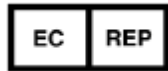


EU DECLARATION OF CONFORMITY

<p>Product Name(s) / Trade Name(s)</p> <p style="text-align: center;">Intended Purpose</p> <p style="text-align: center;">REF</p> <p>Basic UDI-DI (BUDI-DI)</p>	<p>NextSeq™ 550Dx Instrument</p> <p>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.</p> <p>20005715</p> <p>0081627002NEXTSEQAD</p>
<p>Product Name(s) / Trade Name(s)</p> <p style="text-align: center;">Intended Purpose</p> <p style="text-align: center;">REF</p> <p>Basic UDI-DI (BUDI-DI)</p>	<p>NextSeq™ 550Dx High Output Reagent Kit v2.5 (300 cycles)</p> <p>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.</p> <p>20028871</p> <p>0081627002HOKTQU</p>
<p>Product Name(s) / Trade Name(s)</p> <p style="text-align: center;">Intended Purpose</p> <p style="text-align: center;">REF</p> <p>Basic UDI-DI (BUDI-DI)</p>	<p>NextSeq™ 550Dx High Output Reagent Kit v2.5 (75 cycles)</p> <p>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.</p> <p>20028870</p> <p>0081627002HOKTQU</p>



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



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 25, 2023 14:03 PDT

May 25, 2023

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

Date

San Diego, CA

Issued in

Product Components:**NextSeq™ 550Dx High Output Reagent Kit v2.5 (75 cycles); 20028870**

- NextSeq™ 550Dx High Output Reagent Cartridge v2 (75 cycles); 20019560
- NextSeq™ 550Dx Buffer Cartridge v2 (75 cycles); 20019561
- NextSeq™ 550Dx High Output Flow Cell Cartridge v2.5 (75 cycles); 20031098
- NextSeq™ 550Dx Accessory Box (75 cycles); 20019563

NextSeq™ 550Dx High Output Reagent Kit v2.5 (300 cycles); 20028871

- NextSeq™ 550Dx High Output Reagent Cartridge v2 (300 cycles); 20019555
- NextSeq™ 550Dx Buffer Cartridge v2 (300 cycles); 20019556
- NextSeq™ 550Dx High Output Flow Cell Cartridge v2.5 (300 cycles); 20026365
- NextSeq™ 550Dx Accessory Box (300 cycles); 20019558






200016217_01_NextSeq 550Dx_IVDR_Declaration of Conformity_May 25.2023

Final Audit Report

2023-05-25

Created:	2023-05-25
By:	Samson Gong (sgong2@illumina.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAOenli8R7TkMn0b7M6Ao199lozTQnL7GW

"200016217_01_NextSeq 550Dx_IVDR_Declaration of Conformity_May 25.2023" History

-  Document created by Samson Gong (sgong2@illumina.com)
2023-05-25 - 4:17:37 PM GMT- IP address: 192.84.34.98
-  Document emailed to Joe McMullen (jmcullen@illumina.com) for signature
2023-05-25 - 4:18:23 PM GMT
-  Joe McMullen (jmcullen@illumina.com) authenticated with Adobe Acrobat Sign.
2023-05-25 - 9:03:34 PM GMT
-  Document e-signed by Joe McMullen (jmcullen@illumina.com)
Signing reason: Approver
Signature Date: 2023-05-25 - 9:03:34 PM GMT - Time Source: server- IP address: 163.116.248.45
-  Agreement completed.
2023-05-25 - 9:03:34 PM GMT