Wondfo

EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

Manufacturer: **Guangzhou Wondfo Biotech Co., Ltd.**
Address: No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China

EC Authorised Representative: **Qarad BV**
Address: Cipalstraat 3, 2440 Geel, Belgium

***In Vitro* Diagnostic Medical Device(s):**
Product Name: Finecare™ FIA Meter Plus
Model No.: FS-113
IVDD Classification: Other, for professional use

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices, Directive 80/181/EEC and RoHS Directive 2011/65/EU.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN 61010-1: 2010	EN 13612:2002
EN ISO 14971:2019	EN 61010-2-081:2015	EN 62304:2006
EN ISO 18113-1:2011	EN 61010-2-101:2002	EN 62366-1:2015
EN ISO 18113-3:2011	EN 61326-2-6: 2013	EN 61326-1: 2013
EN ISO 15223-1:2016	EN 62321 Series	

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: Annex III, excluding 6

Notified Body (if consulted): Not applicable
Address: /
EC Certificate(s): /
Expiry date of the Certificate(s): /

Signature of manufacturer (Name and function):

Vice-President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China

December 10, 2021