

EC DECLARATION OF CONFORMITY

According to 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

EC Authorised Representative: Qarad BV
Address: Cipalstraat 3, 2440 Geel, Belgium

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

Product Name: SureStep™ Oral Fluid Test Drug Screen Cube
Cat. No.: OFCUBE-5WP, OFCUBE-6POL, OFCUBE-9REH, OFCUBE-10REH
IVDD Classification: 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.

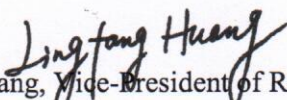
The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 14971:2019	EN ISO 15223-1:2016
EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN 62366:2008

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
Address: /
EC Certificate(s): /
Expiry date of the Certificate(s): /

Signature of manufacturer (Name and function):


Lingfang Huang, Vice-President of Regulatory Affairs

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