

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

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

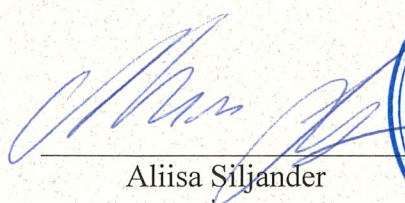
Coverage of Certificate: Design, manufacture and final inspection

Product category: Blood glucose test devices for self-testing

Valid until: 26 May 2025

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: 25 May 2022


Aliisa Siljander




Riikka Kylväjä

Certificate no.
C-02-1073-797-22

Notified Body no. 0537:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: C-02-1073-797-22

Manufacturer:	Tyson Bioresearch, Inc. 5F., No.16, 18, 20, 22, Kedong 3rd Rd., Zhunan Township, Miaoli Country 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	▪ 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	▪ Tyson Bio EVOLVE ▪ plusMED fasTTest ▪ Gluco Dot ▪ Tyson Bio HS100 ▪ Tyson Bio HT100-B ▪ Rossmax HS200 ▪ JT101 ▪ JT100-A ▪ JT100-C ▪ JS200 ▪ JS200-B ▪ GL60 ▪ LGLMV-BT-01 ▪ JU100-B ▪ JU100 ▪ Spengler TB100
	Blood Glucose Meter	▪ 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 EVOLVE ▪ plusMED fasTTest ▪ Gluco Dot ▪ Tyson Bio HS100 ▪ Tyson Bio HT100-B ▪ Rossmax HS200 ▪ JT101 ▪ JT100-A ▪ JT100-C

Eurofins Electric & Electronics Finland Oy is Notified Body no. 0537 under Council Directive 98/79/EC.

Attachment 1 to the Certificate number: C-02-1073-797-22

Blood Glucose
Test Strip



Glucose Control
Solution

- | | |
|---------------------|---------------------|
| ▪ Tyson Bio HS200 | ▪ JS200 |
| ▪ Tyson Bio HS200-B | ▪ JS200-B |
| ▪ JT100 | ▪ GL60 |
| ▪ JT100-B | ▪ LGLMV-BT-01 |
| ▪ JS100 | ▪ JU100-B |
| ▪ JS100-B | ▪ JU100 |
| ▪ Rossmax JS200 | ▪ Spengler TB100 |
| ▪ Tyson Bio TB100 | ▪ Tyson Bio EVOLVE |
| ▪ Tyson Bio TB200 | ▪ plusMED fasTTest |
| ▪ Tyson Bio AC100 | ▪ Gluco Dot |
| ▪ Tyson Bio AC200 | ▪ Tyson Bio HS100 |
| ▪ AC500 | ▪ Tyson Bio HT100-B |
| ▪ Tyson Bio HT100 | ▪ Rossmax HS200 |
| ▪ Tyson Bio HT100-A | ▪ JT100 |
| ▪ Tyson Bio HS100-B | ▪ Rossmax JS200 |
| ▪ Tyson Bio HT100-C | ▪ Spengler TB100 |
| ▪ Tyson Bio HS200 | ▪ JU100 |
| ▪ Tyson Bio HS200-B | ▪ JS100 |
| ▪ BRLMV-BT-01 | ▪ GL60 |
| ▪ Tyson Bio TB100 | ▪ Tyson Bio EVOLVE |
| ▪ Tyson Bio TB200 | ▪ plusMED fasTTest |
| ▪ Tyson Bio AC100 | ▪ Gluco Dot |
| ▪ Tyson Bio AC200 | ▪ Tyson Bio HS100 |
| ▪ AC500 | ▪ Tyson Bio HT100-B |
| ▪ Tyson Bio HT100 | ▪ Rossmax HS200 |
| ▪ Tyson Bio HT100-A | ▪ JT100 |
| ▪ Tyson Bio HS100-B | ▪ Rossmax JS200 |
| ▪ Tyson Bio HT100-C | ▪ Spengler TB100 |
| ▪ Tyson Bio HS200 | ▪ JU100 |
| ▪ Tyson Bio HS200-B | ▪ JS100 |
| ▪ SCLMV-BT | ▪ GL60 |

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EUROFINS ELECTRIC & ELECTRONICS FINLAND OY

Medical Devices
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Business ID FI21741879

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Date:	Valid from: 25 May 2022  Aliisa Siljander   Riikka Kylvä
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