جمهوری اسلامی ایران
وزارت بهداشت، درمان و آموزش پزشکی
آزمایشگاه مرجع سلامت

بسمه تعالی

شماره ۳۰۷/۱۰۲۵
تاریخ ۱۳۹۵/۰۶/۳۱
پیوست ندارد

مدیر عامل محترم شرکت آراد تجهیز آزما

موضوع: نتیجه بررسی نرم افزار BENETECH PRAشرکت آراد تجهیز آزماآراد تجهیز آزما

سلام علیکم

احتراما بازگشت به نامه شماره ۱/۵۹۶۵۲ مورخ ۹٤/۹/۱ به اطلاع می رساند پیرو ارزیابی نحوه طراحی و کیفیت و عملکرد نرم افزار **BENETECH PRA** جهت **غربالگری سندرم داون جنین** و با توجه به بررسی های انجام شده، نتایج اولیه در فاز مقدماتی ارزیابی قابل قبول می باشد و نرم افزار می تواند در مرحله پایلوت طرح کشوری غربالگری سندروم داون مورد استفاده قرار گیرد . از آنجا که اعلام نظر نهایی درخصوص کیفیت و عملکرد نرم افزار منوط به بررسی تعداد نمونه و مطالعات بالینی بیشتری می باشد اعتبار این نامه از تاریخ صدور به مدت یک سال است و شرکت ضمن برقراری سیستم Post Marketing Surveillance (PMS) جهت نظارت بر عملکرد محصول در سطح مصرف می بایست جهت تمدید اعتبار این تاییدیه، نتایج مطالعات انجام شده را بصورت مکتوب به آزمایشگاه مرجع سلامت ارائه نماید.

همچنین عرضه نرم افزار به بازار مصرف می بایست به همراه دستورالعمل کاربری و بروشور و در برنامه نرم افزار منوی راهنما یا Help طراحی شده باشد و به روز رسانی نرم افزار بصورت دوره ای انجام و هر گونه تغییری در برنامه نرم افزار بصورت مکتوب به اطلاع آزمایشگاه مرجع سلامت رسانیده شود.

دکتر سیامک میراب سمیعی
مدیرکل آزمایشگاه مرجع سلامت

آدرس : خیابان نوفل لوشاتو نرسیده به خیابان حافظ ،کوچه کیخسرو شاهرخ پلاک۴۸ آزمایشگاه مرجع سلامت
تلفن:۳۰و۶۶۷۵۰۰۱۰ نمابر:۶۶۷۲۸۱۲۱

CERTIFICATE OF REGISTRATION

Benetech Inc.
555 Richmond Street West, Suite 508
Toronto, ON M5V 3B1 Canada

UL LLC® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with

ISO 13485:2003 / Cor 1:2009
EN ISO 13485:2012

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

File Number A18124
Certificate No. 10798568.PDWS

Effective Date August 2, 2015
Expiry Date August 1, 2018

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

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

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

Ontario

MINISTRY OF GOVERNMENT AND CONSUMER SERVICES

I HEREBY CERTIFY AS FOLLOWS:

MOIRA VISOIU

of the Province of Ontario, whose name is subscribed to the attached Instrument, was, at the time of subscribing thereto, a **NOTARY PUBLIC** in and for the Province of Ontario, Canada, duly commissioned and duly authorized by the laws thereof to administer oaths, to take affidavits and to certify the proof of deeds and other instruments in writing to be recorded within the said Province.

I FURTHER CERTIFY THAT I have compared the signature of the said **NOTARY PUBLIC** subscribed to the attached Instrument with the specimen signature of the said **NOTARY PUBLIC** filed in this office and verily believe the said signature to be genuine; and THAT I have compared the impression of the Seal of the said **NOTARY PUBLIC** appearing on the attached Instrument with the specimen of the Seal filed in this office and verily believe the impression of the Seal to be genuine.

IN TESTIMONY WHEREOF I have hereunto set my Hand and affixed the Seal of the Ministry of Government and Consumer Services of the Province of Ontario at the City of Toronto in the said Province this twenty-second day of January, A.D. 2015.

Christina Netto

for the MINISTER OF GOVERNMENT AND CONSUMER SERVICES

Benetech

January 5, 2015

This letter is to confirm that:

Arad Tajhiz Azma Co. Ltd.

located at:

5/F, No. 47, Taghavi Alley
Sohrevardi Street
Tehran, Iran

is the official distributor of Benetech PRA software in the country of Iran. They are authorized to sell and support all Benetech Pre-Natal Risk Assessment products within the territory.

Sincerely,

Les Hansen
President
Benetech Inc.

MOIRA VISCIU NOTARY PUBLIC ONTARIO

January 15, 2015

Benetech Inc.
555 Richmond Street West, Suite 508, Toronto, ON, Canada, M5V 3B1
www.Benetech.com

CERTIFICATE OF REGISTRATION

Benetech Inc.
555 Richmond Street West, Suite 508
Toronto, ON M5V 3B1 Canada

UL LLC® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with

ISO 13485:2003

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

File Number A18124
Certificate No. 10798568.AZBA

Effective Date August 2, 2015
Expiry Date August 1, 2018

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

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UL is a CMDCAS Recognized Registrar

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

EC CERTIFICATE

Benetech Inc.

555 Richmond Street West, Suite 508
P.O. Box 704
Toronto
Ontario M5V 3B1
Canada

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
0843

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