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® Optical Coagulation Analyzer
	Model No.:	OCG-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 and 2011/65/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 ISO 14971:2012	EN 61010-1:2010	EN 61010-2-101:2015
EN 61326-1:2013	EN 61326-2-6:2013	EN 62366 :2008
EN 13612:2002	EN 301 489-1 V2.1.1	EN 300 328 V2.1.1
EN 301 489-17 V3.1.1	EN 62479:2010	EN 50566:2013
EN 62209-2:2010		

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 Dec. 18th, 2017	Amy Amy Lee, Management Representative
(Place and date of issue)	(name and signature or equivalent marking of authorized person)