulatory authorities' assessment of the enterprise system:    近两年内有无重大顾客投诉：  Have there been any major customer complaints in the past two years:    如有不合格或重大顾客投诉，请进一步说明。  If there are any non-conformities or significant customer complaints, please provide further explanation. | | | | | | | | |
| **申请组织声明：**  **Declaration of the Applying Organization:**  本组织自愿申请质量管理体系认证。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，并对申请及认证过程中所出示材料的真实性负责。  This organization voluntarily applies for Quality Management System certification. The organization has thoroughly read the certification standards (public document) provided by Beijing Hua Guang Certification of Medical Devices Co., Ltd. This organization commits to comply with the provisions of the certification standards (public document) of Beijing Hua Guang Certification of Medical Devices Co., Ltd. and the requirements of the accreditation body, diligently fulfilling the obligations related to certification, and is responsible for the authenticity of the materials presented during the application and certification process.  **申请组织代表Representative of the Applying Organization（签字Signature）:**    **申请组织Applying Organization（盖章Seal） 年Year 月Month 日Day** | | | | | | | | |

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请填写开票信息Please fill in the invoicing information:请确认后填写Please confirm before filling in；

注：开户地址、电话是指开票企业信息，公司税号为统一社会信用代码

Note: The address and phone number refer to the invoicing enterprise information, and the company tax number is the Unified Social Credit Code.

开票类型Invoicing Type □专票Special Invoice □普票Regular Invoice □不开票No Invoice

企业税号Company Tax Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

接收发票邮箱Invoice Receiving Email（必填Required）\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

开户地址Bank Address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

开户电话Phone \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

开户银行Account bank \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

银行帐号Bank Account Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

开户名称Account Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

开票备注Invoice Remarks \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**附件一Attachment 1：**

注：以下是两份表格，初次企业提供表一或表二（生产企业填写表一，经营企业填写表二）

Note: The following are two forms, the initial enterprise should provide either Form 1 or Form 2 (Production enterprises fill out Form One, Operating enterprises fill out Form 2)

**表一： 初次认证生产企业 覆盖范围清单**

**Table 1: Initial Certification Production Enterprise Coverage List**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **企业名称Company Name（盖章Seal）：** | | | | | |
| **序号**  **Serial No.** | **产品名称**  **Product Name**  （严格按注册证/备案信息表所示产品名称填写）  (Please fill in the product name strictly according to the Registration Certificate/Filing Information Form) | **注册（备案证号）**  **Registration (Filing voucher )**  获证产品填写：注册（备案）证号  Fill in certified products Registration certificate (Filing voucher) Number  （非医疗、未取证产品可不填写）  (Non-medical device, uncertified products may be left blank) | **规格型号**  **Specifications and Models**  未获证产品写产品见技术要求，非医疗产品填写规格型号  Uncertified products write see product technical requirements, non-medical products fill in specifications and models  **（获证产品可不填写）**  **(Certified products may be left blank)** | **注册日期**  **Registration Date**  **未取证、非医疗器械可不填写**  **Uncertified, non-medical devices may be left blank** | **备注**  **Remarks** |
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为保证覆盖产品的完整性，请将贵公司的体系覆盖产品名称及规格按此表格要求填写，须向CMD提供电子文档，谢谢！

To ensure the completeness of the covered products, please fill in your company's system covered product names and specifications according to the requirements of this form, and provide an electronic document to CMD, thank you!

**表二：初次认证经营企业 覆盖范围清单**

**Table 2: Initial Certification Coverage List for Operating Enterprises**

库房地址Warehouse Address：

库房面积Warehouse Area： m2 （其中Among them:：恒温库面积Constant Temperature Warehouse Area m2 ，冷藏库容积Refrigerator Volume m3 ，冷冻库容积Freezer Volume m3）

|  |  |
| --- | --- |
| **企业名称Company Name（盖章Seal）：** | |
|  | **经营范围Scope of Business** |
| **三类Class III**  **医疗器械经营范围**  **Scope of Medical Device Business** |  |
| **二类Class II**  **医疗器械经营范围**  **Scope of Medical Device Business** |  |

**备注Remarks：**

**:注：请严格按照经营许可证/经营备案凭证的经营范围填写（包括括号内容以及标点）。**

**Note: Please fill in strictly according to the scope of the business license/business filing voucher (including content in parentheses and punctuation).**

**附件二：认证范围内多场所清单**

**Attachment 2: List of Multi-Site within the Certification Scope**

**客户名称Customer Name（盖章Seal）：**

住所是否有体系覆盖范围内的活动Does the residence have activities within the coverage of the system（销售、人力、研发、采购等过程sales, human resources, research and development, procurement, etc）：

□ 是Yes （填写多场所清单Fill in the multi-sites list）；□ 否No（住所与生产经营为同一地址的请忽略Please ignore if the residence and production operation are at the same address）

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 序号  Serial No. | 基本情况  Basic Information  场所名称  Site Name | 详细地址  Detailed Address | 场所类别  Site Category | 场地面积  Site Area  （㎡） | 联系人/  电话  Contact Person/Phone | 涉及的相关产品或项目及活动过程  Related products or projects and activity processes involved | 场所人数  Number of people at the Site | 与主场所距离  Distance from the main site | 备注  Remarks |
| 1 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |

填写说明Filling Instructions:

：

1. **主场所：**组织产品或业务主要活动负责的法律实体，负责组织策划、建立和实施组织的质量管理体系，并监督和持续改进其有效性。多场所：组织管理体系覆盖下，组织在主场所中心职能控制下对某些过程、活动进行策划和控制，在多个场所（常设的、临时的或虚拟的）中这些过程、活动得到全部或部分实施。以行政区划上同一地址的不同楼栋号不视为多地址。

**Main site:** The legal entity responsible for the main activities of the organization’s products or business, responsible for organizing, planning, establishing, and implementing the organization’s quality management system, and supervising and continuously improving its effectiveness. Multi-sites: Under the coverage of the organization’s management system, the organization plans and controls certain processes and activities under the central functional control of the main location, with these processes and activities being fully or partially implemented in multi-site (permanent, temporary, or virtual). Different building numbers at the same address in terms of administrative divisions are not considered multiple addresses.

1. **场所类别：**对于制造业分为：委托场所、自有场所、临时场所；对于经营企业分为：经营场所、自有库房、外包库房、临时场所。临时场所是企业为在有限的时期内进行特定工作或服务而设立的，且不会成为常设场所的场所（如：安装现场、系统集成类、医用供氧、医用吸引的施工现场、技术服务网点等）。

**Type of site:** For the manufacturing industry, it is divided into: entrusted locations, owned locations, and temporary locations; For operating enterprises, it is divided into: operating locations, owned warehouses, outsourced warehouses, and temporary locations. Temporary locations are places established by enterprises to carry out specific work or services for a limited period and will not become permanent sites (e.g., installation sites, system integration, medical oxygen supply, medical suction construction sites, technical service points, etc.).

1. **场地面积：**根据各分场所信息分别填写相应企业占地面积、建筑面积、使用面积，如涉及特殊环境的，应明确环境级别（百级、万级、十万级、三十万级）、库存环境（冷冻库、冷藏库）及；

**Site area:** Fill in the corresponding enterprise land area, building area, and usable area according to the information of each sub-location. If special environments are involved, the environmental level (Class 100, Class 10,000, Class 100,000, Class 300,000), storage environment (freezer, refrigerator) should be specified;

1. **涉及的相关产品及活动过程：**对于制造业来讲，产品的描述为对应分场所下所涉及的申请书中第几项或多项产品或申请范围下全部产品，所涉及的过程根据各对应分场所下所涉及产品的一个或多个过程，如研发、采购、生产、质量、销售及售后服务、库房等；描述为如：全部产品的研发过程、无菌类产品的灭菌过程、第1、2、3……项产品实现的全过程、第5、6项产品组装、调试过程、全部产品的检验过程、原材料库房、成品库等。对于经营业类企业来讲，主要明确经营类别及活动，如：经营范围内的采购、销售及售后服务、除库房外的其他所有活动、常温库、生物制品类冷冻库、体外诊断试剂类冷藏库等；对于临时安装场所，需明确安装项目及项目所处阶段

**Relevant products and activities involved:** For the manufacturing industry, the description of the products corresponds to which item or multiple items in the application form under the respective sub-location or all products under the application scope. The processes involved are based on one or more processes of the products involved in each corresponding sub-location, such as research and development, procurement, production, quality, sales, after-sales service, warehousing, etc.; Described as: the research and development process of all products, the sterilization process of sterile products, the entire process of achieving items 1, 2, 3..., the assembly and debugging process of items 5 and 6, the inspection process of all products, raw material warehouse, finished product warehouse, etc. For enterprises engaged in business activities, it is essential to clarify the types of business and activities, such as: procurement, sales, and after-sales service within the scope of business, as well as all other activities outside of storage, including ambient temperature storage, frozen storage for biological products, and refrigerated storage for in vitro diagnostic reagents; for temporary installation sites, it is necessary to specify the installation projects and the stages of those projects.

1. **与主场所距离**：应填写具体距离，并明确交通工具所需时间，如距离5公里、步行40分钟；如距离80公里、车程1小时等；

**Distance from the main site**: Specific distance should be filled in, along with the time required for transportation, such as a distance of 5 kilometers, taking 40 minutes on foot; or a distance of 80 kilometers, taking 1 hour by car, etc.;