

QUALITY SYSTEM

**EC-CERTIFICATE**

Directive 98/79/EC

Manufacturer: Tyson Bioresearch Inc.  
5F No. 22 Ke E. Road III, Science-Based  
Industrial Park, Chu-Nan 350, Taiwan, R.O.C

Coverage of Certificate: Design, manufacture and final inspection

Product category: Blood glucose test devices for self-testing

Valid until: 14<sup>th</sup> October, 2018

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).

Tampere, 14<sup>th</sup> October, 2013

  
Aliisa Siljander

Certificate no.

**VTT-C-10404-02-1073-501-13**



  
Markku Helminen

Notified Body no. 0537:  
VTT Expert Services Ltd.  
P.O. Box 345 (Tekniikankatu 1)  
FI-33101 TAMPERE  
FINLAND  
Tel.+358 20 722 111

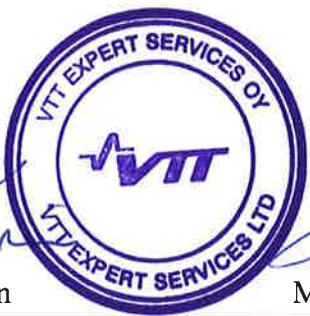
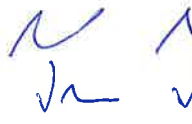

**Attachment 1 to the Certificate number: VTT-C-10404-02-1073-501-13**

<b>Manufacturer:</b>	Tyson Bioresearch Inc. 5F No. 22 Ke E. Road III Science-Based Industrial Park Chu-Nan 350, Taiwan, R.O.C		
<b>Activity and product category:</b>	Design, manufacture and final inspection; Blood glucose test devices for self-testing. GMDN code: 62538		
<b>Products:</b>	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"> <li>▪EZ Smart</li> <li>▪EZ Smart-168</li> <li>▪EZ Smart-606</li> <li>▪EZ Smart-608</li> <li>▪TysonBio TB 100</li> <li>▪TysonBio TB 200</li> <li>▪TysonBio AC100</li> <li>▪TysonBio AC200</li> <li>▪TysonBio AC500</li> <li>▪TysonBio AC800</li> <li>▪TysonBio DA100</li> <li>▪Tyson Bio HT100</li> </ul>	<ul style="list-style-type: none"> <li>▪TysonBio EVOLVE</li> <li>▪TysonBio SUPERB</li> <li>▪EKS Codefree</li> <li>▪Rossmax CB 100</li> <li>▪Ultimate EZ Smart <sup>Plus</sup></li> <li>▪dynaValeo</li> <li>▪plusMED fasTTest</li> <li>▪Guardian TB100</li> <li>▪Gluco Dot</li> <li>▪TysonBio DA101</li> <li>▪AQ TB100</li> </ul>
	- Blood Glucose Meter	<ul style="list-style-type: none"> <li>▪EZ Smart</li> <li>▪EZ Smart-168</li> <li>▪EZ Smart-606</li> <li>▪EZ Smart-608</li> <li>▪TysonBio TB 100</li> <li>▪TysonBio TB 200</li> <li>▪TysonBio AC100</li> <li>▪TysonBio AC200</li> <li>▪TysonBio AC500</li> <li>▪TysonBio AC800</li> <li>▪TysonBio DA100</li> <li>▪Tyson Bio HT100</li> </ul>	<ul style="list-style-type: none"> <li>▪TysonBio EVOLVE</li> <li>▪TysonBio SUPERB</li> <li>▪EKS Codefree</li> <li>▪Rossmax CB 100</li> <li>▪Ultimate EZ Smart <sup>Plus</sup></li> <li>▪dynaValeo</li> <li>▪plusMED fasTTest</li> <li>▪Guardian TB100</li> <li>▪Gluco Dot</li> <li>▪TysonBio DA101</li> <li>▪AQ TB100</li> </ul>



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

**Attachment 1 to the Certificate number: VTT-C-10404-02-1073-501-13**

<i>Name</i>	<i>Model</i>	<i>Model</i>
- Blood Glucose Test Strip	<ul style="list-style-type: none"> <li>▪ EZ Smart</li> <li>▪ EZ Smart-168</li> <li>▪ EZ Smart-606</li> <li>▪ EZ Smart-608</li> <li>▪ TysonBio TB 100</li> <li>▪ TysonBio TB 200</li> <li>▪ TysonBio AC100</li> <li>▪ TysonBio AC200</li> <li>▪ TysonBio AC500</li> <li>▪ TysonBio AC800</li> <li>▪ TysonBio DA100</li> <li>▪ Tyson Bio HT100</li> </ul>	<ul style="list-style-type: none"> <li>▪ TysonBio EVOLVE</li> <li>▪ TysonBio SUPERB</li> <li>▪ EKS Codefree</li> <li>▪ Rossmax CB 100</li> <li>▪ Ultimate EZ Smart<sup>Plus</sup></li> <li>▪ dynaValeo</li> <li>▪ plusMED fasTTest</li> <li>▪ Guardian TB100</li> <li>▪ Gluco Dot</li> <li>▪ TysonBio DA101</li> <li>▪ AQ TB100</li> </ul>
- Glucose Control Solution	<ul style="list-style-type: none"> <li>▪ EZ Smart</li> <li>▪ EZ Smart-168</li> <li>▪ EZ Smart-606</li> <li>▪ EZ Smart-608</li> <li>▪ TysonBio TB 100</li> <li>▪ TysonBio TB 200</li> <li>▪ TysonBio AC100</li> <li>▪ TysonBio AC200</li> <li>▪ TysonBio AC500</li> <li>▪ TysonBio AC800</li> <li>▪ TysonBio DA100</li> <li>▪ Tyson Bio HT100</li> </ul>	<ul style="list-style-type: none"> <li>▪ TysonBio EVOLVE</li> <li>▪ TysonBio SUPERB</li> <li>▪ EKS Codefree</li> <li>▪ Rossmax CB 100</li> <li>▪ Ultimate EZ Smart<sup>Plus</sup></li> <li>▪ dynaValeo</li> <li>▪ plusMED fasTTest</li> <li>▪ Guardian TB100</li> <li>▪ Gluco Dot</li> <li>▪ TysonBio DA101</li> <li>▪ AQ TB100</li> </ul>
<b>Date:</b>	Tampere, 22 <sup>nd</sup> March 2017.	
	<div style="text-align: center;">  </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="text-align: center;">               Tuomas Toivonen         </div> <div style="text-align: center;">               Mikko Soikkeli         </div> </div>	

This attachment 1 supersedes the previous attachment 1, signed 16<sup>th</sup> October 2015.

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

**VTT EXPERT SERVICES LTD**

Medical Devices  
Tekniikkankatu 1, Tampere  
P.O. BOX 345, FI-33101 TAMPERE, FINLAND

Tel. +358 20 722 111  
www.vtt.fi

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