World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

WHO Prequalification Team - Inspection services

WHO PUBLIC INSPECTION REPORT (WHOPIR)

In vitro Diagnostic product

Inspected site/s	
Name of Organization	Shaoxing Shangyu Dongshan Precision Plastic Co., Ltd
Address/es of inspected manufacturing site/s	273 Yuexiu Middle Road, Cao'e Street Shangyu District Shaoxing City Zhejiang 312300 China
Inspection details	
Start of inspection	14/03/2025
Inspection duration (in inspector days)	2
Type of inspection	Initial
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Production of components for the product in scope, including quality control.
General information about the organization	Dongshan Precision Plastics is a critical supplier of filled and sealed extraction buffer tubes for the self-test COVID IVD manufactured by ACON Biotech (Hangzhou). The inspection team focused on the control of production and on the infrastructure considering Dongshan Precision Plastics is a mature manufacturer of a wide range of components for the medical and automotive industry.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	As detailed below, the areas inspected were sampled from the areas of activities performed on site that were relevant to the products in scope. The sampling was performed using a risk-based approach considering, for example, the impact of the area inspected on the product, as well as past inspection findings.
Products in scope	PQDx 12343-021-00 Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)
Criteria	• All applicable clauses of ISO 13485:2016 • WHO PQ requirements • Organization's own requirements
Objective(s)	Verify compliance to the inspection criteria.

Limitations	None.
Out of scope	Any processes or activities not related to the products in scope were considered out of scope of this inspection.
Abbreviations	**Meaning**
CAPA	Corrective and Preventive Action
CoA	Certificate of analysis
IQ	Installation qualification
IVD	In vitro device
MR	Management review
MRM	Management review meeting
MSDS	Material safety data sheet
NC	Non-conformity
PPE	Personal protective equipment
OOS	Out-of-specifications test result
OQ	Operational qualification
PM	Preventive maintenance
PMS	Post Market Surveillance
PQ	Performance qualification
PW	Purified water
QA	Quality assurance
QC	Quality control
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

4 Quality management system

4.2 Documentation requirements

4.2.1 General

The quality management system documentation did include:

a) documented statements of a quality policy and quality objectives;

b) a quality manual;

c) documented procedures and records required by the Standard;

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;

e) other documentation specified by applicable regulatory requirements.

4.2.4 Control of documents

Documents required by the quality management system were controlled. Records were a special type of document and were controlled according to the requirements given in Clause 4.2.5.

The organization did ensure that changes to documents were reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

4.2.5 Control of records

Records were maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.
Records did remain legible, readily identifiable and retrievable. Changes to a record did remain identifiable.
The nonconformities identified were successfully addressed through a CAPA plan.

5 Management responsibility

5.1 Management commitment

Top management did provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;
b) establishing the quality policy;
c) ensuring that quality objectives were established;
d) conducting management reviews;
e) ensuring the availability of resources.

5.2 Customer focus

Top management did ensure that customer requirements and applicable regulatory requirements were determined and met.

6 Resource management

6.1 Provision of resources

The organization did determine and provide the resources needed to:

a) implement the quality management system and to maintain its effectiveness;
b) meet applicable regulatory and customer requirements.

6.3 Infrastructure

The organization did document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure included, as appropriate:

a) buildings, workspace and associated utilities;
b) process equipment (both hardware and software);
c) supporting services (such as transport, communication, or information systems).

The organization did document requirements for the maintenance activities, including the interval of performing the maintenance activities. As appropriate, the requirements did apply to equipment used in production, the control of the work environment and monitoring and measurement.

Records of such maintenance were maintained.
The nonconformities identified were successfully addressed through a CAPA plan.

6.4 Work environment and contamination control

6.4.1 Work environment

The organization did document the requirements for the work environment needed to achieve conformity to product requirements.
If the conditions for the work environment could have an adverse effect on product quality, the organization did document the requirements for the work environment and the procedures to monitor and control the work environment.

6.4.2 Contamination control

As appropriate, the organization did plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

7 Product realization

7.1 Planning of product realization

The organization did plan and develop the processes needed for product realization. Planning of product realization was consistent with the requirements of the other processes of the quality management system.
The organization did document one or more processes for risk management in product realization. Records of risk management activities were maintained.
The output of this planning was documented in a form suitable for the organization's method of operations.
The nonconformities identified were successfully addressed through a CAPA plan.

7.4 Purchasing

7.4.3 Verification of purchased product

The organization did establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements.
Records of the verification were maintained.

7.5 Production and service provision

7.5.1 Control of production and service provision

Production and service provision were planned, carried out, monitored and controlled to ensure that product conforms to specification.
The organization did establish and maintain a record for each medical device or batch of medical devices that provided traceability to the extent specified in Clause 7.5.9 and identified the amount manufactured and amount approved for distribution. The record was verified and approved.
The nonconformities identified were successfully addressed through a CAPA plan.

7.5.6 Validation of processes for production and service provision

The organization did validate processes for production and service provision where the resulting output cannot be or was not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product was in use or the service had been delivered.
Validation did demonstrate the ability of these processes to achieve planned results consistently.
Records of the results and conclusion of validation and necessary actions from the validation were maintained.
The nonconformities identified were successfully addressed through a CAPA plan.

7.5.8 Identification

The organization did document procedures for product identification and identify product by suitable means throughout product realization.
The organization did identify product status with respect to monitoring and measurement requirements.
Only product that had passed the required inspections and tests or released under an authorized concession was dispatched, used or installed.
The nonconformities identified were successfully addressed through a CAPA plan.

7.5.11 Preservation of product

The organization did document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation did apply to the constituent parts of a medical device.

7.6 Control of monitoring and measuring equipment

The organization did determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.
The organization did document procedures to ensure that monitoring and measurement could be carried out and were carried out in a manner that was consistent with the monitoring and measurement requirements.
The organization did perform calibration or verification in accordance with documented procedures.
Records of the results of calibration and verification were maintained.
The nonconformities identified were successfully addressed through a CAPA plan.

8 Measurement, analysis and improvement

8.2 Monitoring and measurement

8.2.6 Monitoring and measurement of product

The organization did monitor and measure the characteristics of the product to verify that product requirements had been met. This was carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.
Evidence of conformity to the acceptance criteria was maintained.
Product release and service delivery did not proceed until the planned and documented arrangements had been satisfactorily completed.

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, ***Shaoxing Shangyu Dongshan Precision Plastic Co., Ltd.*** located at ***273 Yuexiu Middle Road, Cao'e Street, Shangyu District Shaoxing City, Zhejiang 312300, China*** 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 were addressed by the organization 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. WHO Post-market surveillance of in vitro diagnostics 2020 (ISBN 978 92 4 001532 6)
4. Medical devices - Application of risk management to medical devices - ISO14971:2019
5. GHTF/SG3/N19:2012 "Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange"
6. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
7. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy
8. 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.