qarad
European Regulatory Services

DECLARATION

The undersigned, Mrs. Joke Doutreloigne, Consultant at Qarad b.v.b.a.,

hereby declares that Guangzhou Wondfo Biotech Co. Ltd. has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products:

name IVD	Catalogue nr.
Prothrombin Time Reagent Kit (Clotting)	W480
Activated Partial Thromboplastin Time Reagent Kit (Clotting)	W481
Fibrinogen Reagent Kit (Clotting)	W482
Activated Clotting Time Reagent Kit (Clotting)	W483
Thrombin Time Reagent Kit (Clotting)	W484

The notification to the Belgian Competent Authorities has been carried out on September 20, 2017 by Qarad b.v.b.a., the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is *available upon request.*

Joke Doutreloigne

Qarad b.v.b.a.
Authorized Representative

Digitally signed by Marinescu Traian alin
Date: 2024.01.09 12:57:25 EET
Reason: MoldSign Signature
Location: Moldova

EC DECLARATION OF CONFORMITY

According 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	
***in vitro* diagnostic device(s):**	**Product Name:**	Fibrinogen Reagent Kit (Clotting)
	Cat. No.:	W482
	IVDD Classification:	Other, for professional use

This declaration of conformity is issued under the sole responsibility of the manufacturer that 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 980:2008
EN 13641:2002	EN ISO 14971:2012	EN ISO 17511:2003
EN 23640:2015	EN 13612:2002	EN 62366 :2008

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

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

Qarad b.v.b.a., Cipalstraat 3, B-2440 Geel, Belgium

Guangzhou Sep. 15, 2017	Amy Lee Amy Lee, Management Representative
(Place and date of issue)	(name and signature or equivalent marking of authorized person)

EC DECLARATION OF CONFORMITY

According 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	
In vitro diagnostic 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 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 980:2008
EN 13641:2002	EN ISO 14971:2012	EN 62366 :2008
EN 23640:2015	EN 13612:2002	EN ISO 13485: 2012
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

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

Qarad b.v.b.a., Cipalstraat 3, B-2440 Geel, Belgium

Guangzhou Sep. 15, 2017	Amy Lee Amy Lee, Management Representative
(Place and date of issue)	(name and signature or equivalent marking of authorized person)