Audit Report for: Xiamen Wenatone Medical Technology Co., Ltd.

Contract Number:CN/XMN 7297MD
ocument: GP9810 ISO 13485 Audit Report
Issue 2

Medical Device Certification - ISO 13485
Audit Report

This report is confidential and distribution is limited to the audit team, client representative and the SGS office unless requested by an Accreditation / Regulatory Body entitled to the information contained within.

0. CERTIFICATION SUMMARY

Standard	Accreditation Body
ISO 13485:2016	UKAS

1. MANUFACTURER/ ORGANISATION

Organisation:	Xiamen Wenatone Medical Technology Co., Ltd. 厦门维纳通医疗科技有限公司		
Address:	Room 805A, South of Block A, Jianye Building, 96 Xiang Xing Road, Torch Hi-Tech (Xiang'An) industrial Park, Xiang'An District, Xiamen City, 361101, Fujian Province, P.R.China 中国福建省厦门市翔安区火炬高新技术翔安产业区翔星路 96 号建业楼 A 座南 805A 室		
Representative:	Ms. Yanchun WU		
Telephone:	15259281337	**E-mail:**	1257362282@qq.com

Structure and Trading names of the Manufacturer (Corporate Identity):
Xiamen Wenatone Medical Technology Co., Ltd.

Scope of the certified quality management system:			
Site details & senior manager	**Main activities/ processes on site**	**Effective No. of Personnel**	**No. of Shifts**
Room 805A, South of Block A, Jianye Building, 96 Xiang Xing Road, Torch Hi-Tech (Xiang'An) industrial Park, Xiang'An District, Xiamen City, 361101, Fujian Province, P.R.China 中国福建省厦门市翔安区火炬高新技术翔安产业区翔星路 96 号建业楼 A 座南 805A 室 Mr. Leo LIU/GM	Sales order—Materials and parts purchasing—Parts production (key process: Hand Soldering, Assembly, PCBA, and shell forming & Test, Inspection, Packaging), Distribution;	35	1 shift 8:30-17:30

Exclusions and Non-Applications of Requirements in the QMS	
Is ISO 13485 Clause 7.3 excluded?	**Yes**
Any other non-applicable ISO 13485 clauses?	7.5.2; 7.5.3; 7.5.4; 7.5.5; 7.5.7; 7.5.9.2;

2. AUDIT

Audit type & No.:	Renewal	**Date(s) of audit:**	Sep. 15-16, 2022
Site(s) audited:	Room 805, Block A, Jianye Building, 96 Xiang Xing Road, Torch Hi-Tech (Xiang'An) industrial Park, Xiang'An District, Xiamen City, 361101, Fujian Province, P.R.China		
EAC Code(s):	19	**NACE Code(s):**	33.1
ISO 13485 TAC's:	MD7.9		
ISO 9001 TAC's:	N/A		
Simple Code(s):	19E	**Complex Code(s):**	N/A
Lead auditor (Team Leader):	Luke GE (team leader under supervisor)	**Additional team member(s): (roles)**	Wendi SANG (supervisor)
Additional Attendees and Roles:	N/A		
Audit languages:	Chinese / English	**Initial Report Issue Date:**	Sep. 16, 2022
Report Author	Luke GE		
Current Report Issue Date	Sep. 16, 2022 Oct. 11, 2022	**Current Report revision:**	Rev. 0 Rev. 1

3. AUDIT CRITERIA AND OBJECTIVES

The objectives of this audit were:

- to confirm that the quality management system and technical documentation (where appropriate) conform with the requirements of the audit criteria and regulatory requirements of the standards listed in section 0 and/or (as applicable) requirements of the Manufacturer's own documented Quality Management System.
- to confirm that the organisation has effectively implemented the planned quality management system.
- to confirm that the management system is capable of achieving the organisation's policy objectives.
- to confirm the capabilities of the QMS to ensure compliance with applicable regulatory requirements.
- the employee number was changed from 30 to 35

4. SCOPE OF CERTIFICATION

Standard	Accreditation Body	Certificate Number	Company Name	Scope
ISO 13485:2016	UKAS	CN19/42130	Xiamen Wenatone Medical Technology Co., Ltd. 厦门维纳通医疗科技有限公司	Manufacture of Component Assembly used for Hearing Aids 用于助听器的组件的生产。

The client has confirmed that the name(s) and address(s) of the organization and the audit scopes (including translations if applicable) in this report are that required on the certificate (s) to be issued or continued	Yes
Has the preliminary scope or type of certification shown in proposal documents been changed? or has the existing certificate scope(s) been changed ? (see Section 7 - Administration)	Yes

Is this a multi-site audit? if Yes, All relevant sites and/or remote locations agreed with the client must be listed on the Audit Planning Matrix and each site address must be listed in the Scope of Certification section above	No

Note : Only the main address will be shown on the front page of the certificate, with additional sites on subsequent pages.

5. AUDIT FINDINGS

Stage 1 Audit or QMS Documentation Review Findings	
The organisation had previously had quality system management documentation reviewed against the audit criteria and the findings reported in a separate Stage 1 report	No
All issues raised in a Stage 1 report had been subsequently satisfactorily addressed unless raised as a nonconformity in this report.	

Audit Details - Opening and Closing Meetings

The audit started with a meeting attended by senior representatives of the organisation, where the audit criteria, scopes and auditing roles and processes of SGS were outlined. The audit concluded with a meeting attended by senior representatives of the organisation where the audit team presented their findings and recommendations and certificates details and scopes were agreed.

It was confirmed if there have been any significant changes in the quality system since the last audit that have not been reported to SGS in the Pre-Audit Questionnaire (PAQ) prior to the audit. Clients are reminded that all significant changes should be notified to SGS.

The procedure for corrective action plans and corrective actions was explained.

Products and processes were sampled in this process based audit to represent the different relevant technologies, risks and objectives involved and to represent the different regulations covered by the audit. The audit methods used were interviews, observation of activities and review of documentation and records.

The structure of the audit was in accordance with the audit plan and audit planning matrix included as annexes to this audit report.

Opening & Closing Meeting Attendees

Name	Position	Opening Meeting	Closing Meeting
Mr. Leo LIU	GM	☑	☑
Mr. Yanchun WU	QA Dept./Mgr	☑	☑
Mr. Zigen ZHANG	Sales Dept./Mgr.	☑	☑
Mr. Weifu XIE	Production Dept./Mgr./ MR	☑	☑
Ms. Xiulong YE	Admin/Finance Dept./Supervisor	☑	☑
Mr. Shuming LIU	R&D Dept./Mgr.	☑	☑
Ms. Tingting ZHAO	PMC Dept./Supervisor	☑	☑

In Summary this audit included:	
Management Review, Planning and Objectives, Changes, Legal Requirements, Feedback, Internal Audit, Improvement and Corrective Actions including for post-market surveillance, Complaints, Certification Claims and Use of Marks	Yes
Management	Yes
Design and development	No
Production and process control	Yes
Purchasing control	Yes
Documentation and records	Yes
Customer related processes	Yes

6. ADDITIONAL INFORMATION

Additional Information about the Manufacturer	
Product types and Regulatory Markets with Classification	The products are assembly parts used for Hearing Aids, but not the finial medical products.
Main markets or customers:	USA, Japan, India (distributor: SNY, Beisheng)
Critical Processes	Hand Soldering, Assembly, PCBA, and shell forming & Test, Inspection

Information on Critical Subcontractors:	
Critical Subcontractors (those with substantial involvement with the design or manufacture of the device or regulatory compliance, including subcontractors for virtual manufacturers)	SMT process： Xiamen Gaofutong Electronics Co., Ltd Address: zone L, 5th Floor, No. 11 Malong Road, Huli District, Xiamen City, Fujian Province. ISO 9001:2015 certificate: CI/140726Q, 2021.06.16-2024.06.15

Follow up of Previous Audit Results:	
The results of the last audit of this quality management system (SGS or previous certification body) have been reviewed, in particular to assure appropriate corrective and preventative action has been implemented to address any nonconformity identified. This review has concluded that :	
Any nonconformity identified during previous audits has been corrected and the corrective action continues to be effective and no issues have been raised as new nonconformities.	Yes
N/A indicates that no CARs were raised on the previous audit or this was an unscheduled visit and CARs were not reviewed.	

Follow up on this Audit of Specific Issues:
NA

7. AUDIT CONCLUSIONS

Non-Conformities:				
Number of nonconformities identified (CARs):	**Major**	**2**	**Minor**	**2**

Correction Action Requests (CAR), detailing any identified nonconformities and the required corrective action plans are attached to this report as appendices. All nonconformities detailed shall be addressed through the organization's corrective action process, in accordance with the relevant corrective action requirements of the audit standard, including actions to prevent recurrence, and complete records maintained. There are two possible options for close out of any Major nonconformities identified as shown below :	
On-Site Closure of Major CAR – within 90 days Corrective actions to address the identified Major nonconformities shall be carried out **immediately** and SGS notified of the actions taken **within 30 days**. An SGS auditor will perform a **follow up audit on site at an agreed date,** to confirm the actions taken, evaluate their effectiveness, and determine whether certification can be granted or continued. The audit and acceptance of closure of the nonconformities must be completed **within 90 days**	Yes
Off-Site Closure of Major CAR – within 90 days Corrective actions to address the identified Major nonconformities shall be carried out **immediately** and the **supporting evidence must be sent to the SGS auditor** for **off-site** audit review. The acceptance and closure of the nonconformities must be completed **within 90 days**, on an **agreed date**.	N/A

Please note: 90 days is the total time limit allowed for completion of the process to close out Major non-conformities, including submission of evidence, review and acceptance by the auditor, and of the independent certification review and certification decision. If the process is not completed with 90 days, new certificates cannot be issued and current certificates may be suspended, or certificate scope reduced.
At the next scheduled audit visit, the SGS audit team will follow up on **all** identified nonconformities to confirm the effectiveness of the corrective actions taken. The organisation was reminded that delays in submission of corrective action plans and implementation of corrective actions for Major CARs will delay certification by SGS.

Audit Obstacles encountered and Impact on Audit:
No obstacles were encountered that impact the reliability of the audit or the validity of the audit conclusions.

Audit Conclusions - Effectiveness of quality system:
The audit team concludes that the organization has demonstrated the following based on the audit evidence: The organization was not able to provide sufficient evidence of effective implementation and maintenance/ improvement of its quality management system in all areas to meet its quality objectives and to

demonstrate regulatory compliance, and a major non conformity has been raised in these areas.

Conformity with Audit Criteria and Objectives:	
The audit team concludes for the audit criteria and objectives defined in Section 3 of this report and where Yes is indicated below that the organization has established and maintained its quality management system and technical documentation in line with the requirements of the following standards and regulations and demonstrated the ability of the system to systematically achieve agreed requirements for products within the scope and that any non-conformity raised has only been considered minor (insert Y or N against the standards listed below)	
Standard	**Y/N**
ISO 13485:2016	N

Details of audit objective not met (if applicable):
2 Major CARs were raised.

Audit Recommendations:					
Therefore the audit team recommends that, based on the results of this audit, the system's demonstrated state of development and maturity and the demonstrated level of adequacy for the quality management system to systematically meet the agreed requirements certification be :					
	Granted	Continued	Withheld until satisfactory corrective action is completed	Suspended until satisfactory corrective action is completed	N/A
ISO 9001:2015 Initial/Current	☐	☐	☐	☐	☒
ISO 9001:2015 Extension to scope	☐	☐	☐	☐	☒
ISO 13485:2003 Initial/Current	☐	☐	☐	☐	☒
ISO 13485:2016 Initial/Current	☐	☐	☒	☐	☐
ISO 13485:2016 Extension to scope	☐	☐	☐	☐	☒

The audit team concludes that the organisation has established and maintained its quality management system in line with the requirement of			
	Yes	No	N/A
Japanese MHLW Ordinance #169	☐	☐	☑

Audit Explanations:
SGS explained that: • Auditing was a sampling activity and that consequently problems might exist that were not detected on this audit. • Information obtained during the audit would be treated in confidence with the proviso that certain information could be disclosed to Regulatory Bodies where allowed under the relevant regulations. • The organisation had an obligation to inform SGS of any proposed significant change in the quality management system or scope of certification.

- The certification was based on the activities and information shown in the Audit Summary above and that changes may represent significant changes in the quality management system or scope.
- The certification was based on the activities and information shown in the Audit Summary above and that changes may represent significant changes in the quality management system or scope.

SGS explanation of certification process:

- At the conclusion of this audit, the lead auditor will have made an audit recommendation. The audit documentation is then submitted for an independent technical and certification review, as defined under accreditation or designation requirements. All Major CAR and any clarification on the audit documentation must be closed before final approval is granted, and before any certificate, if relevant, is issued.

8. ADMINISTRATION

Is there a need to issue a new or changed certificated now?	No
Will there be a need to issue a new or changed certificate after major CAR close out?	Yes
An unscheduled audit was agreed with the organisation due to immaturity in the quality management system or the number and nature of the non-compliances – see additional comments for details agreed with client.	Yes
An extended next scheduled audit was agreed with the organisation	No
New proposal required – see additional comments for details	No
Major/Minor CAR has been raised with special conditions for acceptance and verification that requires a reviewer with specific complex codes. SGS office required to add note on system, for auditor/expert required for CAR close out.	No
The certification scope has been reworded or the certificate type has been changed as recommend in Section 4 “Scope of Certification and explained below, and must be used for certificate issue.	Yes

Explanation for change to initial proposed scope or current certification scope:

1. Address
The address in current certificate:
Room 805, Block A, Jianye Building, 96 Xiang Xing Road, Torch Hi-Tech (Xiang’An) industrial Park, Xiang’An District, Xiamen City, 361101, Fujian Province, P.R.China
中国福建省厦门市翔安区火炬高新技术翔安产业区祥星路 96 号建业楼 A 座 805 室

Would be change to:
Room 805A, South of Block A, Jianye Building, 96 Xiang Xing Road, Torch Hi-Tech (Xiang’An) industrial Park, Xiang’An District, Xiamen City, 361101, Fujian Province, P.R.China
中国福建省厦门市翔安区火炬高新技术翔安产业区翔星路 96 号建业楼 A 座南 805A 室

Explanation: change the description of address.

2. Scope
The scope in current certificate:
Design and Manufacture of Component Assembly used for Hearing Aids
用于助听器的组件的设计与生产。

Would be changed to:

Manufacture of Component Assembly used for Hearing Aids
用于助听器的组件的生产。

Explanation: OEM and production as per customer requirement, so delete the scope of design.

Additional comments and further actions for SGS Administration:
1.Audit plan was not prepared 30 days before because haven't gotten the documents of the audit. 2. Both English and Chinese certificates were required. 3. 2 Major CARs were raised, so 1MD was needed to close out the major CAR onsite.

9. NEXT AUDIT

Additional Comments or Areas for follow up at next audit for SGS Auditor:
NA

10. FINAL DECLARATION BY LEAD AUDITOR

All members of the audit team confirmed their compliance with the SGS Code of Integrity and Professional Conduct and specifically with the SGS Medical Device Impartiality and Conflict of Interest Statement.
The lead auditor confirms and declares on their own behalf and for all on site audit team members that there is no conflict of interest in performing this audit: **Lead Auditor acknowledged:** ☒