

## DECLARATION OF CONFORMITY

Manufacturer: Illumina Inc.  
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San Diego, CA 92122  
USA

European Authorized Representative: Illumina Cambridge Limited  
Chesterford Research Park  
Little Chesterford  
Saffron Walden  
CB10 1XL  
United Kingdom

Device Name: VeriSeq NIPT Analysis Software (16 Samples)

Device Model/Catalogue Number: RH-400-1001

Classification: Annex II, List B


Conformity Assessment Procedure: Annex IV

Notified Body: BSI  
Notified Body Number 0086

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:



Mya Thomae

Vice President, Regulatory, Clinical and Medical Affairs



Date