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:	**Urine Chemistry Analyzer**
Trademark / Model:	**SR-III**
GMDN(UMDNS) Code:	**35919**
EDMA Code:	**11.02.01.90**

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, June 6, 2019

Signature: _____

Name: Terry Liu

Position: Management Representative

CE

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