Assessment Report

SPRO Medical Products (Xiamen) Co., Ltd.

SkyPro

Assessment dates	29/07/2021 to 30/07/2021 (Please refer to Appendix for details)
Assessment Location(s)	Xiamen (000)
Report Author	Dennis Law

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Executive Summary

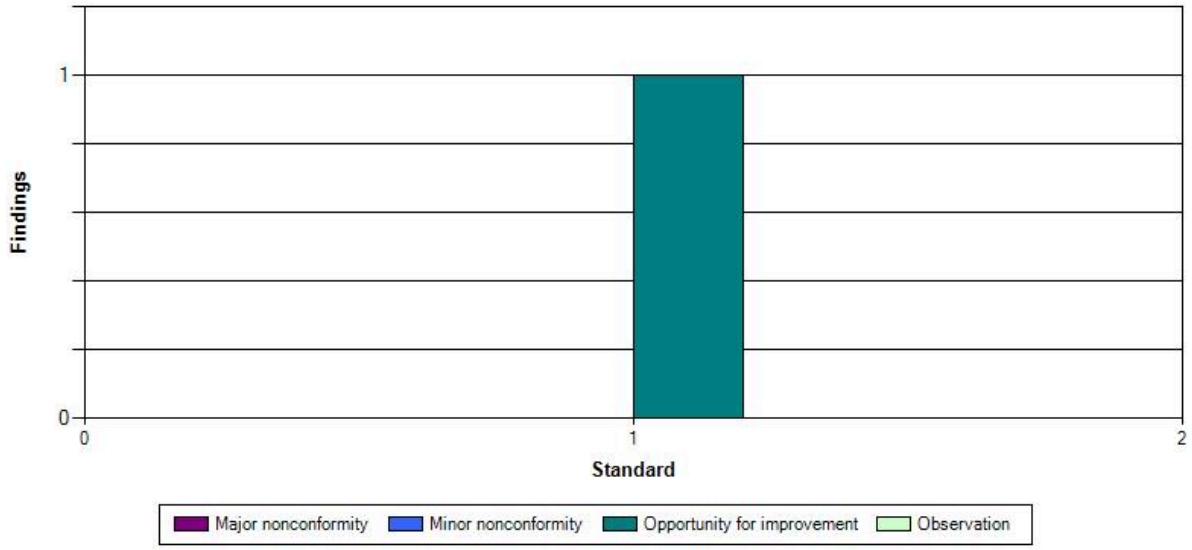
A recommendation is made subject to the final decision made by BSI Product Service. The recommendation will be independently verified within BSI. Upon verification your certificate of certification will be issued.
This remote audit was conducted using Information and Communication Technologies including email, MS TEAMS and phone call. The planned audit objectives have been achieved, there were no connectivity issues which adversely affected the audit.

Changes in the organization since last assessment

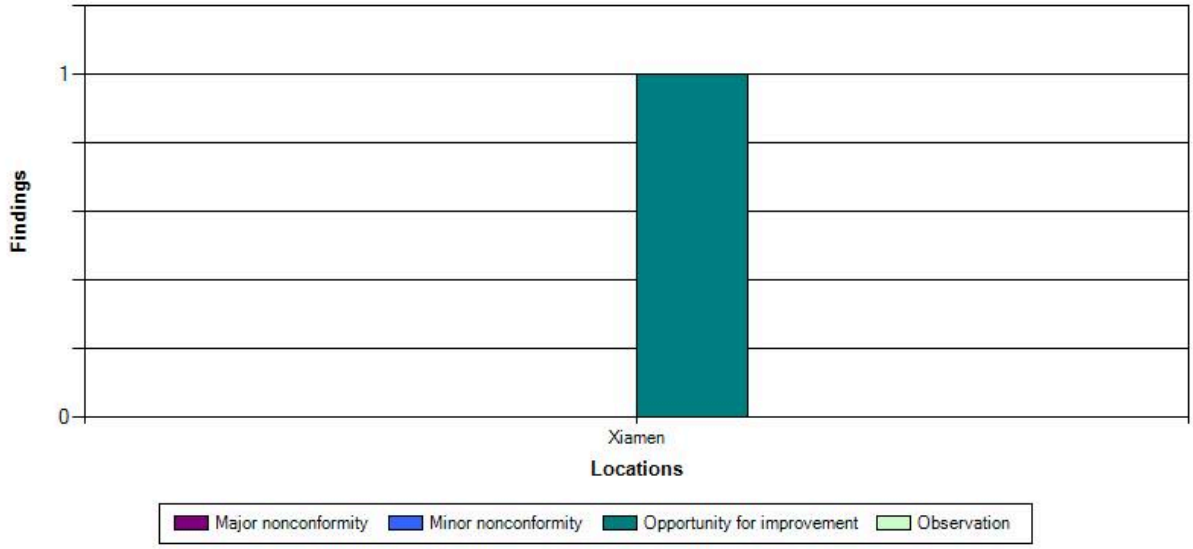
Not applicable.

NCR summary graphs

Which standard(s) BSI recorded findings against



Where BSI recorded findings



Your next steps

NCR close out process

No new nonconformities were identified during the assessment. Enhanced detail relating to the overall assessment findings is contained within subsequent sections of the report.

Please refer to Assessment Conclusion and Recommendation section for the required submission and the defined timeline.

Assessment objective, scope and criteria

The objective of the assessment was to conduct a certification assessment to ensure the elements of the proposed scope of registration and the requirements of the EN149 CE and UKCA Module D certificate, REGULATION (EU) 2016/425 Annex VIII are effectively addressed by the organisation's management system and to confirm the forward strategic plan.

The scope of the assessment is the documented management system with relation to the requirements of the management standards and the defined assessment plan provided in terms of locations and areas of the system and organisation to be assessed.

SPRO EN149 CE and UKCA Module D certificate, REGULATION (EU) 2016/425 Annex VIII management system documentation

Statutory and regulatory requirements

The client's processes were implemented to the client's requirements with reference to statutory and regulatory requirements and were effective.

Assessment Participants

Name	Position	Opening Meeting	Closing Meeting	Interviewed(processes)
Mr XiaoGuang, Ye 叶晓光先生	QC Supervisor品管主管	X	X	X

Assessment conclusion

BSI assessment team

Name	Position
Dennis Law	Team Leader

Assessment conclusion and recommendation

The assessment was completed as planned. A recommendation is made subject to the final decision made by BSI Product Service. The recommendation will be independently verified within BSI. Upon verification your certificate of certification will be issued.

Findings from this assessment

REGULATION (EU) 2016/425 Annex VIII, and relevant BSI requirements:

1. Confirm the product range covered by Module D scope
(list product and applicable standards)

GL009, GL009A (FFP2 NR), EN149:2001 + A1: 2009

2. Quality manual issue status

Quality Manual, Issue A/2, effective 1 Aug 2019, conformed to ISO9001:2015. The organization chart was included.

3. Changes and additions to the Quality Assurance system,

Quality Manual, Issue A/2, effective 1 Aug 2019, conformed to ISO9001:2015.
The recent management review was conducted on 30 Jun 2021.
The KPI for Production: final product pass rate >= 95%;
The KPI for Quality: IQC pass rate >=98%; IPQC pass rate >=95%; etc.
The objective targets were generally achieved in recent months.

4. Review of last ISO 9001 report (if applicable)

Zhongjian Certification Co Ltd audit report dated 21 Oct 2020 (surveillance audit 19 – 21 Oct 2020)

5. Retention of Quality Assurance records

GL/QP-02 (version B/0, dated 22 Jan 2020) Record Control Procedure was checked. The retention period of CE related quality records were at least 10 years from the end of product production.

6. Retention of regulatory and Notified Body records
(10 years from end of product production)

GL/QP-01 (version B/1, dated 24 May 2021) Document Control Procedure was checked. The retention period of records with national authorities and notified bodies relevant to EU2016/425 product certification was at least 10 years from the end of product production.

7. Internal audits

The recent internal audit was conducted during 17-18 Jun 2021. Internal audit plan, checklist, report, Non-conformance Report were checked.

8. Complaints

GL/QP-20 (version B/0, dated 22 Jan 2020) Nonconformance, Corrective and Preventive Actions Control Procedure was adopted. Corrective and Preventive Actions Report form would be used. One complaint was noted for another product model on 23 Jun 2021, and the case was closed effectively.

9. Subcontractors/suppliers (if applicable)
(supplier selection and ongoing assessment)

GL/QP-09 (Version A/6, dated 24 Mar 2020) Supplier and Purchasing Control Procedure was adopted. Supplier Evaluation Form was used for annual supplier re-evaluation. The Approved Supplier List was updated on 23 May 2021.

10. Technical file issue and status
(within the report list products, cert number and standards)

The Technical File folder consisted of the followings:
1 File Content List
2a Product Description (GL009)
2b Product Description (GL009A)
3a Instructions for Use (GL009)
3b Instructions for Use (GL009A)
4a Exploded View Drawing (GL009) dated 23 Apr 2021
4b Exploded View Drawing (GL009A) dated 23 Apr 2021
5a Raw Materials and Suppliers List (GL009) dated 8 Jun 2021
5b Raw Materials and Suppliers List (GL009A) dated 8 Jun 2021
6a Marking (GL009)
6b Marking (GL009A)
7a List of Raw Materials (GL009)
7b List of Raw Materials (GL009A)
8a Manufacturing Flowchart of Particle Filtering Half Masks (GL009) dated 23 Apr 2021
8b Manufacturing Flowchart of Particle Filtering Half Masks (GL009A) dated 23 Apr 2021
9 Machinery for Inspection of Raw Materials and Finished Products
10 Quality Control Plan (GL009 and GL009A)
11a Risk Assessment (GL009)
11b Risk Assessment (GL009A)
12 EHSR List
13 Declaration of Innocuousness
14a EU Declaration of Conformity (GL009)
14b EU Declaration of Conformity (GL009A)
15 Amendment Record Sheet
Note: The client was still waiting for BSI's Module B certificate.

11. Declaration of conformity contents
(wording as per Annex IX of the Regulation)

The Declaration of Conformity draft copy only, as the client was still waiting for BSI's Module B certificate.

12. Review of EU Type Examination Certificates to Module B
(within the report list products, cert number and standards)

The client was still waiting for BSI's Module B certificate.

13. Special processes used in product manufacture

No special processes noted.

14. Production final test and inspection
(check for calibration, competence and procedures)

The quality plan and corresponding work instructions for process control and inspection were followed. The training records checked: e.g. IQC and materials knowledge: 16 Mar 2021

15. Changes and additions to CE marked products
(including feedback to Notified Body of changes)

Nil.

16. Marking and labelling

Not checked in production line since no CE marking products being packaged.

17. Instructions for use

Not checked in production line since no CE marking products being packaged.

18. Use of CE 0086 / CE 2797

Not checked in production line since no CE marking products being packaged.

Implementation of the quality plan:

The production and inspection processes were checked with reference to the Quality Control Plan GL/WI/QC-121 (Chinese version provided by the factory, version A/0, dated May 2021). Maintenance records (daily and weekly) were checked. GL/QP-17 Non-conforming Product Control Procedure was checked. Calibration records of tensile tester, electronic balance, steel rule and mask respiratory resistance tester were traced. The process control and inspections, and records were verified with relevant work instructions.

Incoming Quality Control: Inspection Report of Raw Materials
In-process QC: First Item for Confirmation and In-process Sampling Records (every 2 hours), inspection work instruction GL/WI/QC-97 (version A0) specified MA / MI defects and ACC / REJ numbers
FQC / OQC: Inspection Report for Finished Products, inspection work instruction: GL/SIP/GL009-A0 (dated 25 May 2021)

Finding Reference	2082876-202107-I1	**Certificate Reference**	CE 754045
Certificate Standard		**Clause**	
Location reference	0047824347-000		
Category	Opportunity for Improvement		

Area/Process:	Implementation of the quality plan
Details	OFI-DL1 The "Manufacturing Flowchart of Particle Filtering Half Masks" stated "FQC" and "OQC". The Quality Control Plan GL/WI/QC-121 could be further enhanced so that "FQC" and "OQC" could be more clearly tracked. GL/WI/PD-227颗粒物过滤半面罩生产工艺流程图（GL009）和GL/WI/PD-228颗粒物过滤半面罩生产工艺流程图（GL009A）都提及了"FQC" 和 "OQC"。另一方面，GL/WI/QC-121质量控制计划（Quality Control Plan：QCP）能清楚显示"FQC" 和 "OQC"的话，可进一步完善管理。

Next visit objectives, scope and criteria

The objective of the assessment is to conduct a surveillance assessment and look for positive evidence to ensure the elements of the scope of certification and the requirements of the management standard are effectively addressed by the organisation's management system and that the system is demonstrating the ability to support the achievement of statutory, regulatory and contractual requirements and the organisations specified objectives, as applicable with regard to the scope of the management standard, and to confirm the on-going achievement and applicability of the forward strategic plan.

The scope of the assessment is the documented management system with relation to the requirements of the EN149 CE and UKCA Module D certificate, REGULATION (EU) 2016/425 Annex VIII and the defined assessment plan provided in terms of locations and areas of the system and organisation to be assessed.

SPRO EN149 CE and UKCA Module D certificate, REGULATION (EU) 2016/425 Annex VIII management system documentation

Please note that BSI reserves the right to apply a charge equivalent to the full daily rate for cancellation of the visit by the organisation within 30 days of an agreed visit date.

Next Visit Plan

See Certification assessment program

Appendix: Your certification structure & ongoing assessment programme

Scope of Certification

CE 754045 ()
Certificate Scheme: Negative pressure RPE
BSI Protocol number: PP123
Scheme manager: Nathan Shipley

Assessed location(s)

The audit has been performed at Permanent Locations.

Xiamen / CE 754045 () (2797)

Location reference	**0047824347-000**
Address	SPRO Medical Products (Xiamen) Co., Ltd. No.139 Factory Bldg TongAn Garden TongAn Industrial Area Xiamen Fujian 361100 China
Visit type	Stage 2 Audit
Assessment reference	3490928
Assessment dates	29/07/2021
Audit Plan (Revision Date)	29/07/2021
Deviation from Audit Plan	No
Total number of Employees	120
Effective number of Employees	120
Scope of activities at the site	Main Certificate Scope applies.
Assessment duration	2 day(s)

Certification assessment program

Certificate Number - CE 754045
Location reference - 0047824347-000

		Audit1	Audit2	Audit3
Business area/Location	**Date (mm/yy):**	07/21	07/22	07/23
	Duration (days):	2.0	1.0	1.0
REGULATION (EU) 2016/425 Annex VIII, and relevant BSI requirements (please refer to latest BSI quotations for detail audit days.)		X		

Product certification

Not applicable.

Certified product test data review.

Not applicable.

Definitions of findings:

Non-conformity:

Non-fulfilment of a requirement.

Major nonconformity:

Nonconformity that affects the capability of the management system to achieve the intended results. Nonconformities could be classified as major in the following circumstances:

- If there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- A number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Minor nonconformity:

Nonconformity that does not affect the capability of the management system to achieve the intended results.

Opportunity for improvement:

It is a statement of fact made by an assessor during an assessment, and substantiated by objective evidence, referring to a weakness or potential deficiency in a management system which if not improved

may lead to nonconformity in the future. We may provide generic information about industrial best practices but no specific solution shall be provided as a part of an opportunity for improvement.

Observation:
It is ONLY applicable for those schemes which prohibit the certification body to issue an opportunity for improvement.
It is a statement of fact made by the assessor referring to a weakness or potential deficiency in a management system which, if not improved, may lead to a nonconformity in the future.

How to contact BSI

Visit the BSI Connect Portal, our web-based self-service tool to access all your BSI assessment and testing data at a time that's convenient to you. View future audit schedules, submit your corrective action plans and download your reports and Mark of Trust logos to promote your achievement. Plus, you can benchmark your performance using our dashboards to help with your continual improvement journey.

Should you wish to speak with BSI in relation to your certification, please contact your local BSI office – contact details available from the BSI website:
https://www.bsigroup.com/en-HK/contact-us/

Notes

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This audit was conducted through document reviews, interviews and observation of activities. The audit method used was based on sampling the organization's activities and it was aimed to evaluate the fulfilment of the audited requirements of the relevant management system standard or other normative document and confirm the conformity and effectiveness of the management system and its continued relevance and applicability for the scope of certification.

As this audit was based on a sample of the organization's activities, the findings reported do not imply to include all issues within the system.

Regulatory compliance

BSI requires to be informed of all relevant regulatory non-compliance or incidents that require notification to any regulatory authority. Acceptance of this report by the client signifies that all such issues have been disclosed as part of the assessment process and agreement that any such non-compliance or incidents occurring after this visit will be notified to BSI as soon as practical after the event.