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:	**Na^+, K^+, Cl^-, Ca^{++}, pH Electrolyte Analyzer and Reagent Pack**
Accessories:	**Calcium ISE, Chloride ISE, Potassium ISE, Sodium ISE, Reference ISE, pH ISE, Sample Probe.**
Trademark / Model:	**Biolyte V**

GMDN(UMDNS) Code: **16818**

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

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).

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
Identification number:	Self-Certification
ISO 13485 Certificate(s):	**Q5 077360 0017 Rev. 01**
Expire date of the Certificate:	**2024-01-22**
Place, Date of Issue:	**January. 25, 2021**
Signature:	Shuchi
Name:	**Shuchi Chang**
Position:	**Management Representative**

CE

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