illumina

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 5657EE Eindhoven Netherlands
Device Name:	**MiSeqDx Cystic Fibrosis 139-Variant Assay (20 runs)** **MiSeqDx Cystic Fibrosis 139-Variant Assay (2 runs)** **MiSeqDx Cystic Fibrosis Clinical Sequencing Assay**
Device Model/Catalogue Number:	DX-102-1003 DX-102-1004; DX-102-1001
Basic UDI-DI:	0081627002CYSTFIB8C
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 within this Declaration of Conformity and distributed onwards from the signature date below.

Authorized by:

Bryan Schneider
Associate Director, Regulatory Affairs - HQ

15-APR-2020
Date (DD-MMM-YYYY)

Device Component List

Device Name MiSeqDx Cystic Fibrosis System

Device Components:

Component Name	Part number
MiSeqDx Cystic Fibrosis 139-Variant Assay	
MiSeqDx Cystic Fibrosis 139-Variant Assay (2-run; 96 samples) (ordering catalog DX-102-1004)	15036580
MiSeqDx Cystic Fibrosis 139-Variant Assay (20-run; 960 samples) (ordering catalog DX-102-1003)	15036577
MiSeqDx Cystic Fibrosis Clinical Sequencing Assay (ordering catalog DX-102-1001)	15036620