EC CERTIFICATE

Benetech Inc.

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EC Certificate - Full Quality Assurance System Approval Certificate

Annex IV, section 3 of Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices

Scope of Certificate:
The design and development, manufacture and servicing of software used for the calculation of the risk of prenatal anomalies.

Device Classification:
Annex II List B

Device Descriptions:
Benetech PRA Software for estimating the risk of having a fetus with a range of congenital abnormalities including Trisomy 21

Model:
3.x.x.x

File Number	A18124	Cycle Start Date	21 August 2015
Certificate No.	679.150821	Effective Date	21 August 2015
		Expiry Date	21 August 2018

Authorised by

Paul O'Dea
Certification Manager
For and on Behalf of UL International (UK) Ltd

We hereby declare that an examination of the full quality assurance system has been carried out per report 4786933665, 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.

Notified Body

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