

EC Declaration of Conformity

Document No. HT100-DOC-08

For the following equipment:

Tyson Bio HT100 Blood Glucose Monitoring System

(Product Name)

Tyson Bio HT100 Blood Glucose Meter
Tyson Bio HT100 Blood Glucose Monitoring System
Tyson Bio HT100 Blood Glucose Test Strips
Tyson Bio HT100 Control Solution

(Model, Designation)

Device Classification: Annex II List B

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro Diagnostic Medical Device — IVD Directive (98/79/EC)

The following standards were applied:

1. Quality System	EN ISO 13485:2016
2. Product Related Standard	EN ISO 15197:2015
3. Risk Management	EN ISO 14971:2012
4. Safety	EN 61010-1:2010, IEC 61010-2-101:2015, EN 61010-2-101:2017, IEC 60068-2-64:2008
5. Electromagnetic compatibility	EN 61326-1:2013, EN 61326-2-6:2013
6. Traceability of the calibration	EN ISO 17511:2003
7. Stability	EN ISO 23640:2015
8. Performance	EN 13612:2002
9. Labeling of medical devices	EN ISO 15223-1:2016
10. Information supplied manufacturer with in-vitro diagnostics medical devices for self-testing	EN ISO 18113-1:2011, EN ISO 18113-4:2011 EN ISO 18113-5:2011
11. Information supplied manufacturer with in-vitro diagnostics medical devices for professional use	EN ISO 18113-2:2011, EN ISO 18113-3:2011
12. Software validation	EN 62304:2006
13. Usability	EN 62366:2008

And also Annexes II and IV of the In-Vitro Diagnostic Medical Device Directive

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body:

Eurofins Expert Services Oy (Notified Body no. 0537)

(Company Name)

Kivimiehentie 4, FI-02150 ESPOO, FINLAND

(Company Address)

The Authorized Representative (EC REP) is:

Medical Device Safety Service GmbH(MDSS)

(Company Name)

Schiffgraben 41, D-30175 Hannover, Germany

(Company Address)

Person responsible for making this declaration:

Tyson Bioresearch, Inc.

(Manufacturer Name)

5F., No. 16, 18, 20, 22, Kedong 3rd Rd., Zhunan Township, Miaoli County 35053, Taiwan

(Place, Manufacture Address)

Management Representative

(Position/Title)

(Legal Signature)

(Date)



2022. 09. 14

