认证组织体系标准和法规要求文件对照表

Certification Organization System Standards and Regulatory Requirements Comparison Table

填写说明 Filling Instructions:

1.申请认证组织应按照 GB/T42061 标准对过程或程序形成文件的 32 处要求，对照《医疗器械生产质量管理规范》相关文件要求，识别组织的体系文件的对应关系，将对应的文件名称填写在“组织对应文件”栏目。

The applying certification organization should identify the correspondence of its system documents by comparing the 32 requirements for document formation processes or procedures according to the GB/T 42061 standards with the relevant document requirements of the '*Good Manufacturing Practice for Medical Devices* ', and fill in the corresponding document names in the 'Corresponding Organization Documents' column.

2. 组织的体系文件与标准、规范的文件内容和名称可能不是一一对应关系，在“备注”栏目中简单说明。（如：一份组织的文件内容可能对应多个标准、规范的文件内容，或一个标准、规范的文件要求由多份组织文件体现，这些均在“备注”中说明）

The organization's system documents may not correspond one-to-one with the content and names of the standards and regulations; a brief explanation should be provided in the 'Remarks' column. (For example: the content of one organizational document may correspond to multiple standard or regulatory documents, or a requirement from a standard or regulation may be reflected in multiple organizational documents; all of these should be explained in the 'Remarks' section.)

3.填写本表不仅是文件名称的对应，更重要的是文件内容的符合性、完整性。

Filling out this form is not only about the correspondence of document names, but more importantly, the conformity and completeness of the document content.

序号 Serial No.	**GB/T42061 文件要求 Requirements of GB/T 42061 documents**	**《规范》文件要求 Requirements of the GMP document**	**组织对应文件名称 Corresponding Document Name of the**	**备注 Remarks**

			Organization	
1	4.1.6 用于质量管理体系计算机软件应用的确认程序形成文件 4.1.6 Document for the validation Procedure of Computer Software Applications in the Quality Management System			
2	4.2.4 文件控制 形成文件的程序 4.2.4 Document Control Document procedure	第二十五条 建立文件控制程序 Article 25 Establishing Document Control Procedures		
3	4.2.5 记录控制 建立程序并形成文件 4.2.5 Record Control Establishing Procedures and Documented it	第二十七条 建立记录控制程序 Article 27 Establishing Record Control Procedures		
4	5.6 管理评审程序形成文件 5.6 Documented Management Review Procedures			
5	6.2 将确立能力、提供所需的培训和确保人员的意识等一个或多个过程形成文件 6.2 Establishing one or more processes to confirm capabilities, provide necessary training, and ensure personnel			

	awareness, etc., and documented them.			
6	6.4.1 将工作环境要求以及监视和控制工作环境的程序形成文件。 6.4.1 Document the requirements for the working environment and the procedures for monitoring and controlling the working environment.			
7	7.1 将风险管理的一个或多个过程形成文件 7.1 Document one or more processes of risk management.	第三十八条产品实现全过程中制定风险管理的要求并形成文件 Article 38 Establish requirements for risk management throughout the product realization process and document them.		
8	7.3.1 总则 组织应将设计和开发程序形成文件 7.3.1 General Principles The organization shall document the design and development procedures.	第二十八条 建立设计控制程序并形成文件 Article 28 Establish design control procedures and document them.		
9	7.3.8 设计和开发转换组织应将设计和开发输出向制造转换的程序形成文件 7.3.8 Design and Development Transition			

	The organization shall document the procedures for transitioning design and development outputs to manufacturing.			
10	7.3.9 设计和开发更改的控制 组织应将控制设计和开发更改的程序形成文件 7.3.9 Control of Design and Development Changes The organization shall document the procedures for controlling changes to design and development.			
11	7.4.1 采购过程 组织应将确保采购的产品符合规定的采购信息的程序形成文件 7.4.1 Procurement Process The organization shall document the procedures to ensure that the products purchased meet the specified procurement information.	第三十九条 Article 39 建立采购控制程序 Establish Procurement Control Procedures 第四十一条 企业应当建立供应商审核制度 Article 41 Enterprises shall establish a supplier review system.		
12	7.5.4 服务活动 组织应将服务程序、所涉及的材料和所涉及的测量形成文件 7.5.4 Service Activities The organization shall document the service procedures, the materials	第六十四条 建立健全售后服务制度 Article 64 Establish and Improve After-Sales Service System		

	involved, and the measurements involved.			
13	7.5.6 生产和服务提供过程的确认 组织应将过程确认程序形成文件 7.5.6 Confirmation of Production and Service Provision Processes The organization shall document the process confirmation procedures.			
14	7.5.6 生产和服务提供过程的确认 将用于生产和服务提供的计算机软件应用的确认程序形成文件 7.5.6 Confirmation of Production and Service Provision Processes Document the confirmation procedures for computer software applications used in production and service provision.			
15	7.5.7 灭菌过程和无菌屏障系统确认的专用要求 组织应将灭菌过程和无菌屏障系统的确认程序形成文件 7.5.7 Specific requirements for the validation of sterilization processes and sterile			

	barrier systems. The organization shall document the validation procedures for sterilization processes and sterile barrier systems.			
16	7.5.8 产品标识 组织应将产品标识程序形成文件 7.5.8 Product Identification The organization shall document the product identification procedure.	第五十一条建立产品标识控制程序 Article 51 Establish a product identification control procedure.		
17	7.5.8 产品标识 组织应建立程序并形成文件以确保返回组织的医疗器械能被识别且能与合格的产品区分开。 7.5.8 Product Identification The organization shall establish procedures and document them to ensure that medical devices returned to the organization can be identified and distinguished from qualified products.			
18	7.5.9 可追溯性 组织应将可追溯性程序形成文件 7.5.9 Traceability	第五十三条建立产品的可追溯性程序 Article 53 Establish a traceability procedure for		

	The organization shall document the traceability procedures	products		
19	7.5.11 产品防护 组织应将为产品符合要求提供防护的程序形成文件 7.5.11 Product Protection The organization shall document the procedures for providing protection to ensure product compliance.	第五十四条建立产品防护程序 Article 54 Establishment of Product Protection Procedures		
20	7.6 监视和测量设备的控制 组织应建立程序并形成文件，以确保监视和测量活动可行并以与监视和测量要求相一致的方式实施 7.6 Control of Monitoring and Measurement Equipment The organization shall establish and document procedures to ensure that monitoring and measurement activities are feasible and implemented in a manner consistent with monitoring and measurement requirements.	第五十六条建立质量控制程序 ，规定产品检验部门、人员、操作等要求，并规定检验仪器和设备的使用、校准等要求，以及产品放行的程序 Article 56 Establishment of Quality Control Procedures, stipulating the requirements for the Product Inspection Department, personnel, operations, etc., as well as the requirements for the use and calibration of inspection instruments and equipment, and the procedures for product release.		
21	7.6 监视和测量设备的			

	控制 组织应将用于监视和测量要求的计算机软件应用的确认程序形成文件 7.6 Control of Monitoring and Measurement Equipment The organization shall document the confirmation procedures for computer software applications used for monitoring and measurement requirements.			
22	8.2.1 反馈 组织应将反馈过程程序形成文件 8.2.1 Feedback The organization shall document the feedback process.	第六十六条顾客反馈处理程序 Article 66 Customer Feedback Handling Procedure		
23	8.2.2 抱怨处理 组织应按照适用的法规要求将及时处理抱怨的程序形成文件 8.2.2 Complaint Handling The organization shall document the procedure for timely handling of complaints in accordance with applicable regulatory requirements.			
24	8.2.3 向监管机构报告 组织应将向有关的监管机构报告的程序形成文	第七十二条建立医疗器械不良事件监测制度 Article 72 Establishment		

	件 8.2.3 Reporting to Regulatory Authorities The organization shall document the procedure for reporting to the relevant regulatory authorities.	of Adverse Event Monitoring System for Medical Devices 第七十六条建立产品信息告知程序 Article 76 Establishment of Product Information Notification Procedure		
25	8.2.4 内部审核 组织应建立程序并形成文件以说明策划和实施审核以及记录和报告审核结果的职责和要求 8.2.4 Internal Audit The organization shall establish and document procedures to outline the responsibilities and requirements for planning and conducting audits, as well as for recording and reporting audit results.	第七十七条建立质量管理体系内部审核程序 Article 77 establishes the internal audit procedure for the quality management system		
26	8.2.6 产品的监视和测量 监视和测量应依据形成文件的程序 8.2.6 Product Monitoring and Measurement Monitoring and measurement shall be based on documented procedures	第六十条 规定产品放行程序、条件和放行批准要求 Article 60 stipulates the product release procedures, conditions, and approval requirements 第五十六条建立质量控制程序 ，规定产品检验部门、人员、操作等要		

		求，并规定检验仪器和设备的使用、校准等要求，以及产品放行的程序 Article 56 Establishment of Quality Control Procedures, stipulating the requirements for the Product Inspection Department, personnel, operations, etc., as well as the requirements for the use and calibration of inspection instruments and equipment, and the procedures for product release.		
27	8.3.1 不合格品控制 组织应建立程序并形成文件以规定不合格品控制以及不合格品识别、记录、隔离、评价和处置的有关职责和权限 8.3.1 Nonconforming Product Control The organization shall establish procedures and document them to specify the responsibilities and authorities related to the control, identification, recording, isolation, evaluation, and disposal of nonconforming products.	第六十七条不合格品控制程序 Article 67 Nonconforming Product Control Procedures		

28	8.3.3 交付后发现不合格品的响应措施 组织应按照适用的法规要求将忠告性通知的发布程序形成文件 8.3.3 Response Measures for Nonconforming Products Discovered After Delivery The organization shall document the procedure for issuing advisory notifications in accordance with applicable regulatory requirements.	第七十六条建立产品信息告知程序 Article 76 Establishment of Product Information Notification Procedure		
29	8.3.4 返工 组织应按照考虑了返工对产品的潜在不良影响所形成文件的程序进行返工 8.3.4 Rework The organization shall carry out rework in accordance with documented procedures that consider the potential adverse effects of rework on the product.	第七十条编制返工控制文件 Article 70 Preparation of Rework Control Documents		
30	8.4 数据分析 组织应将确定、收集和分析适当数据的程序形成文件 8.4 Data Analysis The organization shall document the procedures for determining, collecting,	第七十三条数据分析程序 Article 73 Data Analysis Procedures		

	and analyzing appropriate data			
31	8.5.2 纠正措施 规定要求的程序形成文件 8.5.2 Corrective Actions Document a procedure to define requirements	第七十四条建立纠正措施程序 Article 74 Establishing Corrective Action Procedures		
32	8.5.3 预防措施 说明要求的程序形成文件 8.5.3 Preventive Actions Document a procedure to describe requirements	第七十五条建立预防措施程序 Article 75 Establishing Preventive Action Procedures		