

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、CelercareM5)

Myocardial Enzyme Panel Lyophilized Kit[5]

Liver Function Panel Lyophilized Kit[8]

Liver and Renal Function Lyophilized Kit[9]

Electrolyte Panel Lyophilized Kit[7]

Clinical Emergency Lyophilized Kit

Glucose and Lipid Panel Lyophilized Kit[5]

General Chemistry I Lyophilized Kit[13]

General Chemistry II Lyophilized Kit[8]

Renal Function Panel Lyophilized Kit[7]

GLU & Lipid & HCY Panel Lyophilized Kit[5]

Classification: Others (IVDD)

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



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: Zhandun Jiao

Date: 11/17/2020