

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer: EPS Bio Technology Corp.
No. 8, R&D Rd. III, Hsinchu Science Park
Hsinchu
Taiwan 30077, R.O.C.

Coverage of Certificate: Design, manufacture and final inspection

Product category: Blood glucose test devices for self-testing

Valid until: June 5, 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: February 14, 2019







Mikko Soikkeli


Olli Kakkonen

Certificate no.
C-02-1095-664-19

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

Attachment 27 to the Certificate number: C-02-1095-664-19

Manufacturer:	EPS Bio Technology Corp. No. 8, R&D Rd. III, Hsinchu Science Park Hsinchu, Taiwan 30077, R.O.C.															
Activity and product category:	Design, manufacture and final inspection of blood glucose test devices for self-testing. GMDN-code(s): 62537															
Products:	<p>The certificate covers the following products:</p> <table border="1"> <thead> <tr> <th><i>Name</i></th> <th><i>Brand name</i></th> <th><i>Model</i></th> </tr> </thead> <tbody> <tr> <td>Self Monitoring Blood Glucose System</td> <td>EasyMax® Tag</td> <td>EM Tag</td> </tr> <tr> <td>Blood Glucose Meter</td> <td>EasyMax® Tag</td> <td>EM Tag</td> </tr> <tr> <td>Blood Glucose Test Strip</td> <td>EasyMax® Tag</td> <td>EM Tag</td> </tr> <tr> <td>Glucose Control Solution</td> <td>EasyMax® Tag</td> <td>EM Tag</td> </tr> </tbody> </table>	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	Self Monitoring Blood Glucose System	EasyMax® Tag	EM Tag	Blood Glucose Meter	EasyMax® Tag	EM Tag	Blood Glucose Test Strip	EasyMax® Tag	EM Tag	Glucose Control Solution	EasyMax® Tag	EM Tag
<i>Name</i>	<i>Brand name</i>	<i>Model</i>														
Self Monitoring Blood Glucose System	EasyMax® Tag	EM Tag														
Blood Glucose Meter	EasyMax® Tag	EM Tag														
Blood Glucose Test Strip	EasyMax® Tag	EM Tag														
Glucose Control Solution	EasyMax® Tag	EM Tag														
Date:	Valid from: June 25, 2019   Riina Sarkanen  Olli Kakkonen															

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