管理体系认证申请条件及申报材料

Management system certification application conditions and application materials

一、 申请质量管理体系认证注册条件:

Application Conditions for Quality Management System Certification Registration

1. 法律地位的证明文件（包括：企业营业执照、事业单位法人证书、社会团体登记证书、非企业法人登记证书、党政机关设立文件等）的复印件。若管理体系覆盖多场所活动，应附每个场所的法律地位证明文件的复印件（适用时）。

   Copies of legal status documentation (including: business licenses, legal person certificates for public institutions, registration certificates for social organizations, registration certificates for non-enterprise legal persons, establishment documents for party and government agencies, etc.). If the management system covers activities at multiple locations, copies of the legal status documents for each location should be attached (if applicable).

2. 管理体系覆盖的活动和认证产品所涉及法律法规要求的行政许可证明、资质证书、强制性认证证书等的复印件。

   Copies of administrative licensing documents, qualification certificates, mandatory certification certificates, etc., related to the activities covered by the management system and the legal requirements for the certified products.

3. 申请认证的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 management system applying for certification must comply with relevant national standards, industry standards, or the technical requirements of registered products.

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

   The applying organization should establish a management system that meets the

certification standards being applied for, and the quality management system for enterprises engaged in the production and operation of medical devices should also comply with the requirements of GB/T42061 （ISO13485）standard, with the system operating for no less than 3 months.

5. 申请组织至少进行过一次全面内部审核及管理评审。

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

6. 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、环境污染事故、职业健康安全事故。

   Within one year prior to submitting the certification application, the applicant organization's products must not have any significant customer complaints, quality incidents, environmental pollution incidents, or occupational health and safety incidents.

二、 管理体系认证注册申请材料要求（电子版）：

Requirements for Application Materials (Electronic Version) for Management System Certification:

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

   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);

2. 申请组织企业法人营业执照副本复印件；

   Copy of the business license of the applying organization;

3. 申请组织涉及国家或部门法律法规要求的行政许可证明、资质证书、强制性认证证书等的复印件,如计量许可、特种设备许可等证明文件复印件（适用时）；

   Copies of administrative licenses, qualification certificates, mandatory certification certificates, etc., required by national or departmental laws and regulations, such as measurement licenses, special equipment licenses, and other supporting documents (if applicable);

4. 申请组织质量手册及程序文件；

   Management system manual and procedure documents of the applying

organization;

5. 申请组织的管理评审报告、内审报告；

   Management review report and internal audit report of the applying organization;

6. 申请新版标准认证的组织，体系文件满足标准和法规要求对照表；

   The organization applying for the new standard certification must provide documentation that meets the requirements of the standard and the regulatory compliance checklist;

7. 多场所活动、活动分包情况（适用时）；

   Multi-site activities and subcontracting situations (if applicable);

8. 组织申请认证覆盖的范围所适用的法规清单；

   A list of regulations applicable to the scope of the organization's application for certification coverage;

9. 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 (or international) standards and industry standards related to the products or services covered by the organization applying for certification.

10. 申请组织工艺流程图（包含特殊过程、关键过程说明）；

    A process flow chart of the applying organization (including descriptions of special processes and critical processes);

11. 组织申请覆盖产品的说明书；

    The product manual for the products covered by the organization applying for certification;

12. 申请组织医疗器械生产许可证（包括医疗器械生产产品登记表）复印件；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；

    A copy of the medical device production license (including the medical device production product registration form) of the application organization; Class I medical device manufacturing enterprises must provide a copy of the Class I medical device production filing certificate. If the applied product is a non-medical device product, a production site lease agreement must be provided.

13. 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 device products covered by the application, in addition to the above materials, a copy of the medical device product registration certificate must be provided (if there are annexes or change pages, they must be provided together); Class I medical device manufacturing enterprises must provide a copy of the Class I medical device filing certificate and a copy of the Class I medical device filing information form (if there are annexes or change pages, they must be provided together).

14. 申请组织申请认证产品范围覆盖表 word 版、PDF 版（盖公司章）各一份；产品范围登记表 PDF 版可与申请书扫描在一起；

Copies of the application organization's certification product scope coverage table in Word and PDF version (with company seal) one copy each; the product scope registration form in PDF format can be scanned together with the application form;

15. 申请覆盖的医疗器械产品，若尚未取得医疗器械产品注册证的：提供上述 1、2、4、5、6、7、8、9、10、11、14 外，还需提供：

For the medical device products covered by the application, if the medical device product registration certificate has not yet been obtained: in addition to the above 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, and 14, the following must also be provided:

a) 产品标准或产品技术要求；

Product standards or product technical requirements;

b) 产品注册检测报告；

Product registration testing report;

c) 符合相应规定的临床试验资料或豁免临床的说明；

Clinical trial data that meets the corresponding regulations or explanations for clinical exemptions;

d) 医疗器械产品提交产品风险管理报告；

Medical device products must submit a product risk management report;

e) 与取得医疗器械注册证的同类产品的比较说明（适用时）

Comparison with similar products that have obtained medical device

registration certificates (if applicable)

16. 尚未取得生产许可证的：提供上述 1、2、3、4、5、6、7、8、9、10、11、13、14；

For those that have not yet obtained a production license: provide the above items 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14;

17. 委托生产的企业提供上述 1、2、3、4、5、6、7、8、9、10、14 外，还需提供：

a） 医疗器械委托生产授权书或委托生产协议（盖章版）。

For enterprises with entrust production, in addition to the above items 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 14, it is also necessary to provide:

a) Medical device entrust production authorization letter or entrust production agreement (stamped version).

18. 申请覆盖的产品不在国内销售仅供出口时，提供上述 1、2、3、4、5、6、7、8、9、10、14 外，还需提供：

When the products covered by the application are not sold domestically and are only for export, in addition to the above items 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 14, it is also necessary to provide:

a） 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）；

List of applicable product standards and regulations of the exporting country or region (provide regulations if necessary);

b） 符合相关法规要求的型式检验报告；

Type testing report that complies with relevant regulatory requirements;

c） 产品说明书；

Product manual;

d） 产品出口国或地区代理销售协议/销售合同/订单/ CE 认证协议；

Sales agreement/sales contract/order/CE certification agreement with the agent in the product's exporting country or region;

19. 未纳入《医疗器械分类目录》的产品，若申请 GB/T42061 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、10、14 外，还需提供：

For products not included in the '*Medical Device Classification Catalog*', if applying for GB/T 42061(ISO13485) system certification, the scope of acceptance

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 the above items 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, and 14, the following must also be provided:

a) 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和医疗器械相关过程提供技术要求文件；

Product standards and product manuals for independently provided products; Technical requirement documents for medical device raw materials or semi-finished products, dedicated supporting components or kits and related processes;

b) 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）；

Sterile packaging of medical devices should provide environmental testing reports that meet the corresponding level (within one year);

c) 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和医疗器械相关过程提供满足技术要求的证明。

Independently provided products should provide type testing reports; For medical device raw materials or semi-finished products, dedicated supporting components or kits and related processes, proof of meeting technical requirements must be provided.

d) 租赁协议（或租房合同）

Lease agreement (or rental contract)

20. 申请组织是医疗器械企业，应提交“二类医疗器械经营备案”、三类“医疗器械经营许可证”副本复印件（适用时）；

If the applying organization is a medical device enterprise, and should submit a copy of the 'Class II Medical Device Business Filing' and a copy of the 'Class III Medical Device Business License' (if applicable);

21. 申请环境管理体系认证时，提供上述 1、2、3、4、5、7、10、14 外，还需提供：

When applying for environmental management system certification, in addition to the above 1, 2, 3, 4, 5, 7, 10, 14, it is also necessary to provide:

a) 重要环境因素清单；

A list of significant environmental factors;

b) 环评及三同时证明文件（如：批复、竣工验收报告、登记表、备案）、排污许可证复印件（适用时）；

Environmental impact assessment and simultaneous approval documents (e.g., approvals, completion acceptance reports, registration forms, filings), and a copy of the pollutant discharge permit (if applicable);

c) 环境目标指标和环境管理方案一览表

A summary table of environmental objectives and management plans.

d) 地理位置图及厂区平面示意图，包括地下管网和污染监控点（适用时）；

A geographical location map and a layout diagram of the factory area, including underground pipelines and pollution monitoring points (if applicable);

e) 合规义务（适用法律法规及其他要求）清单

List of Compliance Obligations (Applicable Laws, Regulations, and Other Requirements)

22. 申请职业健康安全管理体系认证时，提供上述 1、2、3、4、5、7、10、14 外，还需提供：

When applying for Occupational Health and Safety Management System Certification, in addition to the above 1, 2, 3, 4, 5, 7, 10, 14, the following must also be provided:

a) 与组织过程有关的主要危险源和 OHS 风险，所使用的主要危险材料；

Main hazards and OHS risks related to organizational processes, and the main hazardous materials used;

b) 消防法规符合性证明文件（如：设计审查意见、验收意见等）；

Documents proving compliance with fire safety regulations (e.g., design review comments, acceptance opinions, etc.);

c) 目标指针和职业健康安全管理方案一览表；

Overview of objective indicators and occupational health and safety management programs;

d) 地理位置图及厂区平面示意图（适用时）

Geographical location map and site layout diagram (if applicable)

e) 合规义务（适用法律法规及其他要求）清单

List of Compliance Obligations (Applicable Laws, Regulations, and Other Requirements).

23. 申请信息安全管理体系认证时，提供上述 1、2、3、4、5、7、10、14 外，还需提供：

When applying for Information Security Management System Certification, in addition to the above 1, 2, 3, 4, 5, 7, 10, 14, the following must also be provided:

a) 最新版本适用性声明；

Latest Version Applicability Statement;

b) 组织内部网络结构拓扑图；

Organizational Internal Network Structure Topology Diagram;

c) ISMS 保密性和/或敏感性声明；

ISMS Confidentiality and/or Sensitivity Statement;

d) ISMS 管理体系范围复杂情况调查表；

ISMS Management System Scope Complexity Investigation Form;

e) 与生产/服务/经营过程有关的信息安全法律、法规（国际、国家、地方、行业）；

Information security laws and regulations related to production/service/operation processes (international, national, local, industry);

注：如同时申请多体系或医疗器械产品认证，相同材料可只提交一份。

Note: If applying for multiple systems or medical device product certifications simultaneously, the same materials may be submitted only once.