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

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

***In Vitro* Diagnostic Medical Device(s):**
Product Name: Finecare™ FIA Meter II Plus SE
Cat. No.: FS-114
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.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 14971:2019	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 18113-1:2011	EN ISO 18113-3:2011
EN 62304:2006	EN 62366-1: 2015	EN 61010-1: 2010+A1:2019
EN 61010-2-101:2017	EN 62133-2:2017	EN 61326-1:2013
EN 61326-2-6:2013	EN IEC 62311:2020	EN 61010-2-081:2015
ETSI EN 301 489-17 V3.2.4(2020-09)	ETSI EN 300 328 V2.2.2(2019-07)	ETSI EN 301 489-1 V2.2.3(2019-11)

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): Lingfang Huang

Lingfang Huang, Vice President of Regulatory Affairs

Digitally signed by Varman Irina
Date: 2023.02.16 10:17:39 EET
Reason: MoldSign Signature
Location: Moldova

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