苏州莱标标准认证有限公司
Suzhou LQA Standard Certification Co., Ltd.

管理体系认证申请书
Application for Management System Certification

申请组织名称（盖章）：_____

Organization Name(Stamp):_____

管理体系认证申请书

Application for Management System Certification

一、认证申请类型 Type of Certification for Application

□初次认证 Initial Audit □再认证 Re-registration Audit □转机构 Transfer

二、申请认证组织信息 Organization Information

2.1 申请组织名称：_____

Organization Name:_____

2.2 注册地址及邮编：_____

Registration Address and Post Code: _____

2.3 生产经营（或服务）地址及邮编：_____

Business Address and Post Code_____

2.4 联系人 Contact Person：_____职务 Job Title：_____手机 Phone：_____

2.5 电话 Tel：_____传真 Fax：_____ 邮箱 Mail：_____

2.6 法人 Legal Person:_____ 电话 Tel：_____ 手机 Phone：_____

2.7 企业总人数 Total Number of Employees in the Enterprise：_____

组织人数 Number of Organizational Members：_____

管理体系覆盖的总人数 The Total Number of People Covered by the Management System ：_____

2.7.1 固定员工人数 Fixed Number of Employees:_____ 临时员工人数 Number of Temporary Employees: _____

分包商人数 Number of Subcontractors _____ 季节性人数/高峰月份 Seasonal Population/Peak Month _____

2.7.2 是否有倒班 Is there a Shift System：□是 YES □否 No 轮班制人数 Number of people on shift system：_____

班次时间/人数 Shift Time/ Number of People：_____

主要过程/活动 Main Processes/Activities _____

非轮班人数 Non Shift Personnel _____ 主要过程/活动 Main Processes/Activities _

_____

2.7.3 在组织工作场所外工作的人数 Number of People Working Outside the Organization's Workplace：

涉及的过程/活动 The Processes/Activities Involved：_____

注：申请组织等有多场所（包括临时/固定）时，应在审核方案策划前提供《多场所清单》

Note: When applying for organizations with multiple locations (including temporary/fixed), a "List of Multiple Locations" should be provided before reviewing the plan

2.7.4 有无外包过程 Outsourcing process：□有 YES □无 No 外包过程 Outsourcing process：_____

2.7.5 申请组织的外包方是否已经建立相应管理体系并获得管理体系认证证书 Has the outsourcing party applying for the organization established a corresponding management system and obtained a management system certification： □有 YES □无

2.7.6 外包过程是否有法律法规的强制要求(如强制性资质要求等) Is there any mandatory legal or regulatory requirement for the outsourcing process, such as mandatory qualification requirementsn □不涉及 Not involved □无 No □有 YES

_____

2.7.7 申请组织对外包过程的控制方法(可同时发生) Application organization's control method for outsourcing process (can occur simultaneously): □驻厂 Resident factory □按期检查 inspect on schedule □按采购过程控制 Control according to the procurement process

2.7.8 组织的场所是否存在公众人员(如:医院、学校、机场、火车站、公共交通运输) Whether there are public personnel present in the organization's premises (such as hospitals, schools, airports, train stations, public transportation)：□是 YES □否 No

2.7.9 组织是否正面临与 OHS 相关的法律诉 Is the organization facing legal litigation related to OHS：□是 YES □否

2.7.10 是否发生质量、环境污染、生产安全，并被当地监管部门处罚 Whether there has been quality, environmental pollution, production safety, and punishment by local regulatory authorities：□是 YES □否

三、申请认证依据、证书类型及覆盖范围 Audit Standard and Scope

认证依据标准及证书类型 Audit Standard and Certificate type：

□GB/T19001-2016/ISO 9001:2015 □CNAS □其他 Others
□GB/T42061-2022/ISO 13485:2016 □其他 Others
□GB/T24001-2016/ISO 14001:2015 □CNAS □其他 Others
□GB/T45001-2020/ISO 45001:2018 □CNAS □其他 Others
□IECQ QC080000:2017 □IECQ

申请认证范围 Scope：_____

质量管理体系不适用的标准要求条款及说明 Inapplicable standard terms and instructions of QMS&MDQMS：_____

_____

四、管理体系运行情况

体系 System	管理体系开始运行时间 Management System Start Time	最近一次内部审核时间 Last Internal Audit Time	最近一次管理评审时间 Last Management Audit Time
QMS			
EMS			

OHSMS			
MDQMS			
HSPM			

4.1 希望现场认证审核时间 Desired on-site audit time_____。

4.2 是否聘请外部咨询机构 Whether to hire consultants： □有（Yes）、□无(No)

机构名称(If yes, please identify the consultant body)_____。

4.3 是否有过其它机构的认证 Whether to be audited by other CB：□有（Yes）、□无(No)

机构名称(If yes, please identify the certificate body)_____。

认证证书有效期(Certificate valid date)_____；最近一次监督审核日期(The last surveillance audit date)；_____ □是否发生暂停（Is it suspended）、□是否发生撤销(Is it withdrawn)（请选择相应“□”Please choose the corresponding one），状态变更的时间为(status changed date)_____，原因为（Reasons）_____。

注：认证组织初次申请认证时体系应运行 3 个月以上（特殊行业应 6 个月以上），并已进行内审和管理评审。

Notes: System should be run more than 3 months (Special industry should be more than 6 months) if the organization apply the certification for the first time, and the organization had to performed the internal audit and management review.

五、受审核组织领导承诺 The leadership commitment of the auditee organization

我已阅读了乙方——苏州莱标标准认证有限公司的公开文件，同意遵守认证要求，并提供下列资料 ：

I have read the public documents which issued by Suzhou LQA standard certification Co., Ltd., agree to abide by the certification specifications and submit following documents：

5.1 基本资料（含质量管理体系认证） General Information (Contains QMS certification)：

5.1.1 法律地位证明文件的复印件：企业营业执照、事业单位法人证书、社会团体登记证书、企业非法人登记证书、党政机关设立文件、生产许可证、卫生许可证、排放许可证、特种行业生产/经营许可证、强制性认证证书等资质证书。

Copies of legal documents: Enterprise business license, legal person's registration of institutions, social group registration certificate, unincorporated registration certificate, party and government organs set up files, production license, the hygiene license, emission permits, production/operation license for special industry, compulsory certification qualification certificate, etc.

5.1.2 受控版本的管理手册（或方针/目标和指标、关于体系范围/不适用的要求及其说明）、形成文件的程序。

The controlled version of management manual (Or Policy/ Objectives & Index, scope / inapplicable requirement and instructions)，documented procedure.

5.1.3 生产、服务工艺流程图（含关键、特殊工序），组织机构图。

Process flow diagram (Contains key, special process)for production and service, organization chart。

5.1.4 体系覆盖的产品或服务质量标准清单。

Quality standard lists for product and service which were covered by system.

5.1.5 管理体系已有效运行 3 个月以上（建筑施工类要求 6 个月以上）的证明性信息。

Proof document of the management system which has been run more than 3 months (construction requires more than 6 months).

5.1.6 施工、监理等行业组织的在建和竣工项目清单。

Organization’s constructing project and completed project list under construction and supervision industry.

5.1.7 分包方名录和多场所清单（适用时）。
Subcontractor list and additional location list (When applicable).

5.1.8 一般纳税人资格证（必须含资格认定页）适用时。
General taxpayer qualification(Must contains the qualification page)(When applicable).

5.1.9 开票信息（包括）：企业名称（开户名）、纳税人识别号、开户行、账号、地址、电话。
Invoice information, contains company name (account name), taxpayer's registration Number, opening Bank, account, address and phone number.

5.2 申请环境管理体系认证的组织另提供以下资料。
Please submit these documents if you want to apply EMS certificate：

5.2.1 地理位置示意图和组织区域平面图。
Organization’s Geographical location map and regional map.

5.2.2 地下管网图（至少包括污水、雨水管网）并注明各排污口。
Underground pipe network graph (At least including sewage and rainwater pipe network) which indicate each drainage outlet .

5.2.3 环境监测机构近一年内出具的各项污染物环境监测报告复印件（适用时）。
All kinds of pollutants environmental monitoring report copies which issued by environmental monitoring agency nearly a year (when applicable).

5.2.4 98 年以后新建、扩建或技术改造企业提供“环评”资料、“三同时”验收报告的复印件。
Submit the “eia” materials, a copy of the "three simultaneity" acceptance report who building, expanding or technical transformation enterprises after years 1998.

5.2.5 守法证明原件（适用时）。
Law-abiding original (when applicable).

5.2.6 重要环境因素清单，适用的法律法规清单。
List of important environmental factors, list of applicable laws and regulations.

5.2.7 环境目标、指标和管理方案。
Environmental objectives, indicators and management plan.

5.3 申请职业健康安全管理体系认证的组织另提供以下资料：
Please submit these documents if you want to apply OHSMS certificate：

5.3.1 安全管理状况基本情况简介，包括近一年中是否发生安全事故及处理情况。
Brief introduction of basic information about safety management status, including whether safety accident happened and handling information in the last 1 years.

5.3.2 地理位置示意图和组织区域平面图。
Organization’s Geographical location map and regional map.

5.3.3 不可接受的危险源清单，设备设施清单，适用法律法规清单。
Unacceptable hazards list, equipment list, and list of applicable laws and regulations.

5.3.4 守法证明原件（适用时）。
Law-abiding original (when applicable).

5.3.5 安评报告（适用时），职业病危害预评价批复或备案表（法规有要求时）。
Evaluation report, occupational-disease hazard pre evaluation approval or filing report(when applicable or require for laws and regulations)

5.3.6 作业环境尘、毒、噪监测报告。
Dust, poison, noise monitoring report in the working environment.

5.3.7 职业健康安全目标、指标和管理方案。
Occupational health and safety objectives, indicators and management plan.

5.4 申请医疗器械质量管理体系认证的组织另提供以下资料：
Please submit these documents if you want to apply GMP certificate：

5.4.1 体系文件满足标准和法规要求对照表。
System documents meet standards and regulatory requirements.

5.4.2 产品的说明书和适用的法律法规清单。
Specification of products and list of applicable laws and regulations.

5.4.3 生产 I 类产品的，需提供备案证明。
For the production of Class I products, a record-keeping certificate shall be provided.

5.4.4 生产II、III类产品的，需提供医疗器械注册证及生产许可证。
For the production of II,III products, medical device registration certificate and production license shall be provided.

5.4.5 如为经营企业:销售 II 类医疗器械产品的，需提供经营备案证明；销售 III 类医疗器械产品的，需提供医疗器械经营许可证。
Such as business enterprise: sales of II medical device products, the need to provide business record certificate; sales of III type medical device products, medical device business license should be provided.

5.4.6 申请覆盖的产品不在国内销售时，需提供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）。
When applying for coverage is not for domestic sale, a list of applicable product standards and regulations (if necessary) of the exporting country or region shall be provided.

5.4.7 无菌的医疗器械，应提供符合相应级别的生产环境检测报告（一年之内）。
Sterile medical devices shall provide a corresponding level of production environment test report (within one year).

5.4.8 未纳入《医疗器械分类目录》的产品，需提供满足技术要求的证明。
Products not included in the Medical device Classification list shall be certified to meet the technical requirements.

5.5 申请有害物质过程管理体系要求认证的组织另提供以下资料：
Please submit these documents if you want to apply HSPM certificate：

5.5.1ISO9001 证书及其他已来获得的管理体系证书
ISO9001 certificates and other management system certificates obtained

5.5.2 产品中限用物质的限量要求及对应的现行法规、标准
Limit requirements for restricted substances in products and corresponding existing regulations and standards

5.5.3 HSPM 体系适用法律法规（清单）
Applicable Laws and regulations of HSPM System (List)

5.5.4 组织的 HSPM 体系方针
The organization's HSPM system policy

5.5.5 HSF 产品工序过程分析与评价表
HSF product process analysis and evaluation form

5.5.6 公司文档目录（包括记录）
Company document directory (including records)

注：以上资料随申请书一并提供，不同申请组织根据自身情况提供相应材料。
Note: Please provide the above documents together with the application form. Different organization provide corresponding materials depending on their own situation.

申请组织代表签字(盖章)：　　年 Y　　月 M　　日 D

Organization representatives Signature

附件： 申请认证应提交的资料说明
Attachment: Explanation of Materials to be Submitted for Certification Application

基本资料 Basic information	☐法律地位证明文件（如企业法人营业执照、事业单位法人代码证书、社团法人登记证 等），组织机构代码证。存在时，应提交分支机构的营业执照和组织机构代码证复印件。 如企业三证合一或五证合一，也可提供带有统一社会信用代码的企业证件代替营业执照 和组织机构代码证书； Legal status proof documents (such as business license of enterprise legal person, code certificate of public institution legal person, registration certificate of association legal person, etc.), organization code certificate. When present, copies of the branch's business license and organizational code certificate should be submitted. If the enterprise combines three certificates or five certificates, it can also provide enterprise certificates with unified social credit codes instead of business licenses and organizational code certificates; ☐有效的资质证明、产品生产许可证、强制性产品认证证书等涉及法律法规规定的行政 许可的须提交相应的行政许可证件复印件（需要时）； Effective qualification certificates, product production licenses, mandatory product certification certificates, and other administrative licenses required by laws and regulations must be submitted with corresponding copies of administrative license documents (if necessary); ☐临时场所清单（如：系统集成、维修/运维服务场所等临时服务点）；List of temporary locations (such as system integration, maintenance/operation service locations, and other temporary service points); ☐至少应提供以下文件化信息：方针、目标、范围、组织为过程运行及沟通而保持的信 息，必须提供：组织简介、组织结构（组织机构图）、人员情况和职能分工、过程路线 图/工艺流程图 /过程描述（应明确说明关键过程和特殊过程）及其有关的过程文件，如：风险控制情况、对 IT 的应用等； At least the following documented information should be provided: policies, objectives, scope, and information maintained by the organization for process operation and communication. It must include: organizational profile, organizational structure (organizational chart), personnel situation and functional division, process roadmap/process flow chart/process description (which should clearly indicate key and special processes) and related process documents, such as risk control situation, IT application, etc; ☐排污许可证（需要时）； Pollutant Discharge Permit (if required) ☐安全生产许可证（需要时）； Safety Production License (if required) ☐环评竣工验收报告相关资料（验收批复或验收报告）或环境影响登记表备案结果(必 要时)； Relevant materials for the completion acceptance report of the environmental impact assessment (acceptance approval or acceptance report) or the filing results of the environmental impact registration form (if necessary); ☐关于认证活动的限制条件(如出于安全和/或保密等原因，存在时)； Restrictions on certification activities (such as for security and/or confidentiality reasons, when they exist);
质量管理体系 quality management system	☐与产品/服务有关的技术标准、质量标准清单包括强制性标准清单（必要时） List of technical standards and quality standards related to products/services, including mandatory standard list (if necessary); ☐作业文件或作业文件清单（适用于工程建设施工组织） Homework file or homework file list (applicable to engineering construction organization)。
环境管理体系认证 Environmental management system certification	☐厂区平面图（包括:污染物排放点分布图） Factory floor plan (including: distribution map of pollutant discharge points); ☐环境因素及重大环境因素清单（对应至每一职责部门或运行活动单元、涵盖三种状态 和三种时态）； List of environmental factors and major environmental factors (corresponding to each responsible department or operational activity unit, covering three states and three tenses); ☐国家及行业适用的法律、法规和强制性标准（名称、编号、发布版本/时间）清单。 List of laws, regulations, and mandatory standards applicable to the country and industry (name, number, release version/time). ☐环境检测报告Environmental testing report

职业健康安全管理体系 Occupational Health and Safety	☐厂区平面图；厂区平面图、安全评价证据和安全守法证明（需要时）；消防验收或检 查书面证据、近期“工作场所有害因素职业接触限值”检测报告、守法证明； 识别的与过程有关的主要危险源和OHS 风险评价清单（对应至每一职责部门或运行活动 单元、涵盖三种状态和三种时态）； Factory floor plan; Factory floor plan, safety assessment evidence, and safety compliance certificate (if necessary); Written evidence of fire safety acceptance or inspection, recent "Occupational Exposure Limits for Hazardous Factors in the Workplace" test report, and compliance certificate; Identify the main hazards related to the process and OHS risk assessment checklist (corresponding to each responsible department or operational activity unit, covering three states and three tenses)
Management System	☐在产品和服务提供过程中所使用的主要危险材料（应包括名称、危险性描述、使用量 等） The main hazardous materials used in the process of providing products and services (including name, hazard description, usage amount, etc.)； ☐国家及行业适用的法律、法规和强制性标准（名称、编号、发布版本 / 时间）清单； List of laws, regulations, and mandatory standards applicable to the country and industry (name, number, release version/time); ☐管理体系覆盖范围活动可能涉及的职业健康安全危险说明（本申请书OHSMS 附件）； Explanation of occupational health and safety hazards that may be involved in the scope of management system coverage activities (OHSMS attachment to this application) ☐远离组织场所的工作人员的详细信息 Detailed information of staff who are far away from organizational premises。
医疗器械质量管理体系 Medical Device Quality management system	☐产品说明书； Product manual ☐适用的法律法规清单（适用时）； List of applicable laws and regulations (when applicable) ☐近期国家、行业产品/服务监督抽查报告（如发生）； Recent national and industry product/service supervision and inspection reports (if any); ☐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）（适用于国内不销售仅供出口使用）。 List of applicable product standards and regulations for the exporting country or region (provide regulations if necessary) (applicable for domestic non sales only for export use)
注：1.请在提供的资料前选“☑”。 Note: 1. Please select ☑ " before the provided information 2.扩项申请时，需提供因扩项而增加或变化的部分、有时限要求的证明性文件。When applying for expansion, it is necessary to provide supporting documents for the parts that have been added or changed due to the expansion, as well as the time limit requirements	