

DECLARATION OF CONFORMITY

Manufacturer: Illumina
5200 Illumina Way
San Diego, CA 92122
United States

European Authorized Representative: Illumina Netherlands B.V.
Steenoven 19
5626 DK 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

CE Certificate: 651108

Notified Body: BSI Group The Netherlands B.V. (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

10-AUG-2021

Date

Device Component List

Device Name: **VeriSeq™ NIPT Solution, 20030576**

Device Components:

Component Name	Part Number
VeriSeq™ NIPT Sample Preparation Kit (48 samples)	15066801
<i>VeriSeq™ NIPT Extraction Box (48)</i>	15066803
<i>VeriSeq™ NIPT Library Prep Box (48)</i>	15066809
<i>VeriSeq™ NIPT Accessory Box</i>	15066811
<i>VeriSeq™ NIPT Workflow Tubes and Labels</i>	15071543
VeriSeq™ NIPT Sample Preparation Kit (96 samples)	15066802
<i>VeriSeq™ NIPT Extraction Box (96)</i>	15066807
<i>VeriSeq™ NIPT Library Prep Box (96)</i>	15066810
<i>VeriSeq™ NIPT Accessory Box</i>	15066811
<i>VeriSeq™ NIPT Workflow Tubes and Labels</i>	15071543
VeriSeq™ NIPT Assay Software preloaded onto the VeriSeq™ Onsite Server	15076164

Device Name: **VeriSeq™ NIPT Solution v2, 20030577**

Device Components:

Component Name	Part Number
VeriSeq™ NIPT Sample Preparation Kit (24 samples)	20025895
<i>VeriSeq™ NIPT Extraction Box (24)</i>	20025869
<i>VeriSeq™ NIPT Library Prep Box (24)</i>	20026030
<i>VeriSeq™ NIPT Accessory Box</i>	15066811
<i>VeriSeq™ NIPT Workflow Tubes and Labels</i>	15071543
VeriSeq™ NIPT Sample Preparation Kit (48 samples)	15066801
<i>VeriSeq™ NIPT Extraction Box (48)</i>	15066803
<i>VeriSeq™ NIPT Library Prep Box (48)</i>	15066809
<i>VeriSeq™ NIPT Accessory Box</i>	15066811
<i>VeriSeq™ NIPT Workflow Tubes and Labels</i>	15071543
VeriSeq™ NIPT Sample Preparation Kit (96 samples)	15066802
<i>VeriSeq™ NIPT Extraction Box (96)</i>	15066807
<i>VeriSeq™ NIPT Library Prep Box (96)</i>	15066810
<i>VeriSeq™ NIPT Accessory Box</i>	15066811
<i>VeriSeq™ NIPT Workflow Tubes and Labels</i>	15071543
VeriSeq™ NIPT Assay Software v2 preloaded onto the VeriSeq™ Onsite Server v2	20047024