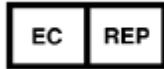


EU DECLARATION OF CONFORMITY

<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>



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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

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