

NextSeq 550Dx Instrument DIR: 1000000044969, Ver. 02 Effective Date: 31-AUG-2021

DECLARATION OF CONFORMITY

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Illumina

5200 Illumina Way San Diego, CA 92122

United States

European Authorized Representative:

Illumina Netherlands B.V.

Steenoven 19 5626 DK Eindhoven The Netherlands

Device Name:

NextSeq 550Dx Instrument

Device Model/Catalogue Number:

20005715

Basic UDI-DI:

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

31-AUG-2021

Date