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	Sysmex Partec GmbH
Address/es of inspected manufacturing site/s	Arndtstrasse 11a-b 02826 Goerlitz Germany
Inspection details	
Start of inspection	18/09/2025
Inspection duration	4 inspector-days
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Design and development, Purchasing, Production of semi-finished and finished product, Quality control, Warehousing, Management
General information about the organization	Sysmex Partec GmbH specializes in the development and production of flow cytometry instruments, cell counters, and related reagents for use in research, clinical diagnostics, and industrial applications. The company operates as a subsidiary of Sysmex Corporation, a global leader in hematology and in-vitro diagnostics. Sysmex Partec's product portfolio includes particle analyzers and flow cytometers used across a wide range of applications, from hematology and immunology to plant biology and microbiology.
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 0350-081-00 CyFlow™ Counter System with CD4 easy count kit and CD4% easy count kit
Criteria	• All applicable clauses of ISO 13485:2016 • WHO PQ requirements • Organization's own requirements
Objective(s)	Verify continued compliance with 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.

4.2.2 Quality manual

The organization did document a quality manual that included:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application;

b) the documented procedures for the quality management system, or reference to them;

c) a description of the interaction between the processes of the QMS.

The quality manual did outline the structure of the documentation used in the quality management system.

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 process.

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.

5.3 Quality policy

Top management did ensure that the quality policy:

a) was applicable to the purpose of the organization;
b) included a commitment to comply with requirements and to maintain the effectiveness of the quality management system;
c) provided a framework for establishing and reviewing quality objectives;
d) was communicated and understood within the organization;
e) was reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management did ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, were established at relevant functions and levels within the organization. The quality objectives were measurable and consistent with the quality policy.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management did ensure that responsibilities and authorities were defined, documented and communicated within the organization.
Top management did document the interrelation of all personnel who manage, perform and verify work affecting quality and did ensure the independence and authority necessary to perform these tasks.

5.5.2 Management representative

Top management did appoint a member of management who, irrespective of other responsibilities, had responsibility and authority that included:

a) ensuring that processes needed for the quality management system were documented;

b) reporting to top management on the effectiveness of the quality management system and any need for improvement;

c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

5.6 Management review

5.6.1 General

The organization did document procedures for management review. Top management did review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review did include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews were maintained.

5.6.2 Review input

The input to management review did include, but was not limited to, information arising from:

a) feedback;
b) complaint handling;
c) reporting to regulatory authorities;
d) audits;
e) monitoring and measurement of processes;
f) monitoring and measurement of product;
g) corrective action;
h) preventive action;
i) follow-up actions from previous management reviews;
j) changes that could affect the quality management system;
k) recommendations for improvement;
l) applicable new or revised regulatory requirements.

5.6.3 Review output

The output from management review was recorded and included the input reviewed and any decisions and actions related to:

a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;
b) improvement of product related to customer requirements;
c) changes needed to respond to applicable new or revised regulatory requirements;
d) resource needs.

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.

6.2 Human resources

Personnel performing work affecting product quality were competent on the basis of appropriate education, training, skills and experience.
The organization did document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.
The organization did:

a) determine the necessary competence for personnel performing work affecting product quality;

b) provide training or take other actions to achieve the necessary competence;

c) evaluate the effectiveness of the actions taken;

d) ensure that its personnel were aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;

e) maintain appropriate records of education, training, skills and experience.

The nonconformities identified were successfully addressed through a CAPA process.

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, when such maintenance activities, or lack thereof, could affect product quality. 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.

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.

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 nonconformities identified were successfully addressed through a CAPA process.

7.4 Purchasing

7.4.1 Purchasing process

The organization did document procedures to ensure that purchased product conforms to specified purchasing information. The organization did establish criteria for the evaluation and selection of suppliers. The criteria were:

a) based on the supplier's ability to provide product that meets the organization's requirements;

b) based on the performance of the supplier;

c) based on the effect of the purchased product on the quality of the medical device;

d) proportionate to the risk associated with the medical device.

The organization did plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product were monitored. The results of the monitoring did provide an input into the supplier re-evaluation process.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities were maintained.

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. The extent of verification activities were proportionate to the risks associated. 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. As appropriate, production controls did include but were not limited to:

a) documentation of procedures and methods for the control of production;

b) qualification of infrastructure;

c) implementation of monitoring and measurement of process parameters and product characteristics;

d) availability and use of monitoring and measuring equipment;

e) implementation of defined operations for labelling and packaging;

f) implementation of product release, delivery and post-delivery activities.

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 process.

7.5.6 Validation of processes for production and service provision

The organization did validate any 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 process.

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 throughout product realization. Identification of product status was maintained throughout production, storage, installation and servicing of product to ensure that only product that had passed the required inspections and tests or released under an authorized concession was dispatched, used or installed.

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.
If special conditions were required, they were controlled and recorded.
The nonconformities identified were successfully addressed through a CAPA process.

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 were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

8 Measurement, analysis and improvement

8.2 Monitoring and measurement

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, the organization did gather and monitor information relating to whether the organization had met customer requirements. The methods for obtaining and using this information were documented.
The organization did document procedures for the feedback process. This feedback process did include provisions to gather data from production as well as post-production activities.
The review of experience from post- production activities did form part of the feedback process.

8.2.2 Complaint handling

The organization did document procedures for timely complaint handling in accordance with applicable regulatory requirements.
These procedures did include at a minimum requirements and responsibilities for:

a) receiving and recording information;
b) evaluating information to determine if the feedback constitutes a complaint;
c) investigating complaints;
d) determining the need to report the information to the appropriate regulatory authorities;

e) handling of complaint-related product;
f) determining the need to initiate corrections or corrective actions.

Any correction or corrective action resulting from the complaint handling process were documented.
Complaint handling records were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

8.2.3 Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, the organization did document procedures for providing notification to the appropriate regulatory authorities.
Records of reporting to regulatory authorities were maintained.

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. The identity of the person authorizing release of product was recorded. As appropriate, records did identify the test equipment used to perform measurement activities.

8.3 Control of nonconforming product

8.3.1 General

The organization did ensure that product which did not conform to product requirements was identified and controlled to prevent its unintended use or delivery. The organization did document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product.
Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions were maintained.

8.3.4 Rework

The organization did perform rework in accordance with documented procedures that took into account the potential adverse effect of the rework on the product. These procedures did undergo the same review and approval as the original procedure.

8.4 Analysis of data

The organization did document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system.
The analysis of data did include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:

a) feedback;
b) conformity to product requirements;
c) characteristics and trends of processes and product, including opportunities for improvement;
d) suppliers;
e) audits;
f) service reports, as appropriate.

If the analysis of data shows that the quality management system was not suitable, adequate or effective, the organization did use this analysis as input for improvement as required in Clause 8.5.
Records of the results of analyses were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

8.5 Improvement

8.5.1 General

The organization did identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review. The nonconformities identified were successfully addressed through a CAPA process.

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, ***Sysmex Partec GmbH*** located at ***Arndtstrasse 11a-b, 02826 Goerlitz, Germany*** 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.