



# Declaration of Conformity

according to Directive 98/79/EC, on *in vitro* diagnostic medical devices

**Maker:**

(Name, Address)

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**Authorized:**

(Name, Address)

Peter Wei

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Registration office: Lotus NL B.V.

**Medical device:**

Description: Diagnostic Kit for Novel-Coronavirus(2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay)

Classification of products according to directive: Diagnostic reagent box others devices indicated in IVD ANNEX II

Batch/serial No. type, production term (if applicable): U20223

**Applicable coordination standards:**

EN 13640:2002	EN ISO 14971:2012
EN ISO 13485:2016	EN ISO 15223-1:2016
EN 13975:2003	BS EN ISO 18113-3:2011
BS EN ISO 18113-2:2011	

Signatory representative declares herein the above mentioned device meets the basic requirement of European *in vitro* diagnostic medical devices directive 98/79/EC Annex I.

This declaration of conformity is based on European *in vitro* diagnostic medical devices directive 98/79/EC Annex III. The compiled technical file and quality system are testified by the Annex III quality system certificate issued according to *in vitro* diagnostic medical devices directive by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager:

Hangzhou

March 20 2020

(place and date of issue)

YIZHI LIN

(name and signature or equivalent marking of authorized person)