

认证审核方案 Certification audit programme

客户名称 Client Name		方案管理人 program owner		审批人 Approved by	
		时间 Date:		时间Date:	

任务号 Project No.					
认证标准 standard	☐ ISO 9001:2015 ☐ ISO 14001:2015 ☐ ISO 45001:2018 ☐ ISO 13485:_____				
本次审核类型 Type	☐ 其他 other: _____				
本次审核方式 method:	☐ 单一体系审核 single audit ☐ 结合审核 combined audit ☐ 联合审核 united audit ☐ 现场审核 On-site audit ☐ 远程审核 Off-site audit ☐ 现场审核与远程审核相结合 On- site audit And Off-site audit 本次审核所使用的 ICT 工具 ICT tools used in this audit : ☐ 企业微信 Enterprise WeChat ☐ 腾讯视讯 Tencent Video ☐ 钉钉 Dingding ☐ zoom ☐ 其他 other · explanation				
专业代码 code/category		风险等级 risk level	分体系填写	管理体系有效人数 staff qty	
不适用条款 (QMS/MDQMS) clause not applicable	☐ 有 Yes _____ ☐ 无 No	现场总数 Sites		认证周期 certification period	3 年
认证范围 scope					
多场所抽样策划 multi sites sampling	1.是否有多场所? ☐ 无 No ☐ 有 Yes · 多场所数量 multi-sites qty : _____ (多场所抽样策划详见附件)				
轮班审核策划及说明 audit in shift work	☐ 无 No ☐ 存在轮班 Yes, 作息时间 Time: 上午 am_____下午 pm_____ 夜班 night shift				
审核时间及人日策划:					
体系	策划审核年月、审核类型、审核人日				其他审核
QMS					
EMS					
OH&SMS					
MDQMS					
合计					
管理体系监督审核条款规定 management system surveillance audit clause					
通用要求 general requirement	1. 国家/地方监督抽查情况; 2.顾客/相关方投诉情况; 3.认证证书/标志的使用情况; 4.上次审核不符合项/审核发现问题所采取的纠正与纠正措施是否继续有效; 5.任何变更的情况:如产品范围/生产现场/生产环境等体系运行所需资源/企业名称/机构设置及其职责等是否变化; 6.企业相关资质证明是否在有效期内, 企业活动是否持续符合相关法律法规规定; 7.管理体系目标是否实现, 体系是否持续改进; 8.内部审核和管理评审是否规范有效. 1 national / local supervision; 2 customers / relevant complaints; the use of certification marks of 3 / 4; the last audit nonconformity / audit findings taken problem correction and corrective measures are effective to 5; any change: such as the range of products / production / production environment system the required resources / enterprise name / organization setting and responsibilities change; 6 enterprises of the relevant qualification certificate is valid, the enterprise activities continued compliance with the provisions of relevant laws and regulations; 7 objectives are achieved, whether the system of continuous improvement; 8 internal rating is standard tube effectively.				

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对应审核体系显示对应内容 现场审核涉及的部门、场所及标准条款 department、location and standard term of on site audit	☐ Q (2015): 监督必查内容 necessary clause: 管理层、主管部门、生产/施工/服务提供现场及所涉及的标准条款 :4.1/4.3/4.4/5.1/5.2/6.1/6.2/6.3/7.1.5/8.1/8.3/8.5.1/8.5.6/8.6/8.7/9.1/9.2/9.3/10.1/10.2/10.3 (其他必审: 销售型企业 8.2; 生产制造型企业 7.1.3/7.1.4; 施工企业 7.1.3, 8.4;) 第一次监督审核还应审核如下条款 SV1: 4.2 /5.3/7.2/7.3/7.4/8.4/8.5.3/8.5.4 第二次监督审核还应审核如下条款 SV2: 7.1/7.5/8.2 /8.5.2/8.5.3/8.5.5 再认证全条款审核 ☐ E (2015) 监督必查内容 necessary clause: 管理层、主管部门、生产/施工/服务提供现场及所涉及的标准条款:4.1/4.3/4.4/5.1/5.2/6.1/6.2/8.1/8.2/9.1/9.2/9.3/10.1/10.2/10.3 第一次监督审核还应审核如下条款 SV1: 4.2/7.2/7.3/5.3/7.4 第二次监督审核还应审核如下条款 SV2: 7.1/7.5 再认证全条款审核 ☐ S (2018) 监督必查内容 necessary clause: 管理层、主管部门、生产/施工/服务提供现场及所涉及的标准条款:4.1/4.3/4.4/5.1/5.2/5.4/6.1/6.2/8.1/8.2/9.1/9.2/9.3/10.1/10.2/10.3 第一次监督审核还应审核如下条款 SV1: 4.2/5.3/7.2/7.3/7.4 第二次监督审核还应审核如下条款 SV2: 7.1/7.5 再认证全条款审核 ☐ M(2016) : 监督必查内容 necessary clause: 管理层、主管部门、生产/施工/服务提供现场及所涉及的标准条款: 4.1/4.2.1/4.2.2/4.2.3/5.1/5.2/5.3/5.4/5.5.1/5.5.2/5.6/6.3/6.4/7.1/7.3/7.5/7.6/8.1/8.2/8.3/8.4/8.5 第一次监督审核还应审核如下条款 SV1: 7.2/7.4 第二次监督审核还应审核如下条款 SV2: 4.2.4/4.2.5/5.5.3/6.1/6.2 再认证全条款审核 注: 本次审核开具的不符合对应的过程和条文应策划为下次审核需要关注的重点; 如下一审核为转版审核, 应策划审核全条款; 销售型企业【产品和服务的要求过程】应策划为每次监督必审条款, 审核组长应依据实际情况对监督审核策划条款进行调整, 确保两次监督审核覆盖全条款。 the non-conformity process and issues in this audit must be re-audited in the next audit;if next is transition audit, all of clauses should be acted in the next audit; the clause [the requirements of product and service]must be acted to sale enterprises .					
对应审核体系显示对应内容 应重点关注 focus concern	☐ Q:对体系运行绩效产生重要影响的过程和部门 An important impact on system performance and the process of division ☐ E:环境因素的识别、评价、控制、管理方案的实施及对体系运行绩效产生重要影响的过程和部门 The identification and evaluation of environmental factors, the implementation of management plans, and the processes and sectors that have an important impact on the performance of the system ☐ S:危险源的辨识、风险评价、风险控制、管理方案的实施及对体系运行绩效产生重要影响的过程和部门 Risk identification, risk assessment, risk control, the implementation of the management plan and the impact on the performance of the system and the process of the Department ☐ M:医疗器械设计和开发、生产、储存和配销、安装、服务、最终停用和处置, 以及相关活动(例如技术支持)的设计开发或提供及对体系运行绩效产生重要影响的过程和部门 Design and development or provision of medical device design and development, production, storage and distribution, installation, service, final decommissioning and disposal, and related activities (such as technical support) and processes and departments that have a significant impact on system performance ☐ 其他 other:					
审核方案调整的记录 Record of audit plan adjustment						
审核类型 type	☐ 初审1阶段 stage 1	审核类型 type	☐ 初审1阶段 stage 1	审核类型 type	☐ 初审1阶段 stage 1	审核类型 type

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		时间 Date:		时间Date:	

调整类型	人日增减man day increase/reduce: ☐ 增加increase ☐ 减少reduce 范围Scope: ☐ 扩大expanding ☐ 缩小reducing 多产品抽样multi-product sampling: ☐ 增加increase ☐ 减少reduce 多场所抽样multi-sites sampling: ☐ 增加increase ☐ 减少reduce ☐ 取消cancel 标准条款增加说明remarks for increase standard clause: _____ 审核方式: ☐ 现场审核 On-site audit ☐ 远程审核Off-site audit ☐ 现场审核与远程审核相结合 _____ ☐ 其他, 请说明others: _____
调整原因 adjust reason	
提醒下次审核关注 next audit concern reminding	
审核不符合报告涉及的部门及条款及下次审核需重点关注的过程及要素 NC found in this audit related Department and clause&Focus on the process and elements of the next audit: (分体系及审核类型填写)	
QMS: EMS: OH&SMS : MDQMS 审核组长/日期 Lead Audit/Time:	
审核不符合报告涉及的部门及条款及下次审核需重点关注的过程及要素 NC found in this audit related Department and clause&Focus on the process and elements of the next audit: (分体系及审核类型填写)	
审核组长/日期 Lead Audit/Time:	
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审核组长/日期 Lead Audit/Time:	
说明 Note: 1.此表传递的关注信息, 务必在下次审核时实施审核 this form of attention transfer information, must be implemented in the next audit; 2.审核组长特别注意, 本方案“现场审核涉及的部门、场所及标准条款”栏涉及的所有信息必须完全纳入相关审核计划中。audit team leader to pay special attention to the project site audit departments involved, places and standard terms "column to all information must be fully integrated into the relevant audit plan. 3.审核组组长必须将本方案随卷宗提交。 the audit team leader must submit this plan with the dossier.	