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## 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.

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

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			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	第二十五条 建立文件		
	文件的程序	控制程序		
	4.2.4 Document Control	Article 25 Establishing		
	Document procedure	Document Control		
		Procedures		
3	4.2.5 记录控制 建立	第二十七条 建立记录		
	程序并形成文件	控制程序		
	4.2.5 Record Control	Article 27 Establishing		
	Establishing Procedures	Record Control		
	and Documented it	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			

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	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	第三十八条产品实现全	
	或多个过程形成文件	过程中制定风险管理的	
	7.1 Document one or more	要求并形成文件	
	processes of risk	Article 38 Establish	
	management.	requirements for risk	
		management throughout	
		the product realization	
		process and document	
		them.	
8	7.3.1 总则 组织应将	第二十八条 建立设计	
	设计和开发程序形成文	控制程序并形成文件	
	件	Article 28 Establish	
	7.3.1 General Principles	design control procedures	
	The organization shall	and document them.	
	document the design and		
	development procedures.		
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		

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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 组织应持控制 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 第三十九条 Article 39				
for transitioning design and development outputs to manufacturing.  7.3.9 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.  7.4.1 采购过程 组织 应将确保采购的产品符 Article 39 定立采购控制程序 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.  7.5.4 服务活动 组织 苏二十元条 企业应当 使立采购控制程序 医tablish a supplier review system. information.  7.5.4 服务活动 组织 苏六十四条 定单位等后服务制度 Article 64 表文件 Establish and Improve 7.5.4 Service Activities The organization shall document the service		The organization shall		
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7.4.1 采购过程 组织		for controlling changes to		
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序形成文件 7.4.1 Procurement Process The organization shall document the procedures 建立供应商审核制度 to ensure that the products purchased meet the specified procurement information.  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  Establish Procurement 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.		应将确保采购的产品符	Article 39	
7.4.1 Procurement Process The organization shall document the procedures  # 四十一条 企业应当  # 立供应商审核制度  Article 41 Enterprises  purchased meet the specified procurement information.  12 7.5.4 服务活动 组织 第六十四条 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  Control Procedures  # 四十一条 企业应当  # 立块应商审核制度  Article 41 Enterprises  shall establish a supplier review system.  ## 第六十四条  ## 建立健全售后服务制度  ## Article 64  ## Establish and Improve  7.5.4 Service Activities The organization shall document the service		合规定的采购信息的程	建立采购控制程序	
The organization shall document the procedures to ensure that the products purchased meet the specified procurement information.  12 7.5.4 服务活动 组织 第六十四条		序形成文件	Establish Procurement	
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to ensure that the products purchased meet the specified procurement information.  12 7.5.4 服务活动 组织 第六十四条		The organization shall	第四十一条 企业应当	
purchased meet the specified procurement review system.  12 7.5.4 服务活动 组织 第六十四条		document the procedures	建立供应商审核制度	
specified procurement review system.  12 7.5.4 服务活动 组织 第六十四条 应将服务程序、所涉及的 建立健全售后服务制度 材料和所涉及的测量形 Article 64 成文件 Establish and Improve 7.5.4 Service Activities After-Sales Service The organization shall document the service		to ensure that the products	Article 41 Enterprises	
information.  12 7.5.4 服务活动 组织 第六十四条 应将服务程序、所涉及的 建立健全售后服务制度 材料和所涉及的测量形 Article 64 成文件 Establish and Improve 7.5.4 Service Activities After-Sales Service The organization shall document the service		purchased meet the	shall establish a supplier	
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材料和所涉及的测量形 成文件 Establish and Improve 7.5.4 Service Activities After-Sales Service The organization shall document the service	12	7.5.4 服务活动 组织	第六十四条	
成文件 Establish and Improve 7.5.4 Service Activities After-Sales Service The organization shall document the service		应将服务程序、所涉及的	建立健全售后服务制度	
7.5.4 Service Activities After-Sales Service  The organization shall document the service System		材料和所涉及的测量形	Article 64	
The organization shall System document the service		成文件	Establish and Improve	
document the service		7.5.4 Service Activities	After-Sales Service	
		The organization shall	System	
procedures, the materials		document the service		
		procedures, the materials		

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	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		

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	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	第五十一条建立产品标	
	应将产品标识程序形成	识控制程序	
	文件	Article 51 Establish a	
	7.5.8 Product	product identification	
	Identification	control procedure.	
	The organization shall		
	document the product		
	identification 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	第五十三条建立产品的	
	织应将可追溯性程序形	可追溯性程序	
	成文件	Article 53 Establish a	
	7.5.9 Traceability	traceability procedure for	

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

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			Г	
	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	第六十六条顾客反馈处		
	反馈过程程序形成文件	理程序		
	8.2.1 Feedback The	Article 66 Customer		
	organization shall	Feedback Handling		
	document the feedback	Procedure		
	process.			
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		第七十二条建立医疗器		
	8.2.3 向监管机构报告	<b>ポート 水之二口/1 品</b>		
	8.2.3 向监官机构报告组织应将向有关的监管	械不良事件监测制度		

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	/ <del>/</del> _	of Adverse Event	
	件 P 2 2 Paranting to		
	8.2.3 Reporting to	Monitoring System for	
	Regulatory Authorities The	Medical Devices	
	organization shall	第七十六条建立产品信	
	document the procedure	息告知程序	
	for reporting to the	Article 76 Establishment	
	relevant regulatory	of Product Information	
	authorities.	Notification Procedure	
25	8.2.4 内部审核 组织	第七十七条建立质量管	
		理体系内部审核程序	
	以说明策划和实施审核	Article 77 establishes the	
	以及记录和报告审核结	internal audit procedure	
	果的职责和要求	for the quality	
	8.2.4 Internal Audit The	management system	
	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.		
26	8.2.6 产品的监视和测	第六十条 规定产品放	
	量 监视和测量应依据	行程序、条件和放行批	
	形成文件的程序	准要求	
	8.2.6 Product Monitoring	Article 60 stipulates the	
	and Measurement	product release	
	Monitoring and	procedures, conditions,	
	measurement shall be	and approval	
	based on documented	requirements	
	procedures	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	
		部门、人员、操作等要	

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			 1
		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	第六十七条不合格品控	
	组织应建立程序并形成	制程序	
	文件以规定不合格品控	Article 67	
	制以及不合格品识别、记	Nonconforming Product	
	录、隔离、评价和处置的	Control Procedures	
	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.		

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			T	
28	8.3.3 交付后发现不合	第七十六条建立产品信		
	格品的响应措施 组织	息告知程序		
	应按照适用的法规要求	Article 76 Establishment		
	将忠告性通知的发布程	of Product Information		
	序形成文件	Notification Procedure		
	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.			
29	8.3.4 返工 组织应按	第七十条编制返工控制		
	照考虑了返工对产品的	文件		
	潜在不良影响所形成文	Article 70 Preparation of		
	件的程序进行返工	Rework Control		
	8.3.4 Rework	Documents		
	The organization shall			
	carry out rework in			
	accordance with			
	documented procedures			
	that consider the potential			
	adverse effects of rework			
	on the product.			
30	8.4 数据分析 组织应	第七十三条数据分析程		
	将确定、收集和分析适当	序		
	数据的程序形成文件	Article 73 Data Analysis		
	8.4 Data Analysis	Procedures		
	The organization shall			
			I	1
	document the procedures			

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