



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:

VeriSeq NIPT Analysis Software (16 Samples)

Device Catalogue Number:

RH-400-1001

Classification:

Annex II, List B

Conformity Assessment Procedure:

Annex IV of IVDD 98/79/EC Council Directive

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

Bryan Schneider

Associate Director, Regulatory Affairs - HQ

Date (DD-MMM-YYYY)

15-APR-2020