

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer: Tyson Bioresearch Inc.
5F., No. 16,18,20,22, Kedong 3rd
Rd., Zhunan Township, Miaoli
County 35053, Taiwan

Coverage of Certificate: Design, manufacture and final inspection

Product category: Blood glucose test devices for self-testing

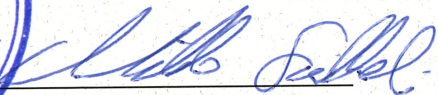
Valid until: 14th October, 2023

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).

Valid from: 14th October, 2018



Olli Kakkonen



Mikko Soikkeli

Certificate no.
C-12492-02-1073-657-18

Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: VTT-C-12278-02-1073-632-18

Manufacturer:	Tyson Bioresearch Inc. 5F., No. 16,18,20,22, Kedong 3rd Rd., Zhunan Township, Miaoli County 35053, Taiwan		
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 ▪Tyson Bio HS100-B 	<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 ▪Tyson Bio HS100
	- 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 ▪Tyson Bio HS100-B 	<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 ▪Tyson Bio HS100



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

VTT EXPERT SERVICES LTD

Medical Devices
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name.surname@vtt.fi
Business ID 2297513-2

Attachment 1 to the Certificate number: VTT-C-12278-02-1073-632-18

<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 ▪ Tyson Bio HS100-B ▪ 	<ul style="list-style-type: none"> ▪ TysonBio EVOLVE ▪ TysonBio SUPERB ▪ EKS Codefree ▪ Rossmax CB 100 ▪ Ultimate EZ Smart ^{Plus} ▪ dynaValeo ▪ plusMED fastTTest ▪ Guardian TB100 ▪ Gluco Dot ▪ TysonBio DA101 ▪ AQ TB100 ▪ Tyson Bio HS100
- 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 ▪ Tyson Bio HS100-B 	<ul style="list-style-type: none"> ▪ TysonBio EVOLVE ▪ TysonBio SUPERB ▪ EKS Codefree ▪ Rossmax CB 100 ▪ Ultimate EZ Smart ^{Plus} ▪ dynaValeo ▪ plusMED fastTTest ▪ Guardian TB100 ▪ Gluco Dot ▪ TysonBio DA101 ▪ AQ TB100 ▪ Tyson Bio HS100

Date:

Tampere, 2nd July 2018.



(Handwritten signature of Tuomas Toivonen)

Tuomas Toivonen

(Handwritten signature of Mikko Soikkeli)

Mikko Soikkeli

This attachment 1 supersedes the previous attachment 1, signed 16th February 2018.

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