

**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 : DIAVUE Prudential**
Blood Glucose Meter : DIAVUE Prudential
Blood Glucose Test strip : DIAVUE Prudential
Control Solution : DIAVUE Normal \ DIAVUE High

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. Manufacture 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**

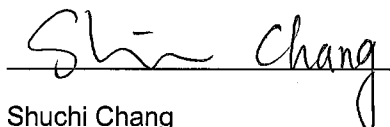
(EC) Certificate(s): **V1 077360 0016 Rev.02**

Expire date of the Certificate: **2024-05-26**

Start of CE Marking: **2013-01-01**

Place, Date of Issue: **Taiwan, January 27, 2022**

Signature:



Name: **Shuchi Chang**

Position: **Management Representative**

