bsi.

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 667916**

Issued To: **Genoma Swiss Biotechnology**
Chemin des Aulx 12
1228 Plan-les-Ouates
Geneva
Switzerland

In respect of:

Design and manufacture of the Tranquility Software for the interpretation of sequencing data in the prenatal diagnosis 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: **2017-06-07** Date: **2017-10-30** Expiry Date: **2022-06-06**

...making excellence a habit.™

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.

EC Declaration of Conformity
Full Quality Assurance

CE IVD

Directive 98/79/EC on In Vitro Diagnostic Medical Device (IVDD), Annex IV, compliant to the essential requirements as stipulated is Annex I of the IVD Directive

Issued By:

Genoma Swiss Biotechnology
Chemin de Aulx, 12
1228 Plan-les-Ouates
Geneva
Switzerland

In respect of:

Design and manufacture of the Tranquility Software for the interpretation of sequencing data in prenatal diagnosis of Trisomy 18, 13 and determination of fetal sex (Cod: GTRACE1701)

Applied common technical specifications, harmonized standards, national standards or other normative documents:

Quality system certified to:	ISO 13485:2016 Medical devices – Quality management systems Requirements for regulatory purposes
Harmonized standards:	ISO 15189:2012 Medical laboratories – Requirements for quality and competence
	EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
	IEC 62304:2006 Medical device software life cycle processes
	ISO 18113-3:2009 In vitro diagnostic medical device – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use.
	ISO 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied.

Cécile Loison

Cécile Loison
Quality Manager

Date: **2017-11-03**
Expiry Date: **2020-11-03**

Genoma
Swiss Biotechnology

FORM-MFG-04b