EU DECLARATION OF CONFORMITY

Product Name	TruSight™ Oncology DNA Control v2
REF	20090155
Basic UDI-DI (BUDI-DI)	0081627002RNADNACTRLMV
Product Name	TruSight™ Oncology RNA Control v2
REF	20090165
Basic UDI-DI (BUDI-DI)	0081627002RNADNACTRLMV

Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122
USA
SRN: US-MF-000013476

EC REP

Illumina Netherlands B.V.
Steenoven 19
5626 DK Eindhoven
The Netherlands
SRN: NL-AR-000012614

We, Illumina, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices

RISK CLASS:

☐ A ☒ B ☐ C ☐ D

INTENDED PURPOSE: Refer to attached page

CONFORMITY ROUTE:

ANNEX IX Full Quality System

EU CERTIFICATE #: IVDR 734191
Name of Notified Body: BSI Group, The Netherlands B.V.
Notified Body Identification: 2797

Common Specification (CS): N/A

Karen Gutekunst
Electronically signed by: Karen Gutekunst
Reason: Approver
Date: Jul 30, 2026 17:23:40 PDT

Karen Gutekunst
Vice President, Regulatory Affairs
Illumina, Inc.

30-Jul-2026
Date

San Diego, CA (USA)

Issued in

Intended Purpose:

TruSight Oncology DNA Control v2

The TruSight™ Oncology DNA Control v2 is intended for qualitative *in vitro* diagnostic use as a quality control to monitor analytical performance of the library preparation, sequencing, and analysis steps of Next Generation Sequencing (NGS) based molecular diagnostic assays used for the detection of select DNA variants. This product is also intended to help monitor performance of an NGS test system by detecting analytical deviations such as those that may arise from reagent or instrument variation in genetic testing.

TruSight Oncology RNA Control v2

The TruSight™ Oncology RNA Control v2 is intended for qualitative *in vitro* diagnostic use as a quality control to monitor analytical performance of the library preparation, sequencing, and analysis steps of Next Generation Sequencing (NGS) based molecular diagnostic assays used for the detection of select RNA variants. This product is also intended to help monitor performance of an NGS test system by detecting analytical deviations such as those that may arise from reagent or instrument variation in genetic testing.

Device Component List

Device Name **TruSight™ Oncology DNA Control v2, 20090155**

Device Components : See below

Component Name	Part Number
TruSight™ Oncology DNA Control v2	20112821

Device Name **TruSight™ Oncology RNA Control v2, 20090165**

Device Components : See below

Component Name	Part Number
TruSight™ Oncology RNA Control v2	20112822

200084377_00_TSOControls_IVDR_Declaration_of_Conformity_v2Only

Final Audit Report 2026-07-31

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