

DECLARATION OF CONFORMITY

Manufacturer: Illumina
5200 Illumina Way
San Diego, CA 92122
United States

European Authorized Representative: Illumina Netherlands B.V.
Steenoven 19
5626 DK Eindhoven
The Netherlands

Device Name: TruSight Oncology Comprehensive (EU)
**Note: See device components for each of the device model/catalogue number on page 2 of this declaration of conformity.*

Device Model/Catalogue Number: 20063092 TruSight™ Oncology Comprehensive (EU) kit
20051843 Local Run Manager TruSight Oncology Comprehensive (EU) Analysis Module

Basic-UDI: 0081627002CDXONCOLOGYJW

Classification: General IVD

Conformity Assessment Procedure: Annex III of IVDD 98/79/EC Council Directive; Self-Declaration

We, Illumina, declare under our sole responsibility that the *in vitro* Diagnostic Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 98/79/EC (including amendments issued in the years following) which apply to them.

This declaration is supported by the EC Quality System Certificate(s) according to the provisions of relevant Annex(es) of this Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Authorized by:

Joe McMullen
Electronically signed by:
Joe McMullen
Reason: Approver
Date: Sep 30, 2022 15:32
PDT

E. Joseph McMullen
Sr. Director, Regulatory Affairs
Illumina, Inc.

30-Sep-2022

Date

Device Component List

Device Name **TruSight Oncology Comprehensive (EU) Kit, 20063092**

Device Components : See below

Component Name	Part Number
TruSight™ Oncology Comp RNA Lib 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 **Local Run Manager TruSight Oncology Comprehensive (EU) Analysis Module, 20051843**

Device Components The software is installed using the TSO Comp (EU) v2.3.5 USB Kit (Illumina PN 20075239). It includes the sub-components listed below.

Component Name	Part Number
TSO Comp (EU) Software Suite v2.3.5	20075244
TSO Comp (EU) Claims Package v2.0.0	20051760






200013862_02_DoC_TSO Comp (EU) TP +NTRK CDx Claims

Final Audit Report

2022-09-30

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