



# 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  
Certificate Number 679.191113  
Initial Issue Date August 22, 2012

Cycle Start Date August 21, 2018  
Effective Date November 13, 2019  
Expiry Date August 20, 2023

Authorised by

**Paul Daysh  
Certification Manager**

For and on Behalf of UL International (UK) Ltd



**Notified Body  
0843**

IVDD A4 S3 FQ  
00-MB-A0043 Issue: 15.0

Check Certificate  
Status: [here](#)

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



# EC CERTIFICATE

## Benetech Inc.

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

### 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	59120

File Number A18124  
Certificate Number 679.191113  
Initial Issue Date August 22, 2012

Cycle Start Date August 21, 2018  
Effective Date November 13, 2019  
Expiry Date August 20, 2023

Authorised by

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



**Notified Body**  
**0843**

IVDD A4 S3 FQ  
00-MB-A0043 Issue: 15.0

Check Certificate  
Status: [here](#)

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