

EU DECLARATION OF CONFORMITY

Product Name(s) / Trade Name(s)
 VeriSeq NIPT Sample Prep Kit (24 samples)
 VeriSeq NIPT Sample Prep Kit (48 Samples)
 VeriSeq NIPT Sample Prep Kit (96 Samples)
 VeriSeq NIPT Assay Software v2

Intended Purpose
 The VeriSeq NIPT Solution v2 is an in vitro diagnostic test intended for use as a screening test for the detection of genome-wide fetal genetic anomalies from maternal peripheral whole blood specimens in pregnant women of at least 10 weeks gestation. VeriSeq NIPT Solution v2 uses whole genome sequencing to detect partial duplications and deletions for all autosomes and aneuploidy status for all chromosomes. The test offers an option to request the reporting of sex chromosome aneuploidy (SCA). This product must not be used as the sole basis for diagnosis or other pregnancy management decisions.

The VeriSeq NIPT Solution v2 includes: the VeriSeq NIPT Workflow Manager v2 for the VeriSeq NIPT Microlab STAR, the VeriSeq NIPT Sample Prep Kits, and the VeriSeq Onsite Server v2 with the VeriSeq NIPT Assay Software v2. The VeriSeq NIPT Solution v2 is intended to be used with a next generation sequencer.

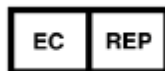


20025895
 15066801
 15066802
 20047024

Basic UDI-DI (BUDI-DI) 0081627002NIPTRP



Illumina
 5200 Illumina Way
 San Diego, CA 92122
 USA
 SRN: US-MF-000013476



Illumina Netherlands B.V.
 Steenoven 19
 5626 DK Eindhoven
 The Netherlands
 SRN: NL-AR-000012614

We, Illumina, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices

RISK CLASS:

A B C D

CONFORMITY ROUTE:

ANNEX IX Full Quality System

EU CERTIFICATE #: IVDR 734191 R000

Name of Notified Body: BSI Group, The Netherlands B.V.
Notified Body Identification: 2797

Common Specification (CS): N/A

E. Joseph McMullen

21-DEC-2021

E. Joseph McMullen
Illumina Regulatory Affairs

Date

San Diego, CA

Issued in

Signature: *E. Joseph McMullen*

Electronically signed
by: E. Joseph McMullen
Reason: Approver
Date: Dec 21, 2021
10:01 PST

Email: jmcullen@illumina.com






VeriSeq Solution NIPT v2 IVDR DoC

Final Audit Report

2021-12-21

Created:	2021-12-21
By:	Debleena Sinha (dsinha@illumina.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAM8ET-jSeU31uwruvFasexo9Feon0FHnP

"VeriSeq Solution NIPT v2 IVDR DoC" History

-  Document created by Debleena Sinha (dsinha@illumina.com)
2021-12-21 - 5:16:14 PM GMT- IP address: 192.84.34.84
-  Document emailed to E. Joseph McMullen (jmcullen@illumina.com) for signature
2021-12-21 - 5:18:38 PM GMT
-  E. Joseph McMullen (jmcullen@illumina.com) verified identity with Adobe Sign authentication
2021-12-21 - 6:01:07 PM GMT
-  Document e-signed by E. Joseph McMullen (jmcullen@illumina.com)
Signature Date: 2021-12-21 - 6:01:07 PM GMT - Time Source: server- IP address: 192.84.34.96
-  Agreement completed.
2021-12-21 - 6:01:07 PM GMT