# Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

*Shanghai ZJ Bio-Tech Co., Ltd.*
*Building #26, 588 Xinjunhuan Road*
*Pujiang High-tech Park*
*201114 Shanghai*
*China*

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

**Please see Annex to EC Declaration of Conformity**

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **EN ISO 13485:2016**

Corporate Contact Information

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**Position: Registration Manager Assistant**

**SIGNATURE :** Yang Hui hui

**Date : 15/02/2020**

**Stamp**


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# Annex to EC Declaration of Conformity

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

| No. | Generic Device Term | Commercial name | Class** | Catalogue reference number | GMDN/EDMS code*** | Short description and intended use |
|---|---|---|---|---|---|---|
| 1 | Multiple respiratory virus nucleic acid IVD, kit, nucleic acid technique (NAT) | Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes) | others | RR-0479-02 | 47922 | Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit (Detection for 3 Genes) is used for the in vitro qualitative detection of 2019 novel coronavirus (2019-nCoV) RNA in upper respiratory tract specimens (nasopharyngeal and oropharyngeal extracts) and lower respiratory tract specimens (bronchoalveolar lavage fluid (BALF) and deep cough sputum) by real time PCR systems.<br>1. Novel CoV (2019-nCoV) Super Mix<br>1 vial, 513μL<br>2. RT-PCR Enzyme Mix<br>1 vial, 27μL<br>3. Novel CoV (2019-nCoV) Internal Control<br>1 vial, 30μL<br>4. Novel CoV (2019-nCoV) Negative Control<br>1 vial, 400μL<br>5. Novel CoV (2019-nCoV) Positive Control<br>1 vial, 30μL |

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

*** GMDN or EDMS codes are mandatory information to complete the Notification.

***Manufacturer's Name***

*Shanghai ZJ Bio-Tech Co., Ltd.*

***Signature:*** Yang Huihui

***Date:*** 15/02/2020

***Stamp:***