DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Tianjin MNCHIP Technologies Co., Ltd

Address: 2102,2202, Building 2, No.19 Xinhuan Rd. West,TEDA, Tianjin, 300457, P.R. China

EC Representative: MNCHIP Europe GmbH

Address: Otto-Hesse-Str. 19 T1 D-64293 Darmstadt, Germany

Product Name: Chemistry Analyzer（Pointcare M4、Celercare M5）
Myocardial Enzyme Panel Lyophilized Kit
Liver Function Panel Lyophilized Kit
Liver and Renal Function Lyophilized Kit
Electrolyte Panel Lyophilized Kit
Clinical Emergency Lyophilized Kit
Glucose and Lipid Panel Lyophilized Kit
General Chemistry I Lyophilized Kit
General Chemistry II Lyophilized Kit
General Chemistry III Lyophilized Kit
General Chemistry IV Lyophilized Kit
General Chemistry V Lyophilized Kit
Renal Function Panel Lyophilized Kit
GLU & Lipid & HCY Panel Lyophilized Kit
Ammonia Panel Lyophilized Kit

Classification: Others (IVDD)

Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

CE

We herewith declare that the above mentioned product meets the transposition into national law, the provision of the following EC Council Directives（IVDD 98/79/EC）and Standards.

All supporting documentation are retained under the premises of the manufacturer.

EN ISO：14971:2019

EN ISO 15223-1:2016

EN ISO：18113-2:2011

EN ISO：18113-1:2011

Signature: _____ Date: December 30, 2021