

## 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 Solution**  
**VeriSeq™ NIPT Solution v2**

*\*Note: See device components for each of the device model/catalogue number on page 2 of this declaration of conformity*

Device Model/Catalogue Number: **20030576**  
**20030577**

Basic UDI-DI 0081627002NIPTRP

Classification: Annex II, List B

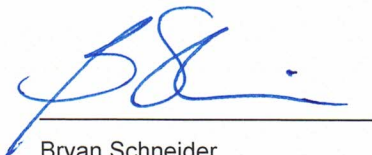
Conformity Assessment Procedure: Annex IV of IVDD 98/79/EC Council Directive

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  
Assoc. Director, Regulatory Affairs

15-APR-2020

Date

## Device Component List

Device Name                    VeriSeq NIPT Solution, 20030576

Device Components:

Component Name	Part number
<b>VeriSeq NIPT Sample Prep Kit (48 samples)</b>	<b>15066801</b>
<i>VeriSeq NIPT Extraction Box (48)</i>	15066803
<i>VeriSeq NIPT Library Prep Box (48)</i>	15066809
<b>VeriSeq NIPT Sample Prep Kit (96 samples)</b>	<b>15066802</b>
<i>VeriSeq NIPT Extraction Box (96)</i>	15066807
<i>VeriSeq NIPT Library Prep Box (96)</i>	15066810
<b>VeriSeq NIPT Accessory Box</b>	<b>15066811</b>
<i>VeriSeq NIPT Workflow Tubes and Labels</i>	15071543
<b>VeriSeq Onsite Server with preinstalled VeriSeq Assay Software</b>	<b>15076164</b>

Device Name                    VeriSeq NIPT Solution v2, 20030577

Device Components:

Component Name	Part number
<b>VeriSeq NIPT Sample Prep Kit (24 samples)</b>	<b>20025895</b>
<i>VeriSeq NIPT Extraction Box (24)</i>	20025869
<i>VeriSeq NIPT Library Prep Box (24)</i>	20026030
<b>VeriSeq NIPT Sample Prep Kit (48 samples)</b>	<b>15066801</b>
<i>VeriSeq NIPT Extraction Box (48)</i>	15066803
<i>VeriSeq NIPT Library Prep Box (48)</i>	15066809
<b>VeriSeq NIPT Sample Prep Kit (96 samples)</b>	<b>15066802</b>
<i>VeriSeq NIPT Extraction Box (96)</i>	15066807
<i>VeriSeq NIPT Library Prep Box (96)</i>	15066810
<b>VeriSeq NIPT Accessory Box</b>	<b>15066811</b>
<i>VeriSeq NIPT Workflow Tubes and Labels</i>	15071543
<b>VeriSeq Onsite Server with preinstalled VeriSeq Assay Software v2</b>	<b>20028403</b>