上海恩可埃认证有限公司

☐质量 ☐环境 ☐职业健康安全

☒**ISO13485** ☐其它

管理体系认证

审核报告

SNQA management system (ISO13485) audit report

审核报告号 Report no.： SNQA/121326

受审核方： 佛山鸿沣医疗科技有限公司

Client name: FOSHAN HONGFENG CO., LTD.

编制日期 Report date： 2024-05-10

审核类型： ☒再认证 ☒单体系审核

Audit type: Recertification, Single Management System

Scope expanding

一、组织的一般信息 Overview

受审核方名称 Client name	佛山鸿沣医疗科技有限公司 FOSHAN HONGFENG CO., LTD.					
受审核方地址 Audit address	广东省佛山市三水区乐平镇乐强大道 4 号之二 No.4-2, Leqiang Road, Leping Town, Sanshui District, Foshan City, Guangdong Province, China				邮编 Post code	528137
受审核方 注册或联系地址 Auditee's Contact address	佛山市三水区乐平镇乐强大道 4 号之二 No.4-2, Leqiang Road, Leping Town, Sanshui District, Foshan City, Guangdong Province, China				邮编 Post code	528137
受审核方联系人 Contact person	程东风 Cheng Dongfeng	职务 Title	总经理 G.M	联系电话/传真 Tel./Fax	0592-5793751/2071351	
认证机构名称 Certification body name	上海恩可埃认证有限公司 Shanghai NQA certification Co., Ltd.					
认证机构地址 Certification body address	中国（上海）自由贸易试验区陆家嘴环路 958 号华能联合大厦 22 楼 Room 2201, No. 958, Lujiazui Ring Road, China (Shanghai) pilot Free Trade Zone				邮编 Post code	200120
审核日期 Audit date	2024-05-08 to 2024-05-10-				现场实际审核人日	Man days 6.0

对体系起关键作用的人员及接受审核的主要人员 Key roles of the company	姓名 Name	部门及职务 Title and Dep.	姓名 Name	部门及职务 Title and Dep.
	程东风 Cheng Dongfeng	总经理 G.M	肖　凌 Xiao Ling	质管部 QC Dep.
	程　哲 Cheng Zhe	管理者代表 Management representative	谢芳钦 Xie Fangqin	采购部 Purchase Dep.
	吴远来 Wu Yuanlai	生产部 Production Dep.	杨春平 Yang Chunping	技术部 Technical Dep.

☑ 主要的基础设施、监测资源 Infrastructure Monitor equipment	主要生产设备：冲床、高频机、打扣机、缝纫机等；检测设施：卡尺、千分尺、万用表、流量计、压力表、噪声计、血压计、耐压测试仪、接地电阻测试仪、泄漏电流测试仪等。 Main production equipment: punching machines, high-frequency machines, sewing machines, etc. Testing facilities: calipers, micrometers, multimeters, flow meters, pressure gauges, noise meters, blood pressure meters, withstand voltage testers, grounding resistance testers, leakage current testers, etc.
组织确定的管理体系主要过程 Main process of the management system	管理职责、资源管理、产品实现、测量分析和改进。 Management responsibility process, resource management process, product implementation process, measurement analysis and improvement process
基本的生产或业务流程（包括：外部提供过程）； 有无灭菌过程，最终用户使用前是否需要灭菌；灭菌方式； Basic production flow (incl. external supply process) Is there a sterilization process, or does the end user need sterilization before use. Sterilization method	基本生产工艺流程： 1） 医用压缩式雾化器：备料→组装→检测→包装。 2） 空气波压力治疗仪：备料→气泵组装→套筒加工→组装成品→检测→包装。 3） 吸痰器：备料→吸痰杯组装→压缩机组装→整机组装→性能检测→包装。 4） 床垫/防褥疮垫：材料→下料→高频熔接（气嘴、成型）→检测→包装。 5） 血压袖带：材料→裁料→布套加工→气囊加工→组装（布套+气囊）→检验→包装； 销售流程：客户订单→转化《订单确认表》→采购→检验→发货→结算。 外包：产品研发、塑胶件、PCBA； 需确认过程：高频熔接；　　产品不属于无菌医疗器械。 Basic production process flow: 1) Compressor nebulizer: Material preparation → assembly → testing → packaging. 2) Air compression therapy system: material preparation → air pump assembly → sleeve processing → assembly of finished products → testing → packaging. 3) Suction machine: Material preparation → Assembly of suction cup → Assembly of compressor → Assembly of whole machine → Performance testing → Packaging. 4) Medical air cushion: Material → Cutting → High frequency fusion welding (air nozzle,

	forming) → Testing → Packaging. 5) Blood pressure cuffs: material → cutting → fabric processing → airbag processing → assembly (fabric + airbag) → inspection → packaging; Sales process: customer order → conversion to Order Confirmation Form → procurement → inspection → shipment → settlement. Outsourcing: product development, plastic parts, PCBA Process to be confirmed: high-frequency fusion welding The product does not belong to sterile medical devices.
二、审核范围 Audit Scoope	
组织活动范围和场所（管理体系覆盖的产品/过程/服务/场所描述）； Scope and place of organization activities	☒ISO13485： 医用压缩式雾化器、充气防褥疮床垫、血压袖带、防褥疮垫的生产和销售（许可资质范围内）；空气波压力治疗仪、吸痰器的生产和销售（出口至欧盟和美国）；电子血压计的销售 ☒医疗器械质量管理体系覆盖产品的预期用途：医用压缩式雾化器：将液态药物雾化供患者吸入；充气防褥疮床垫/防褥疮垫：预防褥疮和缓解患者痛苦；空气波压力治疗仪：通过充气/放气产生的空气压力对身体部门进行循环按摩，压力治疗；血压袖带：与无创血压设备配合使用，用于测量无创血压；吸痰器：供医疗单位对呼吸道疾病患者吸痰用；充气防褥疮床垫：供卧床患者褥疮防治；电子血压计：用于测量人的收缩压、舒张压和脉率； 说明：现场审核中组织要求范围调整，检查相关资质资料、查阅相关产品生产和服务过程提供证据，与组织沟通对认证范围进行调整。 Scope of medical device quality management system: Manufacture and sales of compressor nebulizer, medical air mattress, blood pressure cuffs and medical air cushion (within the scope of licensed qualifications); manufacture and sales of air compression therapy system and suction machine (exported to the European Union and the United States); sales of electronic blood pressure monitor Intended use of products covered by medical device quality management system: Compressor nebulizer: atomizes liquid drugs for patients to inhale. Medical air mattress: For the prevention and treatment of bedsores in bedridden patients, prevent pressure ulcers and alleviate patient pain. Air compression therapy system: circulates and massages the body parts through the air pressure generated by inflation, deflation, providing pressure therapy. Blood pressure cuffs: used in conjunction with non-invasive blood pressure devices for measuring non-invasive blood pressure. Suction machine: used by medical institutions to aspirate phlegm from patients with respiratory diseases. Electronic blood pressure monitor: used to measure human systolic blood pressure, diastolic blood pressure, and pulse rate. Note: During the on-site audit, the organization requested adjustment of the certification scope. The audit team provides evidence by checking relevant qualification information, consulting relevant product production and service processes, communicating with the organization, and confirming adjustments to the certification scope.
1、多场所认证的确认（存在/需要时） Multi-site confirmation 2、需要子证书的分支机构名称/地址和覆盖的产品/服务及主要过	无；None

程。 Details of the branches 3. 如组织存在未纳入管理体系范围内的分支机构需特别说明 If the organization has branches that are not included in the scope of the management system, special instructions should be given	
本次审核活动（现场或非现场，永久或临时现场）的实施地点；（包括多场所） Audit address	广东省佛山市三水区乐平镇乐强大道 4 号之二 No.4-2, Leqiang Road, Leping Town, Sanshui District, Foshan City, Guangdong Province, China
审核覆盖的时期 Period covered by the audit	2023.05.15 to 2024.05.10

三、审核综述 Executive Summary

审核目的 Audit purpose	☒再认证：评价受审核方管理体系在认证有效期内，是否持续满足认证要求，以确定是否推荐保持认证注册资格并换发认证证书。 Recertification: Evaluate whether the auditee's Medical Device Management System continues to meet the certification requirements within the certification validity period, so as to determine whether it is recommended to maintain the certification registration qualification and renew the certification certificate. ☒扩大认证范围：评价组织管理体系是否覆盖申请扩大的范围并运行有效，以确定能否扩大申请的范围。 Expanding the Scope of certification: Evaluate whether the management system covers the scope of the application for expansion and operates effectively to determine whether the scope of the application can be expanded.
审核准则 Audit criteria	☐GB/T19001-2016/ISO9001:2015 ☐GB/T24001-2016/ISO14001:2015 ☐GB/T45001-2020/ISO45001:2018 ☒ISO13485:2016 ☐其它： ☒组织管理体系形成文件的信息 ☒国家有关法律、法规 ☐其它： Standard: ISO 13485:2016 Organization management system documented information Relevant national laws and regulations

审核组成员 Audit team member			
	姓名 Name	程想明 Cheng Xiang ming	杨慧珍 Yang Hui zhen
	组内职责 Duty	组长 Leader Auditor	组员 Team member
	注册资格 Registration qualification	高级审核员 Leader	高级审核员 Leader
	注册证号 Registration Certificate No	SNQA-13485-1230	SNQA-13485-1402
专业代码 Code	ISO13485：MD01.06-L；MD02.06-M；MD02.01.02-M；MD07.05		

认可标志 Accreditation	☒UKAS ☐CNAS ☐其它：
审核计划 完成情况 Audit plan completion	1. 审核组按审核计划，完成了包括与受审核方领导层座谈及有关管理体系各过程包括现场等共 7 个/处，1 个作业班次（包括多场所、作业班次，如存在）预定审核，并达到了预期的审核目的。（见现场审核计划）；如企业实施轮班作业制，但未实施正常办公时间以外的班次，应说明理由： According to the audit plan, the audit team has completed all processes with 7 departments including discussion with the auditee's leadership and relevant management systems.no shift work. 2. 没有覆盖到的过程、区域：☒无 ☐有，说明： Processes not covered by this surveillance audit : None 3. 可能影响审核方案的重要事项：☐有 ☒无 Important matters that may affect the audit plan: None 4. 任何偏离审核计划的情况及其理由（发生时），包括对审核风险及影响审核结论的不确定性的客观陈述：☒无 ☐有，说明： Any deviation from the audit plan and its reasons (when it occurs), including objective statements of audit risks and uncertainties affecting audit conclusions: None.
首末次会议议程及参加人员 注：包括按规定要求而未能参加的理由； Agenda and participants of the opening and close meeting	见“首、末次会议签到表”，会议议程和内容按 SNQA/审核文件包中“首末次会议记录”要求进行。 参加首/末次会议的有总经理、管理者代表、生产部、技术部、质管部等部门负责人员。 Please refer to the "Opening and Close Meeting Attendance Sheet". The meeting agenda and content shall be in accordance with the requirements of the " Opening and Close Meeting Minutes" in the SNQA/audit document package. Participants: G.M., MR, Leaders of production Dep., technical Dep., QC Dep. etc.
审核技术、方法和样本的说明（抽样的过程控制是否与相关的风险和机遇相适应） Description of audit techniques, methods and samples	采取过程方法和基于风险的思维，通过问、看、查等方式对受审核方管理体系运行的工作进行了解，记录检查，现场观察组织充气防褥疮床垫、空气波压力治疗仪产品的组装、高频熔接、测试、包装等过程控制情况，受审核组织提供管理体系的相关记录作为审核的样本。 Adopting a process approach and risk-based thinking, understanding the operation of the management system of the audited party through methods such as questioning, observation, and inspection, recording inspections, and on-site observation of the assembly, high-frequency fusion, testing, packaging, and other process control of medical air mattress and air compression therapy system products. The audited organization provides relevant records of the management system as samples for the audit.
标准删减或不适用要求（条款）的合理性说明（适用 QMS） Rationality statement of standard exclusion or non-application requirements (clauses)	组织生产的“医用压缩式雾化器、充气防褥疮床垫、血压袖带、防褥疮垫、空气波压力治疗仪、吸痰器”及销售的“电子血压计”均没有安装活动、不属于无菌/植入性医疗器械，7.5.3、7.5.5、7.5.7、7.5.9.2 不适用合理。 The products produced and sold within the scope of organizational certification have no installation activities and are not sterile/implantable medical devices. Therefore, the clauses of 7.5.3, 7.5.5, 7.5.7, and 7.5.9.2 are excluded.

在上次审核后发生的影响客户管理体系的重要变更（如有时） Important changes (if any) tht affect the customer management system after the last audit	□客户名称 Client name □客户地址（□注册地址 □经营地址）Client address □客户管理体系覆盖有效人数 Employee numbers □组织结构 Organization structure □管理体系过程 Process of the Management System □生产工艺 Production porcess □资源变更（□增加 □更新）：Resource ☒体系覆盖范围（☒扩大 □缩小） Coverage of the Management System: Expanding □其他 Others
	可能影响审核方案变更：本次再认证按新的范围实施审核。 This recertification audit was conducted according to the new scope.
证书暂停恢复审核情况（存在时） Certificate suspension and resumption of audit (if any)	☒再认证 Recertification ☒未发生暂停 Suspension: None

四、对受审核方管理体系的评价 Evaluation of the auditee's management system

1、 组织的管理体系形成文件的信息，结合现场所审核评价：

Evaluation of the organization's management system documents

□符合标准要求，能反映组织经营活动并具体实施；

Meet the standard requirements, reflect the organization's business activities and implement them

□基本符合标准要求，能反映组织经营活动并具体实施，不足之处已改进；

Basically meet the standard requirements, can reflect the organization's business activities and specific implementation, and the deficiencies have been improved.

☒基本符合标准要求，能反映组织经营活动并具体实施，但还需改进提高可操作性；

It basically meets the standard requirements and can reflect the organization's business activities and implement them, but it still needs to be improved to improve operability.

2、一阶段审核情况： □现场 □非现场 **Stage 1 audit information: N/A**

1）审核时间：QMS：_____ EMS：_____ OHSMS：_____ ISO13485：_____

2）第一阶段审核问题：QMS_____个；EMS_____个；OHSMS_____个；ISO13485_____个

3）第一阶段审核问题验证情况的说明：

3、再认证现场审核情况：On site audit of recertification

1）国家、地方监督检查情况：□合格 □不合格 ☒ 未发生

医疗器械不良事件发生：□发生 ☒未发生

医疗器械产品召回事件：□发生 ☒未发生

医疗器械忠告性通知： □发生 ☒未发生

State and local supervision and inspection: None
Medical device adverse events: None
Medical device recall: None
Medical device Advisory notice: None

2）顾客、相关方或其他投诉情况：

☐没有发生投诉

☒发生过一般/重大投诉并已及时进行了有效处理

☐发生了重大投诉并没有得到及时有效处理

Complaints from customers, interested parties or others:
General complaints have occurred and have been promptly and effectively addressed.

3）认证证书和标志使用情况：☒符合 ☐不符合
Use of certification certificates and marks: qualified.

4）上次审核所开具的不符合验证情况，是否再发生：☒未再发生 ☐再发生

Does the nonconformance verification issued by the last audit happen again: No

5）不符合项和观察项情况：

共开出：轻微不符合项☐QMS ____个；☐EMS _____个；☐OHSMS _____个；☒ISO13485：__1__个
严重不符合项☐QMS ____个；☐EMS _____个；☐OHSMS _____个； ☒ISO13485：__0__个
观察项☐QMS _____个；☐EMS _____个；☐OHSMS _____个；☒ ISO13485：__0__个

不符合项报告 __1__ 份；现场审核观察项报告__0__份，作为本报告附件。
Minor NC: 1, Major NC: 0, OFI: 0
1NC report is attached.

6）其它情况说明：Others: None

4、管理体系覆盖人数经现场确认为 105 人。（包括在现场的非长期人员）
Confirmed the employee numbers covered by the management system on site: 105
(Including non-permanent personnel on site)

5、管理体系与标准的符合性及有效运行情况评价
Evaluation of compliance and effective operation of management system and standards

评价内容 content	审核证据、审核发现、审核结论描述 Description of audit evidence, audit findings and audit conclusions
①组织的基本情况（包括内外部环境、应对风险和机遇的措施）☒认证监督期内组织内外部环境是否有变化，应对风险和机遇的措施是否持续实施 Basic information of the organization The changes of internal and external environment of the organization during the certification supervision period, and whether the measures to deal with risks and opportunities have been continuously implemented	公司成立于 2016 年 7 月，主要从事充气床垫、雾化器、吸痰器、血压袖带等产品的生产及二类医疗器械的销售，根据市场及客户要求导入 ISO13485 标准建立实施了文件化的管理体系，并通过了 SNQA 的认证审核；针对目前的全球经济环境不景气等情况，公司加大市场开发力度，积极拓展市场，加强内部管理，提高生产效率，促进企业持续稳定发展。 The company was established in July 2016, mainly engaged in the production of medical air mattress, compressor nebulizer, suction machine, blood pressure cuffs and other products, as well as the sales of second-class medical devices. The enterprise has established and implemented a documented management system by ISO13485 standard according to market and customer requirements, and has passed the certification audit of SNQA. In response to the current global economic downturn, the company has increased its market development efforts, actively expanded the market, strengthened internal management, improved production efficiency, and promoted the sustained and stable development of the enterprise.

②领导作用和承诺、针对组织方针的管理职责 ☒领导作用和承诺认证监督期内是否持续实现承诺 Leadership role and commitment, management responsibilities for organizational policies	最高管理者已通过以下方面，证实其对质量管理体系的领导作用和承诺：增强顾客满意，满足适用法律法规要求，制定公司的方针 目标，按策划的要求主持管理评审等。 公司管理层推动并组织实施对品质管理体系的内部审核和管理评审活动；通过 PDCA 循环和基于风险的思维，完善品质管理体系。 The top management has confirmed their leadership role and commitment to the quality management system through the following aspects: enhancing customer satisfaction, meeting applicable legal and regulatory requirements, formulating company policies and objectives, and presiding over management reviews as planned. The company's management promotes and organizes the implementation of internal audits and management reviews of the quality management system. Improve the quality management system through the PDCA cycle and risk-based thinking.
③目标的建立、管理体系策划及体系在实现目标方面的有效性： ☐QMS ☑ 13485：为实现质量方针而建立的职能、层次、过程目标是否可测量，是否沟通和监视； 对质量目标和过程质量绩效实现情况进行评价； 质量目标及质量绩效如未达到是否运行内审机制识别了原因，是否运行管理评审机制确定并施了改进措施； Establishment of objectives, planning of management system and effectiveness of the system in achieving objectives: Whether the functions, levels and process objectives established to achieve the quality policy are measurable, communicated and monitored; Evaluate the achievement of quality objectives and process quality performance; If the quality objectives and quality performance are not achieved, whether the	公司目标： a)产品准时交付率≥95%； b)成品抽样检验合格率≥98%； c)顾客满意度≥90% ——查至 2024 年 4 月的质量目标统计情况，各项目标均有达成。 分解情况：公司目标在生产部、采购部、质管部等部门及相关管理体系过程进行了分解，并确定有考核方式，查至 2024 年 4 月的质量目标统计数据，各项目标均能达成。 质量目标可测量，与质量方针一致，体现了满足产品质量要求的承诺。 Company Objectives: a) Product on-time delivery rate ≥ 95%; b) The qualified rate of finished product sampling inspection is ≥ 98%; c) Customer satisfaction ≥ 90% ——According to the statistics of quality objectives as of April 2024, all objectives have been achieved. Objective decomposition: The company's objectives have been decomposed in the production department, procurement department, quality management department, and related management system processes, and assessment methods have been determined. According to the quality target statistical data as of April 2024, all objectives have been achieved. The quality objectives are measurable and consistent with the quality policy, reflecting a commitment to meeting product quality requirements.

internal audit mechanism is operated to identify the causes, and whether the management review mechanism is operated to determine and implement improvement measures	
④受审核方管理体系满足符合适用法律法规要求和顾客、相关方要求的能力（绩效）： ☐ QMS ☑ 13485 认证范围覆盖的产品或服务适用的法律法规及强制性标遵守情况）。 注：如发生不合规，需要追溯是否整改并被相关的行政主管部门认可） The auditee's management system meets the requirements of applicable laws and regulations and the requirements of customers and interested parties Compliance with applicable laws, regulations and mandatory standards for products or services covered by certification Note：In case of non-compliance, it is necessary to trace whether it has been rectified and approved by the relevant competent administrative department	资质资料：营业执照+第二类医疗器械经营备案凭证+医疗器械生产许可证+产品注册证（医用压缩式雾化器）+充气防褥疮床垫/血压袖带/防褥疮垫的第一类医疗器械生产备案凭证/备案凭证信息表； 产品标准备案：产品技术要求（医用压缩式雾化器、充气防褥疮床垫、血压袖带、防褥疮垫）； 出口证据：报关单、CE 及 FDA 相关资料； 适用标准法规：GB/T42062、YY/T42061、GB/T16886.1、GB9706.1、QSR820、MDR、医疗器械生产质量管理规范、医疗器械监督管理条例、医疗器械说明书和标签管理规定等； 产品质量持续满足客户要求，公司运作能遵循相关的法律法规要求。 经营异常/失信行为/行政处罚：无； Qualification information: Sighted the Business license, Class II medical device operation record certificate, medical device production license, Product registration certificate (compressor nebulizer), Class I medical device production record certificate, record certificate information table for medical air mattress, blood pressure cuffs and medical air cushion. Product standard filing: Product technical requirements (compressor nebulizer, medical air mattress, blood pressure cuff, medical air cushion); Export evidence: customs declaration, CE and FDA related documents; Applicable standards and regulations: GB/T42062 YY/T42061, GB/T16886.1, GB9706.1, QSR820, MDR, Medical device production quality management standards, medical device supervision and management regulations, medical device instructions and label management regulations, etc. The product quality continues to meet customer requirements, and the company operates in compliance with relevant laws and regulations. There is no business abnormalities, dishonest behavior and administrative penalties of the company.
⑤资源（人员、基础设施、监视和测量资源、组织知识）的提供和管理情况（设施运行、维护和保持） Resource supply and control of personnel, Infrastructure, monitoring and measuring resources,	管理体系覆盖人数：105人，主要生产设备：冲床、高频机、打扣机、缝纫机等；检测设施：卡尺、千分尺、万用表、流量计、压力表、噪声计、血压计、耐压测试仪、接地电阻测试仪、泄漏电流测试仪等，通过人员培训/设备管理/计量校准工作的开展，保障人员/设施满足公司的要求。 The FTE number covered by the management system is 105. Main production equipments include punching machines, high-frequency machines, sewing machines, etc. Testing facilities: calipers, micrometers, multimeters, flow meters, pressure

organizational knowledge.(Including facility operation and maintenance)	gauges, noise meters, blood pressure meters, withstand voltage testers, grounding resistance testers, leakage current testers, etc. Through personnel training, equipment management, and measurement calibration work, we ensure that personnel and facilities meet the company's requirements.
⑥ 受审核方管理体系覆盖的过程和活动的管理及控制情况（在第一阶段审核中识别的重要审核点的过程控制的有效性），如： ☐QMS ☒13485： 产品实现过程中对目标的实现具有重要影响的关键点的运行控制情况（重要审核点的监视、测量、报告和评审记录的完整性和有效性）； 如： a)产品和服务的设计开发控制(☐产品设计和开发；☐过程设计和开发)； b)外部供方提供的产品、服务和过程的控制； c) 生产和服务提供控制（包括需要确认的过程，如灭菌过程和无菌屏障系统的确认控制；适用时安装服务控制和标识可追溯性控制）； d)产品和服务的放行控制等； Management and control of processes and activities covered by the auditee's management system ☒13485： Operation control of key points that have an important impact on the realization of objectives in the process of product realization (integrity and effectiveness of monitoring, measurement, report and review records of important audit points). For example: a) Design and development control of products and services (product design and development, process design and development) b) Control of products, services and processes provided by	1） 设计和开发管理：建立实施《设计和开发控制程序》规范产品设计开发过程的管理工作，产品设计开发工作委托厦门粤沣公司负责，自上次审核以来没有新产品的设计开发及变更的情况。 2） 外部提供的产品和服务的控制：目前主要材料有：面料、气嘴、胶管、泵芯、塑胶件、PCBA、五金件、雾化配件包、电机、电磁阀等，外包：产品研发、塑胶件、PCBA；建立了供应商初始评价及定期评价的准则并按要求实施，保障了采购过程控制有效。 3） 生产和服务提供过程的控制：目前主要生产活动是裁料、高频熔接、组装等，经识别目前产品实现过程中需实施确认的过程“高频熔接”，建立了过程验证方案并对过程实施了确认；根据产品生产特点，制定了相应的作业文件，明确操作方法/工艺要求/质量要求等对作业过程进行规范，对员工进行培训考核合格上岗；现场控制情况正常。 4） 生物相溶性评价：提供产品用面料及雾化配件包的生物相溶性检测报告，管理情况符合要求。 5） 产品和服务的放行：根据产品备案技术要求及相关标准制定了相应的检验规范，开展的质量检验活动有来料检验、过程检验、成品检验，各项检验工作基本能正常有效的开展。 6） 组织按 ISO13485：2016 标准要求建立并实施了文件化的质量体系，基本符合企业实际情况，通过体系的运行，管理工作得到了一定的规范，企业实际运作方式与体系文件规定一致，保留信息真实可查。 1) Design and Development Management Process: Organize the establishment and implementation of the Design and Development Control Procedure to standardize the management of the product design and development process. The product design and development work has been entrusted to Xiamen Yuefeng Company, and there have been no new product design, development, or changes since the last audit. 2) Control of externally provided products and services: Currently, the main materials include: fabrics, nozzles, hoses, pump cores, plastic parts, PCBA, hardware parts, atomization accessory packages, motors, solenoid valves, etc. Outsourcing: Product research and development, plastic parts, PCBA. The organization has established guidelines for initial and periodic supplier evaluations and implemented them as required, ensuring effective procurement process control. 3) Control of production and service provision process: The main production activities are cutting, high-frequency fusion, assembly, etc. The process that needs to be confirmed during the current product implementation process has been identified as "high-frequency fusion welding". The organization has established a process validation plan and confirmed the implementation of the process. Based on the production characteristics of the product, corresponding operation documents have been formulated, clarifying the operation methods, process requirements, quality requirements, etc. to standardize the operation process, and providing training and assessment for employees to be qualified for work. The on-site control situation is normal. 4) Biocompatibility evaluation: The organization has provided a biocompatibility test report for the fabric and atomization accessory package used in the product, and the management situation meets the requirements. 5) Release of products and services: The organization has developed corresponding inspection specifications based on the technical requirements and relevant standards for product filing. The quality inspection

external suppliers c)Production and service provision control (including processes requiring confirmation, such as confirmation control of sterilization process and sterile barrier system; installation service control and identification traceability control when applicable) d)Release control of products and services, etc. ⑦企业实际工作方式与企业管理体系形成文件的信息是否一致，保留证据是否真实。 Whether the actual working mode of the enterprise is consistent with the documented information of the enterprise management system, and whether the retained evidence is true.	activities carried out include incoming material inspection, process inspection, and finished product inspection. All inspection work can be carried out normally and effectively. 6) The organization has established and implemented a documented quality system in accordance with the requirements of ISO13485:2016 standard, which is basically in line with the actual situation of the enterprise. Through the operation of the system, management work has been standardized to a certain extent. The actual operation mode of the enterprise is consistent with the provisions of the system documents, and the retained information is true and verifiable.
⑧☐QMS ☒ISO13485： 不合格品控制 Control of nonconforming products	建立有《不合格品控制程序》规范不合格品的管理工作，对进料/生产及交付后发生的不合格均按规定进行了及时处理。 The organization has established a Non-Conforming Product Control Procedure to standardize the management of non-conforming products, and promptly handles any non-conformities that occur during feeding, production, and delivery in accordance with regulations.
⑨对上次审核中确定的不符合采取的纠正和纠正措施是否继续有效 Whether the corrective and corrective measures taken for the nonconformities determined in the last audit continue to be effective	上次审核 1 不合格现场验证可关闭。 The NC raised on last audit has been verified and can be closed.
⑩是否及时接受和处理投诉（如：产品质量	建立实施《客户投诉与反馈处理程序》、《医疗器械产品召回控制程序》、《医疗器械报告（MDR）程序》、《上市后监督和上市后临床跟踪控制程序》等文件规范客户反馈、不良事件等情况的报告处理工作，对客户反馈进行了及时有效处理，没有发生不良事件，暂无

或环境行为或职业健康安全） ISO13485：向监管机构报告情况 Are complaints received and handled in a timely manner and reported to the regulatory authority	向监管机构报告的情况。 The organization has established and implemented documents such as the Customer Complaint and Feedback Handling Procedure, Medical Device Product Recall Control Procedure, Medical Device Reporting (MDR) Procedure, and Post market Supervision and Post market Clinical Tracking Control Procedure to standardize the reporting and handling of customer feedback, adverse events, and other situations. Timely and effective handling of customer feedback. There have been no adverse events during this cycle, and there have been no reports to regulatory authorities at the moment.
⑾内审和管理评审策划和实施情况，是否规范有效？ Is the planning and implementation of internal audit and management review standardized and effective?	建立实施《内部审核控制程序》和《管理评审控制程序》，一般每年进行 1 次内部审核和 1 次管理评审工作，在 2024 年 04 月 03 日进行了一次内部审核，在 2024 年 04 月 30 日进行了管理评审，评审证据基本有效。 The company has established and implemented the Internal Audit Control Procedure and Management Review Control Procedure. The internal audits and management reviews are conducted yearly. An internal audit was conducted on April 3, 2024, and a management review was conducted on April 30, 2024. The review evidence is valid.
⑿企业改进活动的策划和实施（如：针对体系运行中发现的问题或投诉，及时制定并实施了有效的改进措施） Planning and implementation of enterprise improvement activities	改进建议：加强质量管理的培训，以及体系的推行管理； Improvement suggestions: Strengthen the training of quality management and the implementation and management of the system.
⒀与以往审核结果的比较（如：管理体系运行的有效性和效率）（再认证或监督时） Comparison with previous audit results	产品质量持续满足标准及客户要求。 The product quality continues to meet standards and customer requirements.
⒁适用时，识别管理体系的潜在改进区域、建议 When applicable, identify potential improvement areas and suggestions for the management system	加强标准的培训学习，提高对体系运行要求的了解，全员参与管理；结合公司实际情况修订相关的文件及表单格式；注重记录的填写及归档工作。 Strengthen standard training and learning, improve understanding of system operation requirements, and involve all staff in management. Revise relevant documents and form formats based on the actual situation of the company, emphasizing the filling and archiving of records.
⒂已识别出的任何未解决的问题 Any unresolved issues identified	无；None
⒃管理体系整体有效性和符合性的评价（说明）： a)组织是否履行	1） 组织能履行适用法律法规情况：组织在日常经营活动中严格执行国家及当地的法律法规，如医疗器械生产质量管理规范、医疗器械监督管理条例等，没有发生违法情况。 2） 组织按 ISO13485:2016 标准建立并实施了文件化的管理体系，采用过程方法和基于风

了满足适用法规要求的承诺； b)管理体系是否满足适用要求和实现预期结果的能力； c)内部审核和管理评审的过程； d) 对认证范围 Evaluation of overall effectiveness and compliance of management system	险的思维，识别了管理体系相关过程及相关的风险和机遇，制定了相应的措施保障过程的运作有效，实现管理体系的预期结果。 3） 建立实施内部审核控制程序和管理评审控制程序规范评审工作，按规定开展内部审核和管理评审，通过审核/评审及时发现问题并改善，提升体系运行的有效性，自我改进机制初步具备。 4） 组织管理体系覆盖范围界定：现场审核证据及查阅相关的资料，组织界定范围适宜。 5） 通过与受审核部门的沟通，查阅体系运行的相关记录，现场观察产品实现过程的控制情况，审核证据表明组织管理体系运行基本能保持持续的有效性，达到本次审核目的。 1) The organizations are able to comply with applicable laws and regulations. Strictly implement national and local laws and regulations in daily business activities, such as the Quality Management Standards for Medical Device Production and the Regulations on Medical Device Supervision and Management, and no illegal activities have occurred. 2) The organization has established and implemented a documented management system in accordance with the ISO13485:2016 standard. Using a process approach and risk-based thinking, it has identified the relevant processes and risks and opportunities of the management system, formulated corresponding measures to ensure the effective operation of the processes, and achieved the expected results of the management system. 3) The company has established and implemented internal audit control procedures and management review control procedures to standardize the review work. Internal audits and management reviews are carried out in accordance with regulations, and problems are identified and improved in a timely manner through audits and reviews, enhancing the effectiveness of system operation. A self-improvement mechanism is initially in place. 4) Confirm that the scope defined by the organization is appropriate through on-site audits and reviewing relevant materials. 5) Through communication with the audited department, reviewing relevant records of system operation, and observing the control situation of product implementation process on site, the audit evidence shows that the organization's management system can maintain sustained effectiveness, achieving the purpose of this audit.

五、审核结论 Audit conclusion

1、☒再认证：受审核方建立并实施的 ☐质量 ☐环境 ☐职业健康安全 ☒其它_____管理体系

Recertification: Medical device quality management system established and implemented by the auditee

☐ 在认证有效期内，持续满足认证要求，同意推荐保持认证注册资格并换发认证证书

During the validity period of the certification, the certification requirements are continuously met, and it is agreed to recommend to maintain the certification registration qualification and renew the certification certificate

☒ 在认证有效期内，持续满足认证要求，存在部分一般不符合，纠正、纠正措施/计划经验证合格后，同意推荐保持认证注册资格并换发认证证书

During the validity period of certification, the certification requirements are continuously met, and there are some minor nonconformities. After the correction and corrective measures / plans are verified to be qualified, it is agreed to recommend to maintain the certification registration qualification and renew the certification certificate.

☐ 存在严重不符合项，不符合标准要求，不同意推荐保持认证注册资格并换发认证证书

There are serious nonconformities and do not meet the standard requirements. It is not recommended to maintain the certification registration qualification and renew the certification certificate.

2、 ☒扩大认证范围：受审核方建立并实施的 ☐质量 ☐环境 ☐职业健康安全 ☒其它 ISO13485 管理体系

Scope expanding: for ISO13485 management system

☐覆盖了申请扩大的产品覆盖范围并运行有效，同意推荐扩大产品覆盖范围

Covering the coverage scope applied for expansion and operating effectively. Agree to recommend expanding

the product coverage scope.

☒覆盖了申请扩大的产品覆盖范围存在部分轻微不符合，纠正、纠正措施/计划经验证合格后，同意推荐扩大产品覆盖范围
Covering the product coverage scope applied for expansion. There are some minor non-conformities. After verification and approval of corrective measures and plans, it is agreed to recommend expanding product coverage.

六、纠正措施验证方面的安排 Arrangements for verification of corrective actions

1、☐ 质量 ☑ 其它 ISO13485 管理体系请受审核方对不符合项制定纠正措施并实施，经自行验证合格后，将实施结果及证实材料，自现场审核后 30 日内提交审核组长对纠正措施的实施和完成情况进行书面验证。必要时保留现场验证的权利。观察项请提供纠正措施计划，在下次审核中验证。

For ISO13485 management system, the auditee is requested to formulate and implement corrective measures for nonconformities. After self-verification, the implementation results and supporting materials shall be submitted to the audit team leader for written verification of the implementation and completion of corrective measures within 30 days after on-site audit. Reserve the right of on-site verification if necessary. For the observation items, please provide the corrective action plan for verification in the next audit.

2、☐ 质量 ☐ 其它_____管理体系请受审核方对不符合项制定纠正措施并实施，经自行验证合格后，将实施结果及证实材料，自现场审核后 90 日内提交审核组长，以便 SNQA 认证中心安排现场验证。

The auditee is requested to formulate and implement corrective measures for nonconformities. After self verification, the implementation results and supporting materials shall be submitted to the audit team leader within 90 days after on-site audit, so that snqa certification center can arrange on-site verification.

注：再认证或再认证转版时需在上一周期认证证书有效期内提交，上一周期认证证书有效期至 2024 年 10 月 24 日

Note: Recertification or recertification version transfer shall be submitted within the validity period of the previous certification certificate, which shall be valid until 10 /24/ 2024.

七、附件((本报告附件审核结束已提供给受审核方) **Attachments for the auditee**

☒管理体系文件审核报告 Management system document audit report

☒首末次会议签到记录 Attendance record of the opening and closing meetings

☒审核计划 audit plan

☒公正性声明 Declaration of impartiality

☒不符合报告 NC report

☐现场观察项报告 OFI report

报告编制审核组长（签字）：  **日期：** 2024 **年** 05 **月** 10 **日**

Report preparation and review(team leader): Cheng Xiang ming, Date: 2024-05-10

说明：①本次审核基于抽样调查，不能包含受审核方全部的管理体系活动，因此未发现的不符合项可能仍存在目前的管理体系中；

②本报告在现场审核末次会议前形成，经受审核方确认后，在末次会议上宣读；并需经上海恩可埃认证有限公司（SNQA）作进一步审查；

③审核报告提交：审核报告原件由审核组长随审核资料提交上海恩可埃认证有限公司（SNQA）审查，SNQA 作出认证决定后 30 个工作日内，将审核报告（复印件）提交受审核方，并请妥善保存,保存时间至少应与认证证书有效期一致。

④保密声明：本报告所述内容为保密信息，严格按上海恩可埃认证有限公司保密制度的规定予以保密。

⑤本认证机构申/投诉电话：021－50813263

NOTE:

1) This audit is based on sampling survey and cannot include all the management system activities of the auditee. Therefore, the undetected nonconformities may still exist in the current management system
2) This report is formed before the final meeting of on-site audit and read out at the final meeting after being confirmed by the auditor; It shall be further reviewed by SNQA.
3) Submission of audit report: the original of the audit report shall be submitted by the audit team leader to SNQA for review along with the audit data. SNQA shall submit the audit report (copy) to the auditee within 30 working days after making the certification decision, and please keep it properly. The storage time shall be at least consistent with the validity period of the certification certificate.
4) Confidentiality statement: the contents of this report are confidential information and shall be kept confidential in strict accordance with the confidentiality system of SNQA
5) Apply for complaint no.: 021 － 50813263