

Declaration of Conformity

Illumina, Inc. hereby declares under its sole responsibility that the product(s) listed are in conformity to the EMC Directive [2014/30/EU] and Low Voltage Directive [2014/35/EU].

MANUFACTURER:

ADDRESS:

Illumina

5200 Illumina Way

San Diego, CA 92122, USA

FACTORY LOCATION:

25861 Industrial Blvd.

Hayward, CA 94545, USA

PRODUCT TYPE:

Genetic Sequencer

MODEL:

HiSeq 1000, HiSeq 1500, HiSeq 2000, HiSeq 2500, HiSeq 3000, HiSeq 4000,

HiSeq X & HiSeq ILS

CE MARK AFFIXED:

2010

The construction of the product is in compliance with the following harmonized and/or consensus standards.

IEC/EN IEC 61010-1:2010 (3rd Edition) UL 61010-1:2012 CAN/CSA 61010-1-12	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
IEC 61010-2-010:2014 (3rd Edition) EN 61010-2-010:2014 (3rd Edition)	Particular requirements for laboratory equipment for the heating of material
IEC 60825-1:2014 (3rd Edition)	Safety of laser products – Part 1:Equipment classification and requirements
EN 61326-1:2013 (Class A) IEC 61326-1:2012 (Class A)	Electrical equipment for the measurement, control and Laboratory use – EMC Requirements Part1, Class A
Title 47, CFR Part 15 Subpart B	Unintentional radio frequency devices

Authorized by:

Mya Chomae

P. Regulatory Affairs

11 August 2016



Declaration of Conformity

Illumina, Inc. hereby declares under its sole responsibility that the product(s) listed are in conformity to the EMC Directive [2014/30/EU], Low Voltage Directive [2014/35/EU], and RED Directive [2014/53/EU].

MANUFACTURER:

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ADDRESS:

5200 Illumina Way

San Diego, CA 92122, USA

FACTORY LOCATION:

25861 Industrial Blvd.

Hayward, CA 94545, USA

PRODUCT TYPE:

Genetic Sequencer

MODEL:

MiSeq, MiSeqDx, MiSeqFGx

CE MARK AFFIXED:

2011

The construction of the product is in compliance with the following harmonized and/or consensus standards.

IEC/EN 61010-1:2010 UL 61010-1:2012 CAN/CSA 61010-1-12 EN 61010-2-081:2015 UL 61010-2-081: 2015 CAN/CSA-22.2 No. 61010-2-081:15 EN 61326-1:2013 IEC 61326-1:2012 IEC 61326-2-6:2012 EN 61326-2-6:2013	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements Particular requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes Electrical equipment for the measurement, control and Laboratory use – EMC Requirements Part 1, Class A EMC requirements Part 2-6: Particular requirements In vitro diagnostic (IVD) medical equipment
EN 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection
EN 55022:2010	Radio-frequency disturbance characteristics - Limits and methods of measurement
EN 50364:2010	Limitation of human exposure to electromagnetic fields from devices operating in the frequency range 0 Hz to 300 GHz, used in electronic article surveillance (EAS), radio frequency identification (RFID) and similar applications
ETSI EN 300 330-1 V1.7.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Part 1: Technical characteristics and test methods
ETSI EN 300 330-2 V1.5.1	Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

EN 301 489-1 V1.9.2	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-3 V1.6.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz
Title 47, CFR Part 15 Subpart C § 15.225	Intentional radiators operating within the band 13.110–14.010 MHz.
Title 47, CFR Part 15 Subpart B	Unintentional radio frequency devices

Authorized by:

Mya Thomae

VP, Regulatory Affairs

Date



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PRODUCT TYPE:

Genetic Sequencer

MODEL:

MiSeqDx

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EN 61010-2-081:2015 UL 61010-2-081: 2015 CAN/CSA-22.2 No. 61010-2-081:15	Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC/EN 61010-2-101:2015	Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-1:2013 IEC 61326-1:2012	Electrical equipment for the measurement, control and Laboratory use – EMC Requirements Part1, Class A
IEC 61326-2-6:2012 EN 61326-2-6:2013	EMC requirements Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
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11 August 2016