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, Section 3**

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.02**
Expire date of the Certificate:	2024-05-26
Start of CE Marking:	2013-01-01
Place, Date of Issue:	Taiwan, January 25, 2022
Signature:	Shu Chang
Name:	Shuchi Chang
Position:	Management Representative

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