EU DECLARATION OF CONFORMITY

Product Name(s) / Trade Name(s)	NextSeq™ 550Dx Instrument
Intended Purpose	The NextSeq™ 550Dx instrument is intended for sequencing of DNA libraries when used with in vitro diagnostic assays. The NextSeq™ 550Dx instrument is to be used with specific registered, certified, or approved in vitro diagnostic reagents and analytical software.
REF	20005715
Basic UDI-DI (BUDI-DI)	0081627002NEXTSEQAD
Product Name(s) / Trade Name(s)	NextSeq™ 550Dx High Output Reagent Kit v2.5 (300 cycles)
Intended Purpose	The Illumina NextSeq™ 550Dx High Output Reagent Kit v2.5 (300 Cycles) is a set of reagents and consumables intended for sequencing of sample libraries when used with validated assays. The kit is intended for use with the NextSeq™ 550Dx instrument and analytical software.
REF	20028871
Basic UDI-DI (BUDI-DI)	0081627002HOKTQU
Product Name(s) / Trade Name(s)	NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles)
Intended Purpose	The Illumina NextSeq™ 550Dx High Output Reagent Kit v2.5 (75 Cycles) is a set of reagents and consumables intended for sequencing of sample libraries when used with validated assays. The kit is intended for use with the NextSeq™ 550Dx instrument and analytical software.
REF	20028870
Basic UDI-DI (BUDI-DI)	0081627002HOKTQU

Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122
USA
SRN: US-MF-000013476

EC REP

Illumina Netherlands B.V.
Steenoven 19
5626 DK Eindhoven
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 (Instrument and Reagents)
- Radio Equipment Directive 2014/53/EU (Instrument)
- RoHS Directive 2011/65/EU as amended by (EU) 2015/863 (Instrument) – Annex III exemptions apply

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: May 5, 2022 09:20 PDT

05-May-2022

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

Date

San Diego, CA

Issued in

200016217_00_NextSeq 550Dx_IVDR_Declaration of Conformity

Final Audit Report 2022-05-05

Created:	2022-05-03
By:	Debleena Sinha (dsinha@illumina.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA_tkUZbPQ_ofkSPW-X9T7k6jme2q1jx5p

"200016217_00_NextSeq 550Dx_IVDR_Declaration of Conformity" History

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