EC CERTIFICATE

Benetech Inc.

555 Richmond Street West
Suite 500
Toronto, Ontario M5V 3B1 CANADA

EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV (excluding sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
Design and development, manufacture and servicing of software used for the calculation of the risk of prenatal anomalies including Trisomy 21.

Device Classifications:
Annex II List B

Device Descriptions and Model Type:
Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex IV (with the exemption of sections 4 and 6) of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 98/79/EC, Annex IV, Section 5. For Annex II, List A devices where they are covered by this certificate, an EC Design Examination certificate according to 98/79/EC, Annex IV, Section 4 is required. This certificate is issued with 1 attachment listing product references.

File Number	A18124	Cycle Start Date	August 21, 2018
Certificate Number	679.180821	Effective Date	August 21, 2018
Initial Issue Date	August 22, 2012	Expiry Date	August 20, 2023

Authorised by

Paul Daysh
Certification Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Model/Type	Classification	G/UMDN Code
Benetech PRA Software, 3.x.x.x	Annex II List B	-

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