

## 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:**

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**EC Certificate(s):**

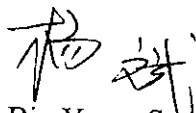
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**Expiry date of the Certificate(s):**

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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