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: MiSeqDx™ Instrument

Device Model/Catalogue Number: DX-410-1001 (20014737)
Basic UDI-DI: 0081627002MISEQQP
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
E. Joseph McMullen
Sr. Director, Regulatory Affairs
Illumina, Inc.

Date: 21-Sep-2021
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