

Certificate of Registration

Certificate number

1663.250923

File number

A18124

Initial issue date

2018-08-02

Cycle start date

2024-08-02

Effective date

2025-09-23

Expiry date

2027-08-01

**Benetech Inc.**

629 Carlaw Avenue
Toronto, Ontario M4K 3K5 CANADA

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

**ISO 13485:2016
EN ISO 13485:2016 + A11:2021**

The design and development, manufacture and servicing of software used for the calculation of the risk of prenatal anomalies and pregnancy disorders

Authorized by:

Paul Daysh
Operations manager – Medical Regulatory



Check certificate status: [here](#)

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

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**Benetech Inc.**

629 Carlaw Avenue
Toronto, Ontario M4K 3K5 CANADA

Facility ID: F001390

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016**EN ISO 13485:2016/A11:2021**

with additional regulatory requirements listed on the final page of this certificate.

The design and development, manufacture and servicing of software used for the calculation of the risk of prenatal anomalies and pregnancy disorders

Certificate with Addendum(s) totals 3 pages.

Authorized by:

A handwritten signature in black ink, appearing to read 'P. Daysh'.

Paul Daysh

Operations manager – Medical Regulatory



Check certificate status: [here](#)

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**UL LLC, UL Solutions medical regulatory services
is an MDSAP Recognized Auditing Organization**

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Addendum 1

Site	Company Name	Location	Performing
1-1	Benetech Inc.	629 Carlaw Avenue Toronto Ontario M4K 3K5 CANADA Facility ID: F001390	All

Additional Regulatory Requirements

Benetech Inc.

629 Carlaw Avenue
Toronto, Ontario M4K 3K5 CANADA

Facility ID: F001390

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282