

**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.
33852 Taoyuan City, TAIWAN

European Representative: **MedNet GmbH**
Borkstrasse 10, 48163 Muenster, Germany

Product Name: **Electrolyte Analyzer**
Analytes: **Na+, K+, Cl-/Li+**
Accessories: **Sodium Ion-Selective Electrode, Potassium Ion-Selective Electrode, Chloride Ion-Selective Electrode, Lithium Ion-Selective Electrode, Reference Electrode, Spacer, Cleaning Solution, Conditioning Na Solution, Tubing Set Biolyte, Air Detector Module, Electrode Carrier, Power Cord, Septum Biolyte, Sample Probe, Thermal Printer Paper**

Trademark / Model: **Biolyte 2000**

GMDN(UMDNS) Code: **16818**
EDMA Code: **21 01 52**

Classification (IVDD, Annex II): **98/79/EC (IVDD) Annex II, Others**

Conformity Assessment Route: **98/79/EC (IVDD) Annex III**

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).

Certification Body: **TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany**

Identification number: **Self-Declaration**

ISO 13485 Certificate(s): **Q5 077360 0017 Rev. 00**

Expire date of the Certificate: **2021-01-22**

Place, Date of Issue: **Taiwan, Aug 6, 2019**

Signature: _____

Name: **Terry Liu**

Position: **Management Representative**



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Product Name: **Reagent Pack**
Analytes: **Na+, K+, Cl-/Li+**
Trademark / Model: **Biolyte 2000**

GMDN(UMDNS) Code: **30216**
EDMA Code: **11.30.01.03**

Classification (IVDD, Annex II): **98/79/EC (IVDD) Annex II, Others**

Conformity Assessment Route: **98/79/EC (IVDD) Annex III**

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Identification number: **Self-Declaration**

ISO 13485 Certificate(s): **Q5 077360 0017 Rev. 00**

Expire date of the Certificate: **2021-01-22**

Place, Date of Issue: **Taiwan, Jul 25, 2019**

Signature: _____

Name: **Terry Liu**

Position: **Management Representative**

