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: VeriSeq NIPT Analysis Software (48 Samples)

Device Model/Catalogue Number: 20016240

Classification: Annex II, List B


Notified Body: BSI (2797)

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: [Signature]
Bryan Schneider
Associate Director, Regulatory Affairs - HQ

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