

## 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 Reagent Kit v3

Device Model/Catalogue Numbers: 20012552  
20037124

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:

*Joe McMullen*

Electronically signed  
by: Joe McMullen  
Reason: Approval  
Date: Sep 21, 2021  
09:15 PDT

21-Sep-2021

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E. Joseph McMullen  
Sr. Director, Regulatory Affairs  
Illumina, Inc.

Date

## Device Component List

Device Name : **MiSeqDx Reagent Kit v3 (20012552)**  
Device Components : MiSeqDx Reagent Kit v3, Box 1 of 2; 20011196  
MiSeqDx Reagent Kit v3, Box 2 of 2; 20011197

Device Name : **MiSeqDx Reagent Kit v3 (20037124)**  
Device Components : MiSeqDx Reagent Kit v3, Box 1 of 2; 20036261  
MiSeqDx Reagent Kit v3, Box 2 of 2; 20036262






# 1000000044429\_03\_Declaration\_of\_Conformity \_MiSeqDx Reagent Kit v3

Final Audit Report

2021-09-21

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