

Technical Document No.: RF-TCF-02

EC Declaration of Conformity

Manufacturer:

Redpharm (Changchun) Biotechnology Co.,Ltd
102, Building 27, Hansengxiangxieli, 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
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We, the manufacturer, herewith declare that the products:

SARS-CoV-2 IgG/IgM Antibody Test Strip (Colloidal Gold Method)
Model: 5 tests / box; 10 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, Hansengxiangxieli, Intersection of Chaoyue Street and Chuangyi Road, High and New
Technology Industrial Development Zone, Changchun, Jilin, China

Changchun, 2020/03/20
Place, date

Legal authentic signature, Function

