By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 651108**

Issued To: **Illumina, Inc.**
5200 Illumina Way
San Diego
California
92122
USA

In respect of:

Design, Development and Manufacture of Reagents and Sequence Software for Prenatal Determination of Trisomy 21.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-07-15** Date: **2021-09-10** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 651108

Issued To:

Illumina, Inc.
5200 Illumina Way
San Diego
California
92122
USA

Device Code	Device Name	Intended Purpose per IFU
Annex II List B		
IVD0308	20030576 VeriSeq NIPT Solution 20030577 VeriSeq NIPT Solution v2 20025895 NIPT Sample Prep Kit (24 kit size) 15066801 NIPT Sample Prep Kit (48 kit size) 15066802 NIPT Sample Prep Kit (96 kit size) 15076164 VeriSeq NIPT Assay Software, preloaded onto the VeriSeq Onsite Server 20047024 VeriSeq NIPT Assay Software v2, preloaded onto the VeriSeq Onsite Server v2	Reagents and Software for prenatal determination of Trisomy 21

First Issued: **2016-07-15** Date: **2021-09-10** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 651108**
Date:	**2021-09-10**
Issued To:	**Illumina, Inc.** **5200 Illumina Way** **San Diego** **California** **92122** **USA**

Subcontractor:	**Service(s) supplied**
Illumina Netherlands B.V. Steenoven 19 5626 DK Eindhoven The Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 651108**
Date: **2021-09-10**
Issued To: **Illumina, Inc.**
5200 Illumina Way
San Diego
California
92122
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Date	Reference Number	Action
15 July 2016	8499613	First Issue.
06 April 2017	8715502	Addition of reagents for detection of trisomy 21 to certificate scope.
20 March 2019	8594511	Traceable to NB 0086.
09 November 2020	3257229	Change of Authorised Representative
08 June 2021	3423039	Update part number for device VeriSeq NIPT Assay Software v2, preloaded onto the VeriSeq Onsite Server v2
13 July 2021	3442808	Certificate renewal.
Current	3510510	Update of Authorised Representative address.