

Technical Document No.: RF-TCF-01

## EC Declaration of Conformity

*Manufacturer:*

**Redpharm (Changchun) Biotechnology Co.,Ltd**  
102, Building 27, Hansenxiangxieli, Intersection of  
Chaoyue Street and Chuangyi Road, High and New  
Technology Industrial Development Zone,  
Changchun, Jilin, China

*whose single Authorized EU-Representative:*

**Name: Share Info Consultant Service LLC**  
**Repräsentanzbüro**  
**Add: Heerdter Lohweg 83, 40549 Düsseldorf**  
**Tel: 0049 1767 0057022**  
**Dimdi Code DE/0000047946**

We, the manufacturer, herewith declare that the products:

**SARS-CoV-2 Nucleic Acid Detection Kit (Fluorescence RT-PCR)**  
**Model: 25 Tests/box**

meet the provisions of 98/79/EC (IVDD) ( In vitro diagnostic medical devices) which apply to them.

The medical device has been assigned to Others according to Annex II of the 98/79/EC. It bears the mark



following the conformity assessment procedures relating to the EC Declaration of Conformity set out in Annex III of 98/79/EC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

*The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:*

**EN 13641:2002; EN13612:2002+AC:2002; EN ISO 23640:2015; EN ISO 17511:2003;**  
**EN ISO 13485: 2016; EN ISO 14971:2012; EN ISO 15223-1:2016;**  
**EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN 13975: 2003**

The above mentioned declaration of conformity is exclusively under the responsibility of

**Redpharm (Changchun) Biotechnology Co.,Ltd**  
102, Building 27, Hansenxiangxieli, Intersection of Chaoyue Street and Chuangyi Road, High and New  
Technology Industrial Development Zone, Changchun, Jilin, China

Changchun, 2020/03/20  
Place, date

Legally binding signature. Function

