

DECLARATION OF CONFORMITY

Manufacturer: Illumina
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San Diego, CA 92122
United States

European Authorized Representative: Illumina Netherlands B. V.
Freddy van Riemsdijkweg 15
5657 EE Eindhoven
The Netherlands

Device Name: **MiSeqDx Reagent Kit v3**
**Note: See device components on page 2 of this declaration of conformity.*

Device Catalogue Number: **20012552**

Basic UDI-DI: 0081627002MISEQQP

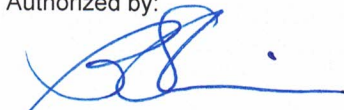
Classification: General IVD

Conformity Assessment Procedure: Annex III of IVDD 98/79/EC Council Directive; Self-certified

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

15-APR-2020

Date (DD-MMM-YYYY)

Device Component List

Device Name : **MiSeqDx Reagent Kit v3 (20012552)**

Device Components : MiSeqDx Reagent Kit v3 1/2, 20011196
MiSeqDx Reagent Kit v3 2/2, 20011197