



## EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W812(1)-01

Version: 00

**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:** Ciplastraat 3, 2440 Geel, Belgium

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

**Product Name:** Finecare™ D-Dimer Control  
**Cat. No.:** W812  
**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 and Regulation (EC) No 1272/2008.

The following (harmonized) standards have been applied:

|                   |                     |                 |
|-------------------|---------------------|-----------------|
| EN ISO 13485:2016 | EN ISO 18113-1:2011 | EN 13612:2002   |
| EN ISO 14971:2019 | EN ISO 18113-2:2011 | EN 13641:2002   |
| EN ISO 23640:2015 | EN ISO 15223-1:2016 | EN 62366-1:2015 |

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):** Bin Yang, Senior Vice President of Regulatory Affairs

**Place and date of issue:** Guangzhou, P.R. China,  
April 20, 2022