

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-02-1073-797-22Notified 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:	<p>The certificate covers the following products:</p> <table border="0" data-bbox="475 757 1445 1993"> <thead> <tr> <th data-bbox="475 757 766 795"><i>Name</i></th> <th data-bbox="778 757 1085 795"><i>Model</i></th> <th data-bbox="1098 757 1445 795"><i>Model</i></th> </tr> </thead> <tbody> <tr> <td data-bbox="475 804 766 842">Blood Glucose</td> <td data-bbox="778 804 1085 842">▪ Tyson Bio TB100</td> <td data-bbox="1098 804 1445 842">▪ Tyson Bio EVOLVE</td> </tr> <tr> <td data-bbox="475 851 766 889">Monitoring System</td> <td data-bbox="778 851 1085 889">▪ Tyson Bio TB200</td> <td data-bbox="1098 851 1445 889">▪ plusMED fasTTest</td> </tr> <tr> <td></td> <td data-bbox="778 898 1085 936">▪ Tyson Bio AC100</td> <td data-bbox="1098 898 1445 936">▪ Gluco Dot</td> </tr> <tr> <td></td> <td data-bbox="778 945 1085 983">▪ Tyson Bio AC200</td> <td data-bbox="1098 945 1445 983">▪ Tyson Bio HS100</td> </tr> <tr> <td></td> <td data-bbox="778 992 1085 1030">▪ AC500</td> <td data-bbox="1098 992 1445 1030">▪ Tyson Bio HT100-B</td> </tr> <tr> <td></td> <td data-bbox="778 1039 1085 1077">▪ Tyson Bio HT100</td> <td data-bbox="1098 1039 1445 1077">▪ Rossmax HS200</td> </tr> <tr> <td></td> <td data-bbox="778 1086 1085 1124">▪ Tyson Bio HT100-A</td> <td data-bbox="1098 1086 1445 1124">▪ JT101</td> </tr> <tr> <td></td> <td data-bbox="778 1133 1085 1171">▪ Tyson Bio HS100-B</td> <td data-bbox="1098 1133 1445 1171">▪ JT100-A</td> </tr> <tr> <td></td> <td data-bbox="778 1180 1085 1218">▪ Tyson Bio HT100-C</td> <td data-bbox="1098 1180 1445 1218">▪ JT100-C</td> </tr> <tr> <td></td> <td data-bbox="778 1227 1085 1265">▪ Tyson Bio HS200</td> <td data-bbox="1098 1227 1445 1265">▪ JS200</td> </tr> <tr> <td></td> <td data-bbox="778 1274 1085 1312">▪ Tyson Bio HS200-B</td> <td data-bbox="1098 1274 1445 1312">▪ JS200-B</td> </tr> <tr> <td></td> <td data-bbox="778 1321 1085 1359">▪ JT100</td> <td data-bbox="1098 1321 1445 1359">▪ GL60</td> </tr> <tr> <td></td> <td data-bbox="778 1368 1085 1406">▪ JT100-B</td> <td data-bbox="1098 1368 1445 1406">▪ LGLMV-BT-01</td> </tr> <tr> <td></td> <td data-bbox="778 1415 1085 1453">▪ JS100</td> <td data-bbox="1098 1415 1445 1453">▪ JU100-B</td> </tr> <tr> <td></td> <td data-bbox="778 1462 1085 1500">▪ JS100-B</td> <td data-bbox="1098 1462 1445 1500">▪ JU100</td> </tr> <tr> <td></td> <td data-bbox="778 1509 1085 1547">▪ Rossmax JS200</td> <td data-bbox="1098 1509 1445 1547">▪ Spengler TB100</td> </tr> <tr> <td data-bbox="475 1597 766 1680">Blood Glucose Meter</td> <td data-bbox="778 1597 1085 1635">▪ Tyson Bio TB100</td> <td data-bbox="1098 1597 1445 1635">▪ Tyson Bio EVOLVE</td> </tr> <tr> <td></td> <td data-bbox="778 1644 1085 1682">▪ Tyson Bio TB200</td> <td data-bbox="1098 1644 1445 1682">▪ plusMED fasTTest</td> </tr> <tr> <td></td> <td data-bbox="778 1691 1085 1729">▪ Tyson Bio AC100</td> <td data-bbox="1098 1691 1445 1729">▪ Gluco Dot</td> </tr> <tr> <td></td> <td data-bbox="778 1738 1085 1776">▪ Tyson Bio AC200</td> <td data-bbox="1098 1738 1445 1776">▪ Tyson Bio HS100</td> </tr> <tr> <td></td> <td data-bbox="778 1785 1085 1823">▪ AC500</td> <td data-bbox="1098 1785 1445 1823">▪ Tyson Bio HT100-B</td> </tr> <tr> <td></td> <td data-bbox="778 1832 1085 1870">▪ Tyson Bio HT100</td> <td data-bbox="1098 1832 1445 1870">▪ Rossmax HS200</td> </tr> <tr> <td></td> <td data-bbox="778 1879 1085 1917">▪ Tyson Bio HT100-A</td> <td data-bbox="1098 1879 1445 1917">▪ JT101</td> </tr> <tr> <td></td> <td data-bbox="778 1926 1085 1964">▪ Tyson Bio HS100-B</td> <td data-bbox="1098 1926 1445 1964">▪ JT100-A</td> </tr> <tr> <td></td> <td data-bbox="778 1973 1085 2011">▪ Tyson Bio HT100-C</td> <td data-bbox="1098 1973 1445 2011">▪ JT100-C</td> </tr> </tbody> </table>			<i>Name</i>	<i>Model</i>	<i>Model</i>	Blood Glucose	▪ Tyson Bio TB100	▪ Tyson Bio EVOLVE	Monitoring System	▪ 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	▪ JT101		▪ Tyson Bio HS100-B	▪ JT100-A		▪ Tyson Bio HT100-C	▪ JT100-C		▪ 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	Blood Glucose Meter	▪ 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	▪ JT101		▪ Tyson Bio HS100-B	▪ JT100-A		▪ Tyson Bio HT100-C	▪ JT100-C
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 Medical Devices
 Kivimiehentie 4
 FI-02150 ESPOO, FINLAND

Business ID FI21741879

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

**Blood Glucose
Test Strip**

- Tyson Bio HS200
- Tyson Bio HS200-B
- JT100
- JT100-B
- JS100
- JS100-B
- Rossmax JS200
- JS200
- JS200-B
- GL60
- LGLMV-BT-01
- JU100-B
- JU100
- Spengler TB100

- 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
- BRLMV-BT-01
- Tyson Bio EVOLVE
- plusMED fasTTest
- Gluco Dot
- Tyson Bio HS100
- Tyson Bio HT100-B
- Rossmax HS200
- JT100
- Rossmax JS200
- Spengler TB100
- JU100
- JS100
- GL60

**Glucose Control
Solution**

- 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
- SCLMV-BT
- Tyson Bio EVOLVE
- plusMED fasTTest
- Gluco Dot
- Tyson Bio HS100
- Tyson Bio HT100-B
- Rossmax HS200
- JT100
- Rossmax JS200
- Spengler TB100
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