



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 the Low Voltage Directive [2014/35/EU].

MANUFACTURER:

ADDRESS:

Illumina, Inc

5200 Illumina Way

San Diego, CA 92122, USA

FACTORY LOCATION:

Tecan Schweiz AG Seestrasse 103

8708 Männedorf, SWITZERLAND

PRODUCT TYPE:

MODEL:

CE MARK AFFIXED:

Automated Liquid Handler

Infinium RoMa

2020

AUTHORIZED EU REPRESENTATIVE:

Illumina Netherlands B. V.

Freddy van Riemsdijkweg 15

5657 EE Eindhoven The Netherlands

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

EN 61010-1:2010/A1:2019 IEC 61010-1:2010, AMD1:2016	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
IEC/EN 61010-2-010:2014	Particular requirements for heating of materials.
IEC/EN 61010-2-081:2015	Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC/EN 60825:2014	Safety of laser products - Part 1: Equipment classification and requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 61326-1:2013	Electrical equipment for the measurement, control and Laboratory use – EMC Requirements Part1, Class A
EN 55011:2016+A1:2017	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement (Class A)
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 61000-3-3:2103	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

Authorized by:

Karen Gutekunst

VP, Regulatory Affairs

30-SEP-2020

Date

Revision: 00

CERTIFICATE OF COMPLIANCE **RoHS Declaration**

MANUFACTURER: Illumina Inc.,

5200 Illumina Way

San Diego, CA 92122 USA

Product Name:

Automated Liquid Handler

Model Number:

Infinium RoMa

Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restriction substances.

This document declares that Illumina Inc. Research Use Only product above are in conformity with 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment with exemptions.

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

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Annex II Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials are:

Restricted Hazardous Substances	
Lead (Pb) – 0.1%	Hexavalent chromium (Cr VI) – 0.1%
Mercury (Hg) – 0.1%	Polybrominated biphenyls (PBB) – 0.1%
Cadmium (Cd) - 0.01%	Polybrominated diphenylethers (PBDE) – 0.1%

The following Annex III exemptions are applied: 6a, 6b, 6c, 7a, 7(c)-1, 7(c)-II & 21

Signature: A

aun Gritekunit Karen Gutekunst

VP, Regulatory Affairs

Date: 30-SEP-2020

Template Effective Date: 25-SEP-2020