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


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:

Joe McMullen
Sr. Director, Regulatory Affairs
Illumina, Inc.

21-Sep-2021
"1000000044432_02_Declaration_of_Conformity_TSCA Dx Kit"

History

Document created by Bryan Schneider (bschneider@illumina.com)
2021-09-21 - 3:05:07 PM GMT - IP address: 192.84.34.97

Document emailed to Joe Mcmullen (jmcmullen@illumina.com) for signature
2021-09-21 - 3:05:33 PM GMT

Joe Mcmullen (jmcmullen@illumina.com) verified identity with Adobe Sign authentication
2021-09-21 - 4:14:44 PM GMT

Document e-signed by Joe Mcmullen (jmcmullen@illumina.com)
Signature Date: 2021-09-21 - 4:14:44 PM GMT - Time Source: server- IP address: 192.84.34.96

Agreement completed.
2021-09-21 - 4:14:44 PM GMT