Wondfo

EU DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Regulation (EU) 2017/746

Document No.: CSD-W911(2)-01-01
Version:01

Manufacturer:	**Guangzhou Wondfo Biotech Co., Ltd.**
SRN:	CN-MF-000000689
Address:	No.8, Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R. China
EU Authorised Representative:	**Qarad EC-REP BV**
SRN:	BE-AR-000000040
Address:	Pas 257, 2440 Geel, Belgium

***In Vitro* Diagnostic Medical Device(s):**

Product Name:	Finecare™ FIA Meter II Plus SE
Catalogue No.:	W911
Basic UDI-DI:	69332898CE0148EZ
EMDN Code:	W02010299
EMDN Term:	IMMUNOCHEMISTRY INSTRUMENTS - OTHER
Model No.:	FS-114
Brand:	Finecare

Intended Purpose: Finecare™ FIA Meter II Plus SE is designed for ***IN VITRO*** **DIAGNOSTIC USE ONLY**, for quantitative, semi-quantitative, qualitative determination of concentrations of various analytes in human blood, urine, feces, swabs etc. or QC solution. The specific sample type is subject to the instructions for use of immunofluorescence quantitative, semi-quantitative, qualitative test reagents that used along with and manufactured by Guangzhou Wondfo Biotech Co., Ltd.

The instrument and test reagents (mentioned as "Test Cartridges" hereinafter) are intended used by healthcare professionals in laboratories as well as for Near-Patient-Testing (NPT).

Finecare™ FIA Meter II Plus SE can be used in central laboratories, ICU/emergency rooms, GP offices, clinics, pharmacy and medical examination centers etc.

Risk Class: Professional use and near-patient testing, Class A, Rule 5

Standards applied:

ISO 18113-1:2022	EN ISO 15223-1:2021	EN ISO 13485: 2016
ISO 18113-3:2022	EN ISO 14971:2019	EN 62366-1:2015
EN 13612:2002	EN 61010-1:2010 +A1:2019	EN 61010-2-101:2022 /A11:2022
EN IEC 61326-1:2021	EN IEC 61326-2-6:2021	EN 62133-2: 2017
EN 62304:2006	EN 62321 series	

Reference to any Common Specifications: Not Applicable

Notified Body (if consulted):	/
Address:	/
No.	/

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Conformity Assessment Route /

EC Certificate No.: /

ISO Certificate No.: Q5 058008 0025 Rev.05

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.
I, the undersigned, on behalf of the Manufacturer hereby declare that the device(s) listed above fulfil(s) the provisions of the European Regulation (EU) 2017/746 for *In Vitro* Diagnostic Medical Devices and is in conformity with this Regulation.

Signature of manufacturer
(Name and function): Yongfang Lv, Director of Regulatory Affairs

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

February 21, 2024