

DECLARATION OF CONFORMITY

Manufacturer: Illumina
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San Diego, CA 92122
United States

European Authorized Representative: Illumina Netherlands B.V.
Steenoven 19
5626 DK Eindhoven
The Netherlands

Device Name: NextSeq™ 550Dx High Output Reagent Kit v2.5 (300 cycles)
NextSeq™ 550Dx High Output Reagent Kit v2.5 (75 cycles)

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

Device Model/Catalogue Number: 20028871
20028870

Basic-UDI: 0081627002NEXTSEQAD

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 within this Declaration of Conformity and distributed onwards from the signature date below.

Authorized by:

25-AUG-2021

Bryan Schneider
Associate Director, Regulatory Affairs

Date

Device Component List

Device Name : **NextSeq 550Dx High Output Reagent Kit v2.5 (300 cycles), 20028871**
Device Components : 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

Device Name : **NextSeq 550Dx High Output Reagent Kit v2.5 (75 cycles), 20028870**
Device Components : 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