

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: 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-168 ▪EZ Smart-606 ▪EZ Smart-608 ▪TysonBio TB 100 ▪TysonBio TB 200 ▪TysonBio AC100 ▪TysonBio AC200 ▪TysonBio AC500 ▪TysonBio DA100 ▪Tyson Bio HT100 ▪Tyson Bio HS100-B 	<ul style="list-style-type: none"> ▪TysonBio EVOLVE ▪TysonBio SUPERB ▪Rossmax CB 100 ▪dynaValeo ▪plusMED fasTTest ▪Guardian TB100 ▪Gluco Dot ▪TysonBio DA101 ▪AQ TB100 ▪Tyson Bio HS100 ▪Tyson Bio DE100
	- Blood Glucose Meter	<ul style="list-style-type: none"> ▪EZ Smart-168 ▪EZ Smart-606 ▪EZ Smart-608 ▪TysonBio TB 100 ▪TysonBio TB 200 ▪TysonBio AC100 ▪TysonBio AC200 ▪TysonBio AC500 ▪TysonBio DA100 ▪Tyson Bio HT100 ▪Tyson Bio HS100-B 	<ul style="list-style-type: none"> ▪TysonBio EVOLVE ▪TysonBio SUPERB ▪Rossmax CB 100 ▪dynaValeo ▪plusMED fasTTest ▪Guardian TB100 ▪Gluco Dot ▪TysonBio DA101 ▪AQ TB100 ▪Tyson Bio HS100 ▪Tyson Bio DE100





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

	<table><tr><td><i>Name</i></td><td><i>Model</i></td><td><i>Model</i></td></tr><tr><td>- Blood Glucose Test Strip</td><td><ul style="list-style-type: none">▪EZ Smart-168▪EZ Smart-606▪EZ Smart-608▪TysonBio TB 100▪TysonBio TB 200▪TysonBio AC100▪TysonBio AC200▪TysonBio AC500▪TysonBio DA100▪Tyson Bio HT100▪Tyson Bio HS100-B</td><td><ul style="list-style-type: none">▪TysonBio EVOLVE▪TysonBio SUPERB▪Rossmax CB 100▪dynaValeo▪plusMED fasTTest▪Guardian TB100▪Gluco Dot▪TysonBio DA101▪AQ TB100▪Tyson Bio HS100▪Tyson Bio DE100</td></tr><tr><td>- Glucose Control Solution</td><td><ul style="list-style-type: none">▪EZ Smart-168▪EZ Smart-606▪EZ Smart-608▪TysonBio TB 100▪TysonBio TB 200▪TysonBio AC100▪TysonBio AC200▪TysonBio AC500▪TysonBio DA100▪Tyson Bio HT100▪Tyson Bio HS100-B</td><td><ul style="list-style-type: none">▪TysonBio EVOLVE▪TysonBio SUPERB▪Rossmax CB 100▪dynaValeo▪plusMED fasTTest▪Guardian TB100▪Gluco Dot▪TysonBio DA101▪AQ TB100▪Tyson Bio HS100▪Tyson Bio DE100</td></tr></table>	<i>Name</i>	<i>Model</i>	<i>Model</i>	- Blood Glucose Test Strip	<ul style="list-style-type: none">▪EZ Smart-168▪EZ Smart-606▪EZ Smart-608▪TysonBio TB 100▪TysonBio TB 200▪TysonBio AC100▪TysonBio AC200▪TysonBio AC500▪TysonBio DA100▪Tyson Bio HT100▪Tyson Bio HS100-B	<ul style="list-style-type: none">▪TysonBio EVOLVE▪TysonBio SUPERB▪Rossmax CB 100▪dynaValeo▪plusMED fasTTest▪Guardian TB100▪Gluco Dot▪TysonBio DA101▪AQ TB100▪Tyson Bio HS100▪Tyson Bio DE100	- Glucose Control Solution	<ul style="list-style-type: none">▪EZ Smart-168▪EZ Smart-606▪EZ Smart-608▪TysonBio TB 100▪TysonBio TB 200▪TysonBio AC100▪TysonBio AC200▪TysonBio AC500▪TysonBio DA100▪Tyson Bio HT100▪Tyson Bio HS100-B	<ul style="list-style-type: none">▪TysonBio EVOLVE▪TysonBio SUPERB▪Rossmax CB 100▪dynaValeo▪plusMED fasTTest▪Guardian TB100▪Gluco Dot▪TysonBio DA101▪AQ TB100▪Tyson Bio HS100▪Tyson Bio DE100
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Date:	<div>Valid from: 10th December 2018</div> <div><div> Riina Sarkanen</div><div> Mikko Soikkeli</div></div>									

This attachment 1 supersedes the previous attachment 1 signed 14th October 2018

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