DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC CONCERNING In VITRO DIAGNOSTIC MEDICAL DEVICES

Manufacturer:	**BioCare Corporation** **4F, No.12, Ln. 5, Sec. 2, Nanshan Rd., Luzhu Dist., Taoyuan City 338028, Taiwan**
European Representative:	**MedNet EC-REP GmbH** **Borkstrasse 10, 48163 Münster, Germany**
Product Name:	**Blood Glucose Monitoring System**
Trademark / Model:	**Blood Glucose Monitoring System : TESTAmed** **Blood Glucose Meter : TESTAmed** **Blood Glucose Test strip : TESTAmed** **Control Solution : TESTAmed**

GMDN(UMDNS) Code: **16488**

Classification (IVDD, Annex II): **98/79/EC (IVDD) Annex II, List B (Self-Testing)**

Conformity Assessment Route: **98/79/EC (IVDD) Annex IV, excluding (4,6)**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Manufacturer is exclusively responsible for DoC.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC concerning medical devices (IVDD 98/79/EC).

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
Identification number:	CE0123
(EC) Certificate(s):	**V1 077360 0016 Rev.03**
Expire date of the Certificate:	2025-05-26
Start of CE Marking:	2013-01-01
Place, Date of Issue:	Taiwan, June 21, 2022
Signature:	Shu chang
Name:	Shuchi Chang
Position:	Management Representative

CE 0123

to which this declaration relates is in conformity with the following standard(s) or other normative document(s):

Standard	Title
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes.
ISO 14971:2019	Medical devices — Application of risk management to medical devices
EN ISO 15197:2015	In vitro diagnosis test systems- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.
EN ISO 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for In vitro diagnostic (IVD) medical equipment.
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment.
EN ISO 15223-1: 2016	Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic instruments for professional use
EN ISO 18113-4:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing
EN ISO 18113-5:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 62304:2006+A1:2015	Medical device software- Software life cycle processes
EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices