By Royal Charter

EU Technical Documentation Assessment Certificate

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

IVDR 821502 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: **2026-04-28**

Current Issue Date: **2026-04-28**

Starting Validity Date: **2026-04-28**

Expiry Date: **2031-04-27**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

TruSight™ Oncology Comprehensive HRD (DRAGEN) is a qualitative in vitro diagnostic test that uses targeted next-generation sequencing to enable assessment of Homologous Recombination Deficiency (HRD) using DNA extracted from formalin-fixed, paraffin-embedded (FFPE) tumor tissue samples from ovarian cancer patients using the Illumina® NextSeq™ 550Dx instrument. The test can be used to detect single nucleotide variants, insertions, deletions, and large rearrangements in BRCA1 and BRCA2 genes, and report a Genomic Instability Score (GIS).

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

Table 1 Companion Diagnostic Indication

Tumor Type	Biomarker(s) Detected	Therapy
Ovarian cancer, including epithelial ovarian, fallopian tube, and primary peritoneal cancer	Homologous Recombination Deficiency (HRD) (defined as deleterious or suspected deleterious mutations in BRCA1 and BRCA2 genes and/or positive Genomic Instability Score)	LYNPARZA® (olaparib)

Risk Classification: Class C Companion Diagnostic

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

Device Name	Model	Basic UDI-DI
TruSight™ Oncology Comprehensive HRD (DRAGEN)	20134650	0081627002TSOHRDDGRK
TruSight™ Oncology Comprehensive (DRAGEN)	20140799	0081627002TSODGTX
Illumina Connected Run TruSight™ Oncology Comprehensive HRD (EU, DRAGEN) Analysis Module	20132935	0081627002ICRTSOHRD6B

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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	30337160	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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