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:**	Wondfo® Blood Gas Analyzer
	Cat. No.:	BGA-102
	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, 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: **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 June 5, 2020	Yaqin Chi, Regulatory Affairs Director Yaqin Chi
(Place and date of issue)	(name and signature or equivalent marking of authorized person)