



EC DECLARATION OF CONFORMITY

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

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: Prothrombin Time Reagent Kit (Clotting)
Cat. No.: W480
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 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13641:2002	EN ISO 13485:2016	EN ISO 14971: 2019
EN 62366-1:2015	EN 13612:2002	EN ISO 23640:2015
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):

Lingfang Huang, Vice-President of Regulatory Affairs

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