

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: C-12492-02-1073-657-18

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: 62537		
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-168 ▪ EZ Smart-606 ▪ EZ Smart-608 ▪ Tyson Bio TB100 ▪ Tyson Bio TB200 ▪ Tyson Bio AC100 ▪ Tyson Bio AC200 ▪ AC500 ▪ Tyson Bio HT100 ▪ Tyson Bio HT100-A ▪ Tyson Bio HS100-B ▪ Tyson Bio HT100-C ▪ Tyson Bio HS200 ▪ Tyson Bio HS200-B ▪ JT100 ▪ JT100-B ▪ JS100 ▪ JS100-B ▪ Rossmax JS200 ▪ Spengler TB100 ▪ JU100 	<ul style="list-style-type: none"> ▪ Tyson Bio EVOLVE ▪ Tyson Bio SUPERB ▪ Rossmax CB 100 ▪ dynaValeo ▪ plusMED fasTTest ▪ Guardian TB 100 ▪ Gluco Dot ▪ AQ TB100 ▪ Tyson Bio HS100 ▪ Tyson Bio DE100 ▪ Tyson Bio HT100-B ▪ Microlife HT100 ▪ Rossmax HS200 ▪ JT101 ▪ JT100-A ▪ JT100-C ▪ JS200 ▪ JS200-B ▪ GL60 ▪ LGLMV-BT-01 ▪ JU100-B
	Blood Glucose Meter	<ul style="list-style-type: none"> ▪ EZ Smart-168 ▪ EZ Smart-606 ▪ EZ Smart-608 ▪ Tyson Bio TB100 	<ul style="list-style-type: none"> ▪ Tyson Bio EVOLVE ▪ Tyson Bio SUPERB ▪ Rossmax CB 100 ▪ dynaValeo



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

EUROFINS EXPERT SERVICES

Medical Devices
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Business ID FI22975132

Attachment 1 to the Certificate number: C-12492-02-1073-657-18

- | | |
|---------------------|---------------------|
| ▪ Tyson Bio TB200 | ▪ plusMED fasTTest |
| ▪ Tyson Bio AC100 | ▪ Guardian TB 100 |
| ▪ Tyson Bio AC200 | ▪ Gluco Dot |
| ▪ AC500 | ▪ AQ TB100 |
| ▪ Tyson Bio HT100 | ▪ Tyson Bio HS100 |
| ▪ Tyson Bio HT100-A | ▪ Tyson Bio DE100 |
| ▪ Tyson Bio HS100-B | ▪ Tyson Bio HT100-B |
| ▪ Tyson Bio HT100-C | ▪ Microlife HT100 |
| ▪ Tyson Bio HS200 | ▪ Rossmax HS200 |
| ▪ Tyson Bio HS200-B | ▪ JT101 |
| ▪ JT100 | ▪ JT100-A |
| ▪ JT100-B | ▪ JT100-C |
| ▪ JS100 | ▪ JS200 |
| ▪ JS100-B | ▪ JS200-B |
| ▪ Rossmax JS200 | ▪ GL60 |
| ▪ Spengler TB100 | ▪ LGLMV-BT-01 |
| ▪ JU100 | ▪ JU100-B |

Blood Glucose
Test Strip

- | | |
|---------------------|---------------------|
| ▪ EZ Smart-168 | ▪ Tyson Bio EVOLVE |
| ▪ EZ Smart-606 | ▪ Tyson Bio SUPERB |
| ▪ EZ Smart-608 | ▪ Rossmax CB 100 |
| ▪ Tyson Bio TB100 | ▪ dynaValeo |
| ▪ Tyson Bio TB200 | ▪ plusMED fasTTest |
| ▪ Tyson Bio AC100 | ▪ Guardian TB 100 |
| ▪ Tyson Bio AC200 | ▪ Gluco Dot |
| ▪ AC500 | ▪ AQ TB100 |
| ▪ Tyson Bio HT100 | ▪ Tyson Bio HS100 |
| ▪ Tyson Bio HT100-A | ▪ Tyson Bio DE100 |
| ▪ Tyson Bio HT100-B | ▪ Tyson Bio HT100-B |
| ▪ Tyson Bio HT100-C | ▪ Microlife HT100 |
| ▪ Tyson Bio HS200 | ▪ Rossmax HS200 |
| ▪ Tyson Bio HS200-B | ▪ JT100 |
| ▪ JS100 | ▪ Rossmax JS200 |
| ▪ GL60 | ▪ Spengler TB100 |
| ▪ BRLMV-BT-01 | ▪ JU100 |





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	<p>Glucose Control Solution</p> <ul style="list-style-type: none"> ▪ EZ Smart-168 ▪ EZ Smart-606 ▪ EZ Smart-608 ▪ Tyson Bio TB100 ▪ Tyson Bio TB200 ▪ Tyson Bio AC100 ▪ Tyson Bio AC200 ▪ AC500 ▪ Tyson Bio HT100 ▪ Tyson Bio HT100-A ▪ Tyson Bio HS100-B ▪ Tyson Bio HT100-C ▪ Tyson Bio HS200 ▪ Tyson Bio HS200-B ▪ JS100 ▪ GL60 ▪ SCLMV-BT ▪ Tyson Bio EVOLVE ▪ Tyson Bio SUPERB ▪ Rossmax CB 100 ▪ dynaValeo ▪ plusMED fasTTest ▪ Guardian TB 100 ▪ Gluco Dot ▪ AQ TB100 ▪ Tyson Bio HS100 ▪ Tyson Bio DE100 ▪ Tyson Bio HT100-B ▪ Microlife HT100 ▪ Rossmax HS200 ▪ JT100 ▪ Rossmax JS200 ▪ Spengler TB100 ▪ JU100
Date:	<p>Valid from: 22nd November 2021</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  Laura Petäjämäki </div> <div style="text-align: center;">  Aliisa Siljander </div> </div>

This attachment 1 supersedes the previous attachment 1, signed 24th September 2021.

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