EU Quality Management System Certificate

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

IVDR 734191 R001

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: **2026-09-02**

Starting Validity Date: **2026-11-05**

Expiry Date: **2031-11-04**

...making excellence a habit.™

EU Quality Management System Certificate

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

IVDR 734191 R001

Device Schedule: Class D, C, and B devices

Class C companion diagnostic devices	**Intended purpose**
TruSight™ Oncology Comprehensive	See IVDR 787983
TruSight™ Oncology Comprehensive HRD (DRAGEN)	See IVDR 821502
Class C devices	**Intended purpose**
W0106 – Genetic Testing IVP 3004 - In vitro diagnostic devices which require knowledge regarding chromosomal analysis	In vitro diagnostic next generation sequencing devices intended to analyse DNA to identify genomic abnormalities.
W0106 - Genetic Testing IVP 3011 – In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	In vitro diagnostic next-generation sequencing devices intended to assess DNA for inherited genetic conditions.
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.

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

Current Issue Date: **2026-09-02**

Starting Validity Date: **2026-11-05**

Expiry Date: **2031-11-04**

...making excellence a habit.™

EU Quality Management System Certificate

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

IVDR 734191 R001

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.
2025-06-19	30426228	Supplemented – Addition of IVR 0701 device category.
2026-03-31	30636093	Supplemented – Addition of TruSight™ Oncology Comprehensive. Amended – Alignment of intended purpose statements to device group / category for Class B IVR 0701, Class C W0106 + IVP 3004, and Class C W0106 + IVP 3011.
2026-04-28	30702439	Supplemented – Addition of TruSight™ Oncology Comprehensive HRD (DRAGEN).
Current	30518001	Re-Issued – Certificate Renewal.

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

Current Issue Date: **2026-09-02**

Starting Validity Date: **2026-11-05**

Expiry Date: **2031-11-04**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
A Member of the BSI Group of Companies.