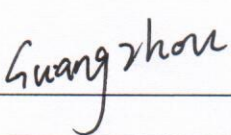



EC DECLARATION OF CONFORMITY  
According to the In Vitro Diagnostic Medical Device Directive 98/79/EC

<b>Manufacturer:</b>	Guangzhou Wondfo Biotech Co. Ltd.	
<b>Address:</b>	No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China	
<b>In vitro diagnostic device(s):</b>	<b>Product Name:</b>	Wondfo® Blood Gas Analyzer
	<b>Cat. No.:</b>	BGA-102
	<b>IVDD Classification:</b>	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 Directive 2011/65/EU.		
The following (harmonized) standards have been applied:		
EN ISO 13485:2016	EN ISO 14971:2012	EN ISO 15223-1:2016
EN ISO 18113-1:2011	EN ISO 18113-3:2011	EN 13612:2002
EN 62304:2006	EN 62366:2008	EN 61010-1:2010+A1:2019
EN 61010-2-101:2017	EN 61326-1:2013	EN 61326-2-6:2013
EN 62133-2:2017	EN 62311:2008	EN 62471:2008
EN 300 328 V2.1.1	EN 301 489-1 V2.1.1	EN 301 489-17 V3.1.1
The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: <u><b>Annex III, excluding 6</b></u>		
<b>Notified Body (if consulted):</b>	<u>Not Applicable</u>	
Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:  <u><b>Qarad b.v.b.a., Ciplstraat 3, B-2440 Geel, Belgium</b></u>		
 <u>Guangzhou</u>	Yaqin Chi, Regulatory Affairs Director  <u>Yaqin Chi</u>	
(Place and date of issue)	(name and signature or equivalent marking of authorized person)	