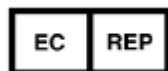


## EU DECLARATION OF CONFORMITY

<b>Product Name(s) / Trade Name(s)</b>	TruSight™ Whole Genome		
<b>Intended Purpose</b>	<p>TruSight Whole Genome is a qualitative in vitro diagnostic device intended for whole genome sequencing and detection of single nucleotide variants, insertion/deletions, copy number variants, runs of homozygosity, short tandem repeat expansions, and mitochondrial variations in human genomic DNA extracted from blood.</p> <p>TruSight Whole Genome includes the TruSight Whole Genome Dx Library Prep with UD Indexes and the TruSight Whole Genome Analysis Application Software. The device is intended to be used with compatible downstream germline applications to develop in vitro diagnostic assays, and by qualified laboratory personnel and assay developers.</p> <p>TruSight Whole Genome is intended to be used on the NovaSeq 6000Dx Instrument.</p>		
	<b>REF</b>	<b>Product Component</b>	<b>Basic UDI-DI (BUDI-DI)</b>
	20106190	TruSight Whole Genome Analysis Application	081627002TSWGAX
	20093209	TruSight Whole Genome Dx Library Prep with UD Indexes, 24 sample	0081627002TSWGLP3W



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 SRN: US-MF-000013476



Illumina Netherlands B.V.  
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 The Netherlands  
 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

**CONFORMITY ROUTE:**

Annex I & II+III of Regulation EU 2017/746; Self-Declaration

**Common Specification (CS): N/A**

*Joe McMullen*

Electronically signed by: Joe McMullen  
Reason: Approver  
Date: Apr 25, 2024 13:38 PDT

April 25, 2024

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

**Date**

San Diego, California, USA  
**Issued in**

**Product/Device Component List**Product/Device Name: **TruSight Whole Genome Dx Library Prep with UD Indexes, 24 sample - 20093209**

Product/Device Components: See below

<b>Component Name</b>	<b>Part Number</b>
TruSight Whole Genome Dx Library Prep Box 1	20072256
TruSight Whole Genome Dx Library Prep Box 2	20072257
TruSight Whole Genome Dx 32 Unique Dual Indexes	20072258








# 200054140 \_01\_Trusight Whole Genome, IVDR EU Declaration of Conformity

Final Audit Report

2024-04-25

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