

# DECLARATION OF CONFORMITY

## Regarding In Vitro Diagnostic Regulation (IVDR (EU) 2017/746)

**Manufacturer:** Tianjin MNCHIP Technologies Co., Ltd  
**Address:** 1-4F,Area,No.122 Dongting Rd,Development  
Zone,300457 Tianjin P.R.China  
**EC Representative:** Umedwings Netherlands B.V.  
**Address:** Treubstraat 1, 2288EG, Rijswijk, the Netherlands  
**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:** IVDD (98/79/EC) 、 IVDR (EU2017/746/ARTICLE110(3)) 、  
(IVDR (EU) 2017/746)



We herewith declare that the above mentioned product meets the transposition into national law, the provision of the following EC Council Directives and Standards. All supporting documentation are retained under the premises of the manufacturer.

EN ISO: 14971:2019

EN ISO: 15223-1:2021

EN ISO: 18113-2:2022

EN ISO: 18113-1:2022

Signature: Zhenhua Wang

Date: July 31, 2023