

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer: Tyson Bioresearch Inc.
5F No. 22 Ke E. Road III, Science-Based
Industrial Park, Chu-Nan 350, Taiwan, R.O.C

Coverage of Certificate: Design, manufacture and final inspection

Product category: Blood glucose test devices for self-testing

Valid until: 14th October, 2018

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex IV in Directive 98/79/EC. Products covered by the certificate are specified in the attachment(s).

Tampere, 14th October, 2013


Aliisa Siljander




Markku Helminen

Certificate no.
VTT-C-10404-02-1073-501-13

Notified Body no. 0537:
VTT Expert Services Ltd.
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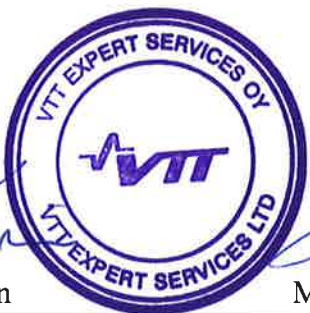


Attachment 1 to the Certificate number: VTT-C-10404-02-1073-501-13

Manufacturer:	Tyson Bioresearch Inc. 5F No. 22 Ke E. Road III Science-Based Industrial Park Chu-Nan 350, Taiwan, R.O.C		
Activity and product category:	Design, manufacture and final inspection; Blood glucose test devices for self-testing. GMDN code: 62538		
Products:	The certificate covers the following products:		
	<i>Name</i>	<i>Model</i>	<i>Model</i>
	- Blood Glucose Monitoring System	<ul style="list-style-type: none"> ▪EZ Smart ▪EZ Smart-168 ▪EZ Smart-606 ▪EZ Smart-608 ▪TysonBio TB 100 ▪TysonBio TB 200 ▪TysonBio AC100 ▪TysonBio AC200 ▪TysonBio AC500 ▪TysonBio AC800 ▪TysonBio DA100 ▪Tyson Bio HT100 	<ul style="list-style-type: none"> ▪TysonBio EVOLVE ▪TysonBio SUPERB ▪EKS Codefree ▪Rossmax CB 100 ▪Ultimate EZ Smart^{Plus} ▪dynaValeo ▪plusMED fasTTest ▪Guardian TB100 ▪Gluco Dot ▪TysonBio DA101 ▪AQ TB100
	- Blood Glucose Meter	<ul style="list-style-type: none"> ▪EZ Smart ▪EZ Smart-168 ▪EZ Smart-606 ▪EZ Smart-608 ▪TysonBio TB 100 ▪TysonBio TB 200 ▪TysonBio AC100 ▪TysonBio AC200 ▪TysonBio AC500 ▪TysonBio AC800 ▪TysonBio DA100 ▪Tyson Bio HT100 	<ul style="list-style-type: none"> ▪TysonBio EVOLVE ▪TysonBio SUPERB ▪EKS Codefree ▪Rossmax CB 100 ▪Ultimate EZ Smart^{Plus} ▪dynaValeo ▪plusMED fasTTest ▪Guardian TB100 ▪Gluco Dot ▪TysonBio DA101 ▪AQ TB100



VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 98/79/EC.

Attachment 1 to the Certificate number: VTT-C-10404-02-1073-501-13

<i>Name</i>	<i>Model</i>	<i>Model</i>
- Blood Glucose Test Strip	<ul style="list-style-type: none"> ▪EZ Smart ▪EZ Smart-168 ▪EZ Smart-606 ▪EZ Smart-608 ▪TysonBio TB 100 ▪TysonBio TB 200 ▪TysonBio AC100 ▪TysonBio AC200 ▪TysonBio AC500 ▪TysonBio AC800 ▪TysonBio DA100 ▪Tyson Bio HT100 	<ul style="list-style-type: none"> ▪TysonBio EVOLVE ▪TysonBio SUPERB ▪EKS Codefree ▪Rossmax CB 100 ▪Ultimate EZ Smart^{Plus} ▪dynaValeo ▪plusMED fasTTest ▪Guardian TB100 ▪Gluco Dot ▪TysonBio DA101 ▪AQ TB100
- Glucose Control Solution	<ul style="list-style-type: none"> ▪EZ Smart ▪EZ Smart-168 ▪EZ Smart-606 ▪EZ Smart-608 ▪TysonBio TB 100 ▪TysonBio TB 200 ▪TysonBio AC100 ▪TysonBio AC200 ▪TysonBio AC500 ▪TysonBio AC800 ▪TysonBio DA100 ▪Tyson Bio HT100 	<ul style="list-style-type: none"> ▪TysonBio EVOLVE ▪TysonBio SUPERB ▪EKS Codefree ▪Rossmax CB 100 ▪Ultimate EZ Smart^{Plus} ▪dynaValeo ▪plusMED fasTTest ▪Guardian TB100 ▪Gluco Dot ▪TysonBio DA101 ▪AQ TB100
Date:	Tampere, 22 nd March 2017.	
	  Tuomas Toivonen  Mikko Soikkeli	

This attachment 1 supersedes the previous attachment 1, signed 16th October 2015.

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