

## **DECLARATION OF CONFORMITY**

Manufacturer:

Illumina

5200 Illumina Way San Diego, CA 92122

**United States** 

European Authorized Representative:

Illumina Netherlands B. V.

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5657 EE Eindhoven
The Netherlands

Device Name:

TruSeq™ Custom Amplicon Dx Kit

\*Note: See device components on page 2 of this declaration of conformity.

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:

Bryan Schneider

Associate Director, Regulatory Affairs - HQ

Date (DD-MMM-YYYY)

15-APR-2020





## **Device Component List**

Device Name

TruSeq™ Custom Amplicon Kit Dx, 20005718

**Device Components:** 

TruSeq™ Custom Amplicon Kit Dx 1/3, 20003227

TruSeq™ Custom Amplicon Kit Dx 2/3, 20003460

TruSeq<sup>™</sup> Custom Amplicon Kit Dx 3/3, 20003463