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:**	**Model:**
	Finecare™ FIA Meter Plus	FS-113
	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 18113-3:2011	EN 980:2008
EN 62304: 2006	EN 62366 : 2008	EN ISO 14971: 2012
EN 61010-2-081:2015	EN 13612:2002	EN 61010-1: 2010
EN 61010-2-101:2002	EN 61326-1: 2013	EN 61326-2-6: 2013

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. Jun. 12th, 2016	Amy Lee, Management Representative
(Place and date of issue)	(name and signature or equivalent marking of authorized person)

Digitally signed by Stoianova Elena
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