

## **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:

Illumina

ADDRESS:

5200 Illumina Way

San Diego, CA 92122, USA

**FACTORY LOCATION:** 

25861 Industrial Blvd.

Hayward, CA 94545, USA

PRODUCT TYPE:

Genetic Sequencer

AUTHORIZED EU REPRESENTATIVE:

MODEL:

NovaSeq<sup>™</sup> X, NovaSeq<sup>™</sup> X Plus

Illumina Netherlands B. V Steenoven 19

CE MARK AFFIXED:

2023

5626 Dk Eindoven The Netherlands

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

IEC 61010-1:2010/A1:2016 EN 61010-1:2010/A1:2019	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
IEC 61010-2-010:2019	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of Materials
IEC 61010-2-081:2019	Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 60825:2014 (Third Edition)	Safety of laser products. Equipment classification and requirements
EN 61326-1:2013(Class A)	Electrical equipment for the measurement, control and Laboratory use – EMC Requirements Part1, Class A
IEC 61326-1:2020 (Class A)	Electrical equipment for the measurement, control and Laboratory use – EMC Requirements Part1, Class A
EN 55032:2015/A11:2020	Electromagnetic compatibility of multimedia equipment. Emission Requirements
EN 61000-3-2:2019	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 301 489-1 V2.2.3	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 V2.2.0	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
EN 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Illumina declares the product listed above is in compliance with RoHS Directive 2011/65/EU, as amended by (EU) 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This declaration is based on analysis of raw materials used in the manufacturing process and supplier's declarations.

Lead (0,1%)	Polybrominated diphenylethers (PBDE) (0,1%)
Mercury (0,1%)	Bis(2-Ethylhexyl) phthalate (DEHP) (0,1%)
Cadmium (0,01%)	Benzyl butyl phthalate (BBP) (0,1R%)
Hexavalent chromium (0,1%)	Dibutyl phthalate (DBP) (0,1%)
Polybrominated biphenyls (PBB) (0,1%)	Diisobutyl phthalate (DIBP) (0,1%)

Annex III exemptions are applied.

Authorized by:

Karen Gutekunst

VP, Regulatory Affairs

10-FEB-2023

Date



## **Declaration of Conformity**

Illumina, Inc. hereby declares under its sole responsibility that the product(s) listed are in conformity to the LVD [2014/35/EU], EMC Directive [2014/30/EU], Radio Equipment Directive (RED) [2014/53/EU] and RoHS Directive [2011/65/EU] as amended by Commission Delegated Directive (EU) 2015/863.

MANUFACTURER:

ADDRESS:

Illumina, Inc

5200 Illumina Way

San Diego, CA 92122, USA

Illumina Singapore Pte. Ltd North Tech Lobby 3 #02-13118 29 Woodlands Industrial Park E1

**FACTORY LOCATION:** 

Singapore, 757716

PRODUCT TYPE:

MODEL:

RFID Reader TR-001-44

CE MARK AFFIXED:

2013

**AUTHORIZED EU REPRESENTATIVE:** 

Illumina Netherlands B. V. Freddy van Riemsdijkweg 15

5657 EE Eindhoven The Netherlands

Illumina Netherlands B. V.

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

IEC 62638-1:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
ETSI EN 301 489-1 V2.2.3	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
ETSI EN 301 489-3 V2.2.0	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro Magnetic 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
EN 55032:2020	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement
ETSI EN 300 330 V2.1.1	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; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Illumina declares the product listed above is in compliance with RoHS Directive 2011/65/EU, as amended by (EU) 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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The following Annex III exemptions are applied: 7(c)-1

Authorized by:

Karen Gutekunst

**VP, Regulatory Affairs** 

Intekund

10-FEB-2023

Date