Wondfo

EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W203(1)-01
Version: 02

Manufacturer: **Guangzhou Wondfo Biotech Co., Ltd.**
Address: No.8, Lizhishan Road, Science City, Huangpu 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™ cTn I Rapid Quantitative Test
Cat. No.: W203
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	ISO 18113-1:2022	EN 13612:2002
EN ISO 14971:2019	ISO 18113-2:2022	EN 13641:2002
EN ISO 23640:2015	EN ISO 15223-1:2021	EN 62366-1:2015
EN ISO 17511:2021		

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): /

This is a legacy device which was CE marked in 05, 2013 under IVDD Directive 98/79/EC.

Signature of manufacturer

(Name and function): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China, July 24, 2023

Digitally signed by Stoianova Elena
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