EU DECLARATION OF CONFORMITY

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

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SRN: US-MF-000013476

EC REP

Illumina Netherlands B.V.
Steenoven 19
5626 DK Eindhoven
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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:	**EU CERTIFICATE #:**
ANNEX IX Full Quality System	IVDR 734191 (QMS) - (EU) 2017/746 Annex IX Chapter I and III IVDR 821502 (Product-Specific) (EU) 2017/746 Annex IX Chapter II

Name of Notified Body: BSI Group, The Netherlands B.V.
Notified Body Identification: 2797

Common Specification (CS): N/A

Electronically signed by: Karen Gutekunst
Reason: Approver
Date: Jun 25, 2026 09:55:29 PDT

Karen Gutekunst

Karen Gutekunst
Vice President, Regulatory Affairs
Illumina, Inc.

25-Jun-2026
Date

San Diego, CA (USA)
Issued in

Intended Purpose:

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 Indications

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)

Device Component List

Device Name: **TruSight™ Oncology Comprehensive HRD (DRAGEN), 20134650**

Device Components: See below

Component Name	Part Number
TruSight Oncology Comp Enrichment HRD (Refrigerate)	20140116
TruSight Oncology Comp Enrichment HRD (Freeze)	20140115
TruSight Oncology Comp HRD Content	20140117

Device Name: **TruSight™ Oncology Comprehensive (DRAGEN), 20140799**

Device Components: See below

Component Name	Part Number
TruSight™ Oncology Comp RNA Library Prep	20031127
TruSight™ Oncology Comp Library Prep (Freeze)	20031118
TruSight™ Oncology Comp Library Prep (Refrigerate)	20031119
TruSight™ Oncology Comp UP Index Primers	20031120
TruSight™ Oncology Comp CP Index Primers	20031126
TruSight™ Oncology Comp Enrichment (Refrigerate)	20031123
TruSight™ Oncology Comp Enrichment (Freeze)	20031121
TruSight™ Oncology Comp Content Set	20031122

Device Name **Illumina Connected Run TruSight™ Oncology Comprehensive HRD (EU, DRAGEN) Analysis Module, 20132935**

200081898_01_TSO Comp HRD Wave 1 IVDR DoC

Final Audit Report 2026-06-25

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