

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 Controls*
**Note: See device components for each of the device model/catalogue number on page 2 of this declaration of conformity.*

Device Model/Catalogue Number: 20065041 TruSight™ Oncology DNA Control
20065042 TruSight™ Oncology RNA Control

Basic-UDI: 0081627002RNADNACTRLMV

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: Mar 11
2022 10:03 PST

11-Mar-2022

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

Date

Device Component ListDevice Name **TruSight™ Oncology DNA Control, 20065041**

Device Components : See below

| Component Name | Part Number |
|--------------------------------|--------------------|
| TruSight™ Oncology DNA Control | 20049024 |

Device Name **TruSight™ Oncology RNA Control, 20065042**

Device Components : See below

| Component Name | Part Number |
|--------------------------------|--------------------|
| TruSight™ Oncology RNA Control | 20049023 |






TSO Controls DoC

Final Audit Report

2022-03-11

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