illumina®

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	FACTORY LOCATION:
ADDRESS:	5200 Illumina Way San Diego, CA 92122, USA	llumina Singapore Pte. Ltd North Tech Lobby 3 #02-13118 29 Woodlands Industrial Park E1 Singapore, 757716
PRODUCT TYPE:	Genetic Sequencer	AUTHORIZED EU REPRESENTATIVE: Illumina Netherlands B. V Steenoven 19 5626 Dk Eindoven The Netherlands
MODEL:	MiSeq i100, MiSeq i100 Plus	
CE MARK AFFIXED:	2024	

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

EN 61010-1:2010/A1:2019	*Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements*
EN 61010-2-010:2020	*Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of Materials*
EN 61010-2-081:2020	*Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*
EN/IEC 61326-1:2021	*Electrical equipment for the measurement, control and Laboratory use – EMC Requirements Part1, Class A*
EN 55011:2013+A1:2017+A11:2020+A2:2021	*Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement*
CENELEC EN 55032:2015	*Electromagnetic compatibility of multimedia equipment. Emission Requirements*
CENELEC EN 61000-3-2:2014	*Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)*
CENELEC 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 V2.3.2	*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 *Electronically signed by: Karen Gutekunst Reason: Approver Date: Sep 12. 2024 11:51 PDT*

Karen Gutekunst
VP, Regulatory Affairs

Date

MiSeq i100_MiSeq i100 Plus_CE DoC_09Sept2024

Final Audit Report 2024-09-12

Created:	2024-09-12
By:	Carol Escano (cescano@illumina.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAnb_50QMyHi0aMz1t7LDRMPgzZTtoN8Tv

"MiSeq i100_MiSeq i100 Plus_CE DoC_09Sept2024" History

Document created by Carol Escano (cescano@illumina.com)
2024-09-12 - 6:19:58 PM GMT- IP address: 208.56.48.14

Document emailed to Karen Gutekunst (kgutekunst@illumina.com) for signature
2024-09-12 - 6:20:36 PM GMT

Email viewed by Karen Gutekunst (kgutekunst@illumina.com)
2024-09-12 - 6:51:00 PM GMT- IP address: 192.84.34.85

Karen Gutekunst (kgutekunst@illumina.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-09-12 - 6:51:18 PM GMT

Karen Gutekunst (kgutekunst@illumina.com) authenticated with Adobe Acrobat Sign.
2024-09-12 - 6:51:57 PM GMT

Document e-signed by Karen Gutekunst (kgutekunst@illumina.com)
Signing reason: Approver
Signature Date: 2024-09-12 - 6:51:58 PM GMT - Time Source: server- IP address: 192.84.34.85

Agreement completed.
2024-09-12 - 6:51:58 PM GMT