



## EC DECLARATION OF CONFORMITY

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

No.: DOC-W205(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™ CK-MB Rapid Quantitative Test  
**Cat. No.:** W205  
**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
EN ISO 17511:2003		

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):** Senior President of Regulatory Affairs

**Place and date of issue:** Guangzhou, P.R. China,  
March 11, 2022