

Illumina, Inc 25861 Industrial Boulevard Hayward, CA 94545-2991 Tel: 510.670.9300

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### **Certificate of Conformance**

Manufacturer: Illumina, Inc.

Name: MiSeqDx Sequencing System

Model/Part Number: MiSeqDx Instrument / 20014737

Serial Number: M70890

Date of Manufacture: 2020-08-24

RTA Version: 1.18.54.3

MOS Version: 2.2.4.3

LRM Version: 1.4.5.0

This document certifies that each instrument conforms to Illumina specifications and is developed and validated following a certified Quality System, which conforms to ISO 13485 requirements. The integrity of the Illumina Quality System is routinely audited and is certified by the British Standards Institute (BSI, Inc.), a quality management system registrar, as meeting the requirements of ISO 13485.

Each instrument goes through a sequencing run in the Final Instrument Test with defined acceptance criteria. In accordance with the Device History Record, each instrument must pass the Final Instrument Test and cosmetic and labeling verifications, which are performed by qualified and trained manufacturing personnel. The Device History Record is then approved by independent, qualified Quality Assurance personnel.

Verified by:	Judilyne Mercado  Reason: Reviewer Date: Sep 1, 2020 09:52 PDT
	Judilyne Mercado, MFG/Ops Quality Manager
Date:	01-Sep-2020

DIR: 100000091969 v01 Effective: 22-Aug-2019



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### **Certificate of Conformance**

Manufacturer: Illumina, Inc.

Name: MiSeqDx Sequencing System

Model/Part Number: MiSegDx Instrument / 20014737

Serial Number: M70892

Date of Manufacture: 2020-08-25

RTA Version: 1.18.54.3

MOS Version: 2.2.4.3

LRM Version: 1.4.5.0

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## **Certificate of Conformance**

Manufacturer: Illumina, Inc.

Name: MiSeqDx Sequencing System

Model/Part Number: MiSeqDx Instrument / 20014737

Serial Number: M70893

Date of Manufacture: 2020-08-28

RTA Version: 1.18.54.3

MOS Version: 2.2.4.3

LRM Version: 1.4.5.0

This document certifies that each instrument conforms to Illumina specifications and is developed and validated following a certified Quality System, which conforms to ISO 13485 requirements. The integrity of the Illumina Quality System is routinely audited and is certified by the British Standards Institute (BSI, Inc.), a quality management system registrar, as meeting the requirements of ISO 13485.

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Judilyne Mercado, MFG/Ops Quality Manager

01-Sep-2020

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# CoCs Ready for Signature

Final Audit Report 2020-09-01

Created: 2020-08-29

By: Ricky Voong (rvoong@illumina.com)

Status: Signed

Transaction ID: CBJCHBCAABAAGynq7L8RxzgBs2\_e2SMaKTXQ2N9s4KJu

# "CoCs Ready for Signature" History

Document created by Ricky Voong (rvoong@illumina.com) 2020-08-29 - 9:46:35 PM GMT- IP address: 64.125.128.230

Document emailed to Judilyne Mercado (jmercado@illumina.com) for signature 2020-08-29 - 9:48:25 PM GMT

Judilyne Mercado (jmercado@illumina.com) verified identity with Adobe Sign authentication 2020-09-01 - 4:52:02 PM GMT

Document e-signed by Judilyne Mercado (jmercado@illumina.com)

Signature Date: 2020-09-01 - 4:52:02 PM GMT - Time Source: server- IP address: 192.84.34.99

Signed document emailed to Judilyne Mercado (jmercado@illumina.com) and Ricky Voong (rvoong@illumina.com)

2020-09-01 - 4:52:02 PM GMT

