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 33852, Taiwan**
European Representative:	**MedNet GmbH** **Borkstrasse 10, 48163 Muenster, Germany**
Product Name:	**Blood Glucose Monitoring System**
Trademark / Model:	**DIAVUE Puro/ Puro BLE**

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):	New Product
Expire date of the Certificate:	20xx-xx-xx
Start of CE Marking:	New Product
Place, Date of Issue:	Taiwan, Aug 27, 2019
Signature:	Liu
Name:	Terry Liu
Position:	Management Representative

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