

DECLARATION OF CONFORMITY

Manufacturer: Illumina
5200 Illumina Way
San Diego, CA 92122
United States

European Authorized Representative: Illumina Netherlands B. V.
Freddy van Riemsdijkweg 15
5657 EE Eindhoven
The Netherlands

Device(s) Name: NextSeq™ 550Dx High Output Reagent Kit v2 (300 cycles)
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: **20019554**
20028871
20028870

Basic-UDI: 0081627002NEXTSEQAD

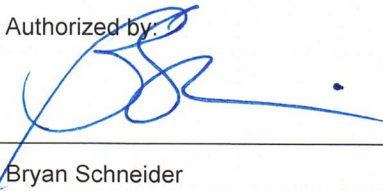
Classification: General IVD

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:



Bryan Schneider
Associate Director, Regulatory Affairs - HQ

15-APR-2020

Date (DD-MMM-YYYY)

Device Component List

Device Name	: NextSeq 550Dx High Output Reagent Kit v2 (300 cycles), 20019554
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 (300 cycles), 20019557 NextSeq™ 550Dx Accessory Box (300 cycles), 20019558
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