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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **15 July 2016** Date: **06 April 2017** Expiry Date: **14 July 2021**

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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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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

List of Significant Subcontractors

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

Certificate No:	**CE 651108**
Date:	**06 April 2017**
Issued To:	**Illumina, Inc.** **5200 Illumina Way** **San Diego** **California** **92122** **USA**

Subcontractor:	**Service(s) supplied**
Illumina Cambridge Limited Chesterford Research Park Little Chesterford Saffron Walden CB10 1XL United Kingdom	**EU Representative**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 651108**

Date: **06 April 2017**

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.

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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.

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