World Health Organization

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Prequalification Unit Inspection Services
WHO INSPECTION REPORT

Report of Desk Assessment of ISO 13485

Part 1	**General information**
Company information	
Name of manufacturer	Cepheid AB
Corporate address of manufacturer	Röntgenvägen 5, Solna, Stockholms län, 17127, Sweden
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	**Manufacturing:** Röntgenvägen 5, 171 54 Solna SWEDEN Latitude: 59.357071 Longitude: 17.977341 **External warehouse:** Mätarvägen 45a, 196 37 Kungsängen SWEDEN Latitude: 59.509037 Longitude: 17.724722
Desk assessment details	
Date of review	23 – 25 March 2026
Last WHO inspection	Cepheid AB has been inspected by WHO on the following occasions: • I-03853 – 24 March 2022. Compliant Desk Assessment. • I-03674 – 23-25 June 2015. Found compliant on 23 March 2016. (Onsite inspection) EUL submission - Desk Assessment • I-04088 - 22 April 2020 • I-04089 – 10 December 2021 • I-04090 – 30 August 2023
Introduction	
History of the site	Cepheid was founded in 1996 to develop a process for the detection and analysis of nucleic acids, including DNA, in samples such as blood, urine, food and industrial water. The company has sites throughout the world and has implemented a global Quality Management System with an overarching

	Quality Manual. They currently have production sites situated in the United States, Sweden, and India.	
WHO Product(s) to be covered by this desk assessment	• PQDx 0260-070-00 - Xpert HCV Viral Load with GeneXpert Dx, GeneXpert Infinity-48s, and GeneXpert Infinity-80 • PQDx 0268-070-00 - Xpert HPV • PQDx 0453-070-00 - Xpert HCV VL Fingerstick • PQDx 0652-070-00 - Xpert HIV-1 Qual XC • PQDx 0691-070-00 - Xpert HIV-1 Viral Load XC • PQDx 10295-070-00 - Xpert MTB/RIF Ultra • PQDx 10308-070-00 - Xpert MTB/XDR • PQDx 0443-070-00 - Xpert Ebola Assay	
Abbreviations	**Meaning**	
NC	Non-conformity	
NCR	Non conformity Report	
OOS	Out-of-specification	
QC	Quality control	
QMS	Quality management system	
SCAR	Supplier Corrective Action Request/Report	
Part 2	**Summary of the assessment of ISO evidence submitted**	
Inspection Report 1		
Competent authority names	bsi	
Dates of inspection	18 August 2025	
Type of inspection	Continuing Assessment (Surveillance audit)	
	Products:	Included but not limited to the above listed WHO prequalified products.
	Scope:	**CE 708525 (2797)** Design and manufacture of nucleic acid amplification tests for the quantitative detection of HIV-1, Hepatitis B (HBV), Hepatitis C (HCV) and qualitative detection of HIV-1 and Chlamydia Trachomatis infections. **UKCA 790584 (0086)** Design and manufacture of nucleic acid amplification tests for the qualitative detection of Chlamydia Trachomatis infections.
	Activities:	Management, Device Marketing Authorization and Facility registration, Measurement, Analysis and Improvement,

		Medical Device Adverse Events and Advisory Notices, including complaints, Reporting to regulatory authorities, Design and Development including changes, Production and Service Controls, Corrective and Preventive Actions (CAPA), Internal audits, Supplier control and purchasing.
Final conclusion of the inspection report	The audit report was comprehensive. All major areas of the standard used were covered and reported upon with details of documentation reviewed. The audit concluded that the management systems meet the applicable requirements and expected outcomes for IVDD, IVDR and for UK MDR 2002.	
Inspection Report 2		
Competent authority names	bsi	
Dates of inspection	19-21 August 2025	
Type of inspection	Continuing Assessment (Surveillance audit)	
	Products:	Included but not limited to the above listed WHO prequalified products.
	Scope:	**MDSAP 774673** Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits, Reagents and analyzers used for Monitoring and Patient Management. Service and Installation of analyzers used for Monitoring and Patient Management. **MD 774674** Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management. Design, Development, Manufacture, Service, Installation, Distribution and Refurbishment of Analyzers used for Monitoring and Patient Management. **MD 775253** Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management. Distribution of Analyzers used for Monitoring and Patient Management.

		MDSAP 775255 Design, Development, Manufacture and Distribution of Nucleic Acid Test kits and reagents used for monitoring and patient management. Distribution of Analyzers used for Monitoring and Patient Management.
	Activities:	Management, Device Marketing Authorization and Facility registration, Measurement, Analysis and Improvement, Medical Device Adverse Events and Advisory Notices, including complaints, Reporting to regulatory authorities, Design and Development including changes, Production and Service Controls, Corrective and Preventive Actions (CAPA), Internal audits, Supplier control and purchasing.
Final conclusion of the inspection report	The sites were found to meet the criteria of the audit (ISO 13485:2016 under the MDSAP requirements) and therefore the requirements were considered to be adequately implemented. It was recommended for continued certification to ISO 13485:2016 MDSAP, including Australia, Brazil, Canada, Japan and USA.	

Part 3	**Review of additional documents**

1. Certification and audit reports:
The manufacturer provided a copy of the bsi Certificate, ISO 13485:2016. The following jurisdictions were included within the certification: Australia, Brazil, Canada, Japan, and the USA.

The scope of certification was as follows:
Cepheid
904 Caribbean Drive, Sunnyvale, California, 94089 USA

Scope:

Design, Development, Manufacture and Distribution of Nucleic Acid Test kits and reagents used for monitoring and patient management, Distribution of Analyzers used for Monitoring and Patient management.

Cepheid AB
Röntgenvägen 5, Solna, Stockholms län, 17127, Sweden

Scope:

Design, Development, Manufacture and Distribution of Nucleic Acid Test kits and reagents used for monitoring and patient management, Distribution of Analyzers used for Monitoring and Patient management.

The comprehensive audit reports were provided.

2. Quality Manual:

The manufacturer provided a copy of the Quality. The company has sites throughout the world and has implemented a global Quality Management System with an overarching Quality Manual. The high-level quality manual was set out according to the requirements of ISO 13485:2016 with endorsement from top management on the effectiveness and maintenance of the QMS. Top management was committed to the development and continual improvement of the quality management system.

Top management was responsible for implementing the Quality Policy and that the policy was understood, implemented, and maintained at all levels of the organizations. This high-level document briefly described the role that Cepheid take in the product life cycle to include design controls, device marketing authorization, risk management, purchasing controls, production and process controls, traceability and measurement, analysis and improvement to just name a few.

The manufacturer provided a copy of the organogram with clear separation of roles and reporting responsibilities.

Relevant international standards and regulations were available.

3. List of current quality management procedures:

A list of the relevant Quality Documents was available.

4. Standard operating procedures for:

i. Complaint handling and vigilance:

A copy of the global Complaint Handling Process was reviewed. Complaints were generally received by the Technical Support or Field Service, and this was lodged into the Complaint Management System (CMS), a salesforce platform. Once in the system, the complaint was reviewed and classified, and it was determined if an adverse event occurred or if medical device reporting was required. This process was performed by the Technical Support team in conjunction with listed work instructions. If a serious incident or injury was reported an automated notification was sent to the Medical and Scientific Affairs team (MedSci), PMQ and TS managers for immediate evaluation. Investigation and trending process documents were referenced within the procedures.

The manufacturer provided a copy of the PMQ Review of Customer Complaints Procedure. This document clearly described the roles and responsibilities including QA investigations. Timelines for complaint closures were available. Specific reference to notification to WHO was available within the document titled Global Adverse Event Reporting.

ii. Post Market Surveillance:

The manufacturer provided a copy of the Post Market Surveillance Policy. Roles and responsibilities were clearly documented with a process for reactive and proactive measures in place.

A copy of the Global Adverse Event reporting procedure was provided and reviewed. There was reference within the procedure for reporting timelines to WHO. The manufacturer provided a copy of the various decision tree documents that outlined as to how reporting was determined.

iii. Control of nonconforming goods/processes:

A copy of the Global Policy for the Control of Nonconforming product procedure was reviewed. Nonconformances were recorded in the corporate wide system, including investigation and root cause analysis. The manufacturer provided a series of documents that clearly described the process for identification, investigation, and closure of nonconformities.

iv. Change control/change notifications (product and processes):

The manufacturer provided a copy of the high-level Global Change Management Policy and the Global Change Control Procedure. Upon the identification for the need for change, the change was classified as either major or minor which then determined the change plan criteria (complex, simple or optional). All changes were controlled within the Agile software. All major changes require an assessment and approval from the Regulatory Affairs department where reportability and or notification to regulatory bodies was required before proceeding.

A copy of the Change Request (eCR)/ Order (AWF) Impact Assessment was reviewed that described in detail the process that was to be followed including an extensive list of types of changes and the respective requirements, for example if regulatory notification was required.

A copy of the US/EU/UK/WHO Change Assessment template was available with a section devoted to competing WHO change notifications.

v. Quality Control and Batch release:

The manufacturer provided a copy of the Global Inspection, Testing and Acceptance Policy. This high-level procedure described the incoming, in process and final acceptance inspection and testing for all components and materials.

A specific quality control procedures for each of the prequalified products was available. The testing procedures provided were detailed, they included sample sizes and acceptance criteria, as well as increased sampling and retesting for failed or invalid runs.

The ROBAL (Reagents On Board Assembly Line) Product Testing procedure was reviewed. The procedure detailed how sampling was to occur, it also included details on functional testing, seal tests and visual inspection of the product.

The Batch Record Review Process at Cepheid AB was provided. This document was specific to the Solna site and described the batch document review process including responsible teams for each stage in production.

vi. Risk management:

A copy of the Global Risk Management and the Global Safety Risk Management SOP were available. Top management were committed to ensuring risk as well as product safety, was managed throughout the full lifecycle for medical devices. Roles and responsibilities were clearly defined.

The procedures described how the verification of implementation and effectiveness was to be conducted and methods to support this process, including complaint trending, usability testing or clinical performance studies, proficiency testing and External Quality Assurance.

The manufacturer had a process in place for the post-marketing monitoring of the products that included the collection of quality data.

vii. Supplier evaluation and control, verification of purchased product:

The manufacturer provided a copy of the Purchasing Controls. Within this document it described the requirements of suppliers to include written agreements for change control, supplier audits, surveys, and performance monitoring.

Suppliers and service providers were classified according to criticality. With critical suppliers and service providers required to have a supplier audit conducted every two years.

A copy of the Incoming Inspection Standard Operation Procedure at Cepheid AB and the Goods Receiving and Incoming Inspection document were reviewed. The detailed procedures clearly described the process of entering incoming deliveries into SAP and material was only released once it passed QAR (Quality Assurance Release). If material was damaged after releasing it was blocked in SAP preventing use.

viii. Design and development:

The manufacturer provided a copy of the Design Control for Assay Product Development procedure. The procedure described in detail the phases of the product life cycle:

- Design and development planning including input and outputs
- Design review and verification
- Design transfer and validation.
- Commercialization and post launch phase.

Applicable procedures for each of the phases was available.

For IVDs, studies used to assess product performance included pre-clinical studies, clinical and analytical studies. A regulatory check would be performed to ensure all laws and regulations were addressed in each of the marketed countries.

Post-market assessment activities were performed once the design transfer and commercial release phase was completed.

ix. Internal Audits:

The manufacturer had a documented process available for internal audits (Global Quality Audits Policy). Direct conflict of interest was prevented when selecting the audit team, disallowing auditing of own work.

5. List of critical raw materials (including details of the supplier of each material):

The manufacturer provided a list of the class 1 critical suppliers.

6. List of outsourced processes with direct product impact (e.g. outsourced manufacturing of components, outsourced laboratory testing, packaging, printing, etc.) including details of the supplier for each process:

The manufacturer provided a list of suppliers of outsourced processes.

Part 5	Desk assessment conclusion

Based on the QMS evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site **Cepheid AB** located at ***Röntgenvägen 5, Solna, Stockholms län, 17127, Sweden*** is considered to be operating at an acceptable level of compliance with ISO 13485:2016 and WHO requirements.

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.

Part 6	List of guidelines referenced in this inspection report

1. Overview of WHO's prequalification procedure for in vitro diagnostics (ISBN 978-92-4-011802-7)

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

3. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. (ISBN 978 92 4 001531-9)

4. Reportable changes to WHO prequalified and emergency use listed in vitro diagnostics – Application guide (ISBN 978 92 4 010984-1)

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