illumina®

DECLARATION OF CONFORMITY

Manufacturer:	Illumina Inc. 5200 Illumina Way San Diego, CA 92122 USA
European Authorized Representative:	Illumina Cambridge Limited Chesterford Research Park Little Chesterford Saffron Walden CB10 1XL United Kingdom
Device Name(s):	MiSeqDx® Instrument MiSeqDx Universal Kit MiSeqDx Cystic Fibrosis 139-Variant Assay (20 runs) MiSeqDx Cystic Fibrosis 139-Variant Assay (2 runs) MiSeqDx Cystic Fibrosis Clinical Sequencing Assay (6 runs)
Device Model/Catalogue Number:	DX-410-1001; DX-103-1001; DX-102-1003; DX-102-1004; DX-102-1001
Classification:	General IVD
Conformity Assessment Procedure:	Annex III
Notified Body:	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 above distributed from the signature date forward.

Authorized by:

08-SEP-2017

Bryan Schneider
Associate Director, Regulatory Affairs

Date (DD-MMM-YYYY)