

Product Name(s) / Trade Name(s)

Title: VeriSeq NIPT Local Run Manager IVDR EU

Declaration of Conformity Document Number: 1000000138416, Ver. 00

Effective Date: 08-FEB-2022

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## **EU DECLARATION OF CONFORMITY**

Local Run Manager VeriSeq NIPT module

REF	20044989
Basic UDI-DI (BUDI-DI)	0081627002NIPTLRM95
	Illumina 5200 Illumina Way San Diego, CA 92122 USA SRN: US-MF-000013476
EC REP	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	$\Box$ D
CONFORMITY ROUTE:	
Annex I & II+III of Regulation EU 2017/746; Self-Declaration	
Common Specification (CS): N/A	
	<u>08-FEB-2022</u>
E. Joseph McMullen Illumina Regulatory Affairs	Date
San Diego, CA	
Issued in	
Signature: JOE MCMUNEN Back	ctronically signed Joe Mcmullen son: Approver e: Feb 8, 2022 34 PST

Email: jmcmullen@illumina.com

## Request Signature for VeriSeq NIPTv2 LRM

Final Audit Report 2022-02-08

Created: 2022-02-07

By: Debleena Sinha (dsinha@illumina.com)

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## "Request Signature for VeriSeq NIPTv2 LRM" History

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