World Health Organization

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WHO Prequalification Team - Inspection services
WHO PUBLIC INSPECTION REPORT (WHOPIR)
MEDICAL DEVICES

Inspected site		
Manufacturer	SD Biosensor Inc.	
Address of inspected manufacturing site	74, Osongsaengmyeong 4-ro, Osong-eup Heugdeok-gu, Cheongju-si Chungcheongbuk-do, 28161 République de Corée	
Inspection details		
Dates of inspection	08-10 April 2019	
Type of inspection	Follow-up inspection	
Introduction		
Brief description of manufacturing activities	SD Biosensor Inc. is responsible for the control of the design and development of rapid diagnostic tests, as well as the production process, packing, labelling, storage and delivery.	
General information about the manufacturer	SD Biosensor Inc. was established in 2010 The inspected site was built in 2013. The line of rapid diagnostic tests Standard Q was launched in 2016.	
History	SD Biosensor Inc. was inspected by WHO prequalification services in May 2017 and April 2018. SD Biosensor Inc. received ISO 13485:2012 certification in March 2017 (valid till March 2020).	
Brief report of inspection activities undertaken – Scope and limitations		
Areas inspected	Design and Development Quality management system Management responsibility Purchasing Production and Service Controls Measurement, analysis and improvement Adverse Events and Advisory Notices Reporting WHO pre-qualification-specific requirements	
Scope	STANDARD Q Malaria P.f. Ag Test STANDARD Q Malaria P.f. Pan Ag Test STANDARD Q Malaria P.f./P.v Ag Test STANDARD HCV Ab Test STANDARD™ Q HIV/Syphilis Combo Test STANDARD™ Q HIV 1⁄2 Ab 3-Line Test	PQDx 0346-117-00 PQDx 0347-117-00 PQDx 0348-117-00 PQDx 0360-117-00 PQDx 0382-117-00 PQDx 0383-117-00
Criteria	ISO 13485:2016 and WHO Prequalification specific requirements	
Objective(s)	Assess if the manufacturing site met the audit criteria	

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Limitations	None
Out of scope	Exclusions and non-applications from ISO 13485:2016: • 7.5.3 Installation activities • 7.5.5 Particular requirements for sterile medical devices • 7.5.9.2/8.2.4.2 Requirements for implantable and active medical devices
Abbreviations	**Meaning**
CoA	Certificate of analysis
IQ	Installation qualification
IVD	In vitro device
MR	Management review
MSDS	Material safety data sheet
NC	Non-conformity
PPE	Personal protective equipment
OOS	Out-of-specifications test result
OQ	Operational qualification
PM	Preventive maintenance
PQ	Performance qualification
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure

Summary of the findings and comments (where applicable)

The inspection findings are listed below, following the numbering of the clauses of the ISO 13485:2016 standard for easy reference.

4. Quality management system

4.2. Documentation requirements

4.2.2. Quality manual

The manufacturer's Quality Manual applied to the intended practices of SD Biosensor Inc. It was updated to reflect compliance with the requirements of ISO 13485:2016. It contained a description of the interaction between the processes of the Quality Management System (QMS), defined the structure of the QMS, how it was reflected in the documentation system, and listed non-applicable clauses of ISO13485:2016 ("the standard") with appropriate justification.

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4.2.3. Medical device file

The manufacturer established and maintained documents demonstrating conformity to the requirement of the standard. These included descriptions of the labelling requirements. Labelling of the finished product was verified. The required information (e.g. the content, number of tests, preservation temperature, product codes, batch number and expiry dates) was clearly visible and would not smudge.

4.2.4. Control of documents

The documented procedures for control of documents met the requirements of the standard. Document retention was confirmed as being longer than the lifetime of the product.

4.2.5. Control of records

The documented procedures for control of records met the requirements of the standard. Records were legible, readily identifiable and retrievable and any changes to a record remained identifiable. Records retention was confirmed as being longer than the lifetime of the product. The records reviewed were legible, readily identifiable and easily retrieved.

5. Management responsibility

5.1. Management commitment

There was evidence of top management's commitment to the development and implementation of the quality management system and maintenance of its effectiveness. Top management had established an adequate Quality Policy including a commitment to comply with regulatory requirements and to maintain the effectiveness of the QMS.

5.2. Customer focus

The manufacturer had established and documented processes that were designed to meet the requirements of the standard and regulations.

5.3. Quality policy

Senior staff interviewed during the inspection were informed of the manufacturer's quality priorities and were willing to share information and contribute to the inspection process. The quality policy was applicable to the purpose of the organization and related to quality objectives.

5.4. Planning

5.4.1. Quality objectives

Quality objectives were established, measurable and had defined targets and were consistent with the quality policy.

5.4.2. Quality management system planning

The manufacturer had documented the organizational structure and defined designated responsibilities and authorities for staff undertaking or verifying work affecting quality. Reporting lines for quality and production were independent of the other.

5.5. Responsibility, authority and communication

5.5.1. Responsibility and authority

Mr G.K.Song was the nominated management representative, and had the responsibilities and authorities as defined in the standard.

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5.6. Management review

5.6.1. General

Documented requirements for management review were implemented and the review meetings were to be held at least once per year with the last review held on 17 December 2018. The reviewed meeting minutes and the reviewed data demonstrated that a detailed review of data trends was undertaken including customer complaints, feedback and product performance.

6. Resource management

6.2. Human resources

The manufacturer had determined and provided the resources needed to implement the quality management system, to maintain its effectiveness, and to meet regulatory and customer requirements (with 87 employees at the time of this audit).

6.3. Infrastructure

The manufacturing environments were adequately planned for the current volume of production.

6.4. Work environment and contamination control

6.4.1. Work environment

The premises were maintained satisfactorily and had an appearance of being clean and tidy. Production was carried out in rooms with environments adequately controlled for the type of products manufactured. There were adequate instructions with pictures to guide personnel in gowning requirements.

7. Product realization

7.1. Planning of product realization

The manufacturer's approach to planning of product realization followed the requirements of the standard and the procedures and work instructions reviewed indicated that they included all relevant production processes. The requirements for risk management were documented in relevant procedures.

7.4. Purchasing

7.4.1. Purchasing process

The manufacturer used defined and documented requirements for purchasing controls and supplier management. Criteria for selection, approval evaluation and re-evaluation of suppliers followed the requirements of the standard. The list of approved suppliers of critical materials was maintained.

7.4.3. Verification of purchased product

Inwards goods testing was performed in accordance with documented specifications. The incoming QC standard operating procedures and specifications reviewed were found in compliance with the standard.

7.5. Production and service provision

7.5.1. Control of production and service provision

Several manufacturing activities were observed, including strip cutting, cassette assembly, buffer manufacturing and filling, device packaging, final kitting, QC and product release. Deficiencies initially identified during the inspection were satisfactorily addressed and brought to compliance as part of the manufacturer's corrective/preventative action plan.

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7.5.8. Identification

The manufactured had documented procedures to identify product status throughout product realization. These included procedures to adequately identify products that had passed the required inspections and QC.

7.5.9. Traceability

7.5.9.1. General

The deficiencies related to provisions for ensuring traceability that were initially identified during the onsite inspection had been satisfactorily addressed and brought to compliance as part of the manufacturer's corrective/preventative action plan.

7.5.11. Preservation of product

The manufacturer had documented the procedures for preserving the conformity of the product to the requirements of the standard during processing, storage, handling, and distribution. Prescribed preservation conditions were based on studies investigating real-time stability, including temperatures outside the recommended temperature range.

7.6. Control of monitoring and measuring equipment

The manufacturer had an adequate procedure and tracking system for equipment maintenance. The records for Preventative Maintenance of Manufacturing Equipment, as well as the Equipment Calibration Schedule reviewed were found generally adequate.

8. Measurement, analysis and improvement

8.2. Monitoring and measurement

8.2.1. Feedback

The procedure for Post Market Surveillance specified different methods of receiving feedback other than customer complaints. The manufacturer was sending questionnaires to distributors and users asking for feedback. The requirements of the standard related to reporting to regulatory authorities was brought to compliance.

8.2.2. Complaint handling

The reviewed records of complaints generally supported compliance with the procedures. Initial non-conformities were satisfactorily addressed by the manufacturer and brought to compliance.

8.2.4. Internal audits

The manufacturer implemented an internal audit program, including documented requirements that audit schedules and audits should be performed by appropriately qualified auditors independent of the areas being audited. The audit schedule took into account the status and importance of the areas to be audited. Records of internal audits were available. The review of the available records demonstrated that the manufacturer implemented significant improvements to its internal auditing system.

8.2.6. Monitoring and measurement of product

The manufacturer had established QC processes to monitor and measure the characteristics of the product to verify that product requirements had been met. This was carried out for incoming goods, during product realization and before lot release. Evidence of conformity to the acceptance criteria was maintained and the identity of the person authorizing release recorded.

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8.3. Control of nonconforming product

8.3.1. General

The manufacturer implemented procedures for managing nonconformities and corrective actions. The handling of nonconformities was satisfactorily described in a documented procedure, where systems were in place to investigate nonconformities, conduct root cause analysis, document investigations. The procedure for the assessment of the effectiveness of corrective actions taken and their potential impact on product quality was improved. The documented OOS procedure did not originally include requirements to investigate product testing failures and the product was simply retested. Since the audit, the manufacturer established OOS procedures.

8.4. Analysis of data

The manufacturer had implemented a procedure for this clause of the standard. The procedure required data sourced from several areas of the QMS to be included in the analysis, such as post-market surveillance, customer feedback and complaints and nonconformities.

9. WHO pre-qualification-specific requirements

The products manufactured at the site had already been pre-qualified or were under assessment. As such, the assessment of compliance to WHO pre-qualification requirements was limited to site-specific requirements, which were met.

Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report the company, ***SD Biosensor Inc.***, located at ***74, Osongsaengmyeong 4-ro, Osong-eup, Heugdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea*** was considered to be operating at an acceptable level of compliance with ISO 13485:2016 and WHO Information for Manufacturers on Pre-qualification Inspection Procedures for the Sites of Manufacture of Diagnostics (PQDx_014).

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided the outcome of any WHO pre-qualification inspection or other audit from regulatory authorities that WHO relies on conducted during this period provides evidence of current compliance with the audit criteria.

List of WHO Guidelines referenced in the inspection report

1. WHO Information for Manufacturers on Prequalification Inspection Procedures for the Sites of Manufacture of Diagnostics (PQDx_014). (https://www.who.int/diagnostics_laboratory/evaluations/en/)

2. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

3. ISO 9001:2015 Quality management systems - Requirements

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4. WHO Post-market surveillance of in vitro diagnostics 2015 (ISBN 978 92 4 150921 3)

5. Medical devices - Application of risk management to medical devices - ISO14971:2007

6. GHTF/SG3/N19:2012 “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange”

7. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements

8. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy

9. GHTF/SG4(pd1)/N33R16:2007 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports ISO 13485:2016, Commitments to WHO PQ.

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