EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 734191 R000

Manufacturer: Illumina, Inc.

Address:
5200 Illumina Way
San Diego
CA 92122
USA

Single Registration Number: US-MF-000013476

EU Authorised Representative: Illumina Netherlands B.V.

Address:
Steenoven 19
5626 DK Eindhoven
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-11-05**

Current Issue Date: **2025-06-19**

Starting Validity Date: **2025-06-19**

Expiry Date: **2026-11-04**

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Device Schedule: Class D, C, and B devices

Class C devices	Intended purpose
W0106 – Genetic Testing IVP3004 - In vitro diagnostic devices which require knowledge regarding chromosomal analysis	In vitro diagnostic whole genome sequencing devices intended to be used for genetic testing to detect partial duplications, deletions and aneuploidy status in fetal DNA isolated from maternal peripheral whole blood.
W0106 - Genetic Testing IVP3011 - Molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	In vitro diagnostic sequencing devices, intended to be used for genetic testing to detect monogenetic disorders in DNA isolated from human peripheral whole blood.
Class B devices	**Intended purpose**
IVR 0701 - Devices which are controls without a quantitative assigned value	In vitro diagnostic controls without a quantitative assigned value to be used for monitoring performance of molecular diagnostic testing for the detection of DNA and RNA variants.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-11-05	3271628	Issued
2023-05-22	3886854	Supplemented – Addition of device group W0106 + IVP3011.
Current	30426228	Supplemented – Addition of IVR 0701 device category.

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