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Certificate of Conformance

Manufacturer: Illumina, Inc.
Name: MiSeqDx Sequencing System
Model/Part Number: MiSeqDx Instrument / 20014737
Serial Number: M70891
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.

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
Electronically signed by: Judilyne Mercado
 Reason: Reviewer
 Date: Sep 1, 2020 09:45 PDT
 Judilyne Mercado, MFG/Ops Quality Manager

Date: 01-Sep-2020







CoC Ready for Signature

Final Audit Report

2020-09-01

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