

Certificate of Approval

This is to certify that the Management System of:

Cepheid

904 Caribbean Drive, Sunnyvale, CA, 94089, United States

has been approved by LRQA to the following standards:

ISO 13485:2016



Chris Koci - President, LRQA Americas

Issued By: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current Issue Date: 18 February 2018

Expiry Date: 17 February 2021

Certificate Issue Number: 10056768

Original Approvals:

ISO 13485 12 January 2015

Approval Certificate Number: ISO 13485 – 0013442

The scope of this approval is applicable to:

Design, Development, Manufacture and Service of Nucleic Acid Detection Systems, including Analyzers, Reagents, and Test Kits. Refurbishment of Analyzers.



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Certificate Schedule

Certificate Issue Number: 10056768

Location	Activities
904 Caribbean Drive, Sunnyvale, CA, 94089, United States	ISO 13485:2016 Design, Development, Manufacture and Service of Nucleic Acid Detection Systems, including Analyzers, Reagents, and Test Kits. Refurbishment of Analyzers.
1327 Chesapeake Terrace, building 4, Sunnyvale, CA, 94089, United States	ISO 13485:2016 Engineering Development, Software Development, Order Management and Quality Assurance.
1339 Moffett Park Drive, building 3, Sunnyvale, CA, 94089, United States	ISO 13485:2016 Technical Support and Quality Assurance.
632 Caribbean Drive, building 2, Sunnyvale, CA, 94089, United States	ISO 13485:2016 Warehouse, Shipping, Receiving, Incoming Inspection and Servicing.
918 Caribbean Drive, Sunnyvale, CA, 94089, United States	ISO 13485:2016 Reagent Manufacturing and Quality Control.
1324 Chesapeake Terrace, Sunnyvale, CA, 94089, United States	ISO 13485:2016 Purchasing and Document Control.
1315 Chesapeake Terrace, building 5, Sunnyvale, CA, 94089, United States	ISO 13485:2016 Assay Development, R&D, Regulatory, Project Management and Technical Support.



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