By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

IVDR 787983 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 assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2026-03-31**

Current Issue Date: **2026-03-31**

Starting Validity Date: **2026-03-31**

Expiry Date: **2031-03-30**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

TruSight™ Oncology Comprehensive is a qualitative in vitro diagnostic test that uses targeted next-generation sequencing to detect variants in 517 genes using nucleic acids extracted from formalin-fixed, paraffin embedded (FFPE) tumor tissue samples from cancer patients with solid malignant neoplasms using the Illumina® NextSeq™ 550Dx instrument. The test can be used to detect single nucleotide variants, multinucleotide variants, insertions, deletions, and gene amplifications from DNA, and fusions and splice variants from RNA. The test also reports a Tumor Mutational Burden (TMB) score and Microsatellite Instability (MSI) status.

The test is intended to be used as a companion diagnostic to identify cancer patients who may benefit from treatment with the targeted therapies listed in Table 1, in accordance with the approved therapeutic product labeling.

In addition, the test is intended to provide tumor profiling information as an assessment of clinically significant or potentially clinically significant variants present in the tumor tissue as an aid for use by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Genomic findings other than those listed in Table 1 of the intended use statement are not conclusive or prescriptive for labeled use of any specific therapeutic product. Any detected clinically significant variant with an associated therapy in the selected cancer type must be confirmed with follow-up testing.

Table 1 Companion Diagnostic Indications

Tumor Type	**Biomarkers(s) Detected**	**Targeted Therapy**
Solid Tumors	NTRK1/2/3 Fusions	VITRAKVI® (larotrectinib)
Non-Small Cell Lung Cancer (NSCLC)	RET Fusions	RETSEVMO® (selpercatinib)

Risk Classification: Class C Companion Diagnostic

Type (Codes as per (EU) 2017/2185): IVR 0302

Device Name	**Model**	**Basic UDI-DI**
TruSight™ Oncology Comprehensive	20032573	0081627002CDXONCOLOGYJW
Local Run Manager TruSight™ Oncology Comprehensive (EU) Analysis Module	20100341	0081627002TSOSWWC

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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
Current	3896313	Issued

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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.

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