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 630524**

Issued To: **BGI Europe A/S**
Ole Maaløes Vej 3
Copenhagen
DK-2200
Denmark

In respect of:

The design, development and manufacture of software for non-invasive pre-natal testing for 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):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **12 June 2015** Date: **12 June 2015** Expiry Date: **11 June 2020**

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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 630524**
Date:	**12 June 2015**
Issued To:	**BGI Europe A/S** **Ole Maaløes Vej 3** **Copenhagen** **DK-2200** **Denmark**

Subcontractor:	**Service(s) supplied**
BGI Europe A/S 518083, Main Building Beishan industry area Yantian district, Shenzhen China	**Design** **Manufacture**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 630524**
Date: **12 June 2015**
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Ole Maaløes Vej 3
Copenhagen
DK-2200
Denmark

Certificate History

Date	Reference Number	Action
12 June 2015	8282424	First Issue

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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: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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