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 5657 EE Eindhoven The Netherlands
Device Name:	**TruSight Cystic Fibrosis Library Prep** **Note: See device components for each of the device model/catalogue number on page 2 of this declaration of conformity*
Device Model/Catalogue Number:	**20036925**
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

17-APR-2020
Date

Device Component List

Device Name: TruSight Cystic Fibrosis Library Prep 20036925
Device Components

Component Name	Part number
Cystic Fibrosis Library Prep Box 1/3	20036244
Cystic Fibrosis Library Prep Box 1A	20036207
Cystic Fibrosis Library Prep Box 1B	20036208
Cystic Fibrosis Library Prep Box 2/3	20036209
Cystic Fibrosis Library Prep Box 3/3	20036250
Cystic Fibrosis Library Prep Box 3A	20036251
Cystic Fibrosis Library Prep Box 3B	20036245