



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 Name:

TruSeq™ Custom Amplicon Dx Kit - FFPE QC

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

Device Model/Catalogue Number:

20006259

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

22-APR-2020

Date (DD-MMM-YYYY)





Device Component List

Device Name : TruSeq™ Custom Amplicon Dx Kit – FFPE QC, 20006259

Device Components : TruSeq™ Custom Amplicon Kit Dx 1/1, 20003464