Wondfo

EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

Document No.: DOC-W039(2)-01
Version: 03

Manufacturer:	**Guangzhou Wondfo Biotech Co., Ltd.**
Address:	No.8, Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, P.R. China
EC Authorised Representative:	Qarad BV
Address:	Cipalstraat 3, 2440 Geel, Belgium

***In Vitro* Diagnostic Medical Device(s):**

Product Name:	One Step Strep A Swab Test
Cat. No.:	W039P0001, W39-CH, W39-SH
IVDD Classification:	Non-Annex II, for self-testing

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.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	ISO 18113-1:2022	EN 13532:2002
EN ISO 14971:2019	ISO 18113-4:2022	EN 13612:2002
EN ISO 23640:2015	EN ISO 15223-1:2021	EN 13641:2002
EN 62366-1:2015		

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **Annex IV, excluding 4 and 6.**

Notified Body (if consulted):	**TÜV SÜD Product Service GmbH (NB # 0123)**
Address:	Ridlerstraße 65, 80339 Munich,Germany
EC Certificate(s):	V1 058008 0030 Rev.02
Expiry date of the Certificate(s):	2025-05-26

This is a legacy device which was CE marked in December, 2010 under IVDD Directive 98/79/EC.

Signature of manufacturer

(Name and function): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

December 6, 2023