

DECLARATION OF CONFORMITY

Manufacturer: 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: TruSeq Custom Amplicon Dx Kit

Device Model/Catalogue Number: 20005718
Basic UDI-DI 0081627002TSCAS6
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 above distributed from the signature date forward.

Authorized by:



Electronically signed
by: Joe McMullen
Reason: Approver
Date: Sep 21, 2021
09:14 PDT

21-Sep-2021

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

Date






1000000044432_02_Declaration_of_Conformity _TSCA Dx Kit

Final Audit Report

2021-09-21

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