EC Declaration of Conformity

Manufacturer:
Shenzhen Heto Medical Tech Co., Ltd.
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European Representative：
Wellkang Ltd
Suit B,29 Harley Street,LONDON W1G 9QR,England,United Kingdom
Tel: +44(20)30869438,32876300 Fax: +44(20)76811874

Product Name：
SARS-CoV-2 IgG/IgM Diagnostic Test Kit (Colloidal Gold)

Classification:
Other device, not in annex Ⅱ and not for self-testing,not for performance evaluation.

Conformity Assessment Route:IVDD 98/79/EC Annex Ⅲ
We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

General Applicable Directive:
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:
EN 13612:2002 EN ISO 13485:2016 EN ISO 15223-1:2016 EN ISO 18113-1:2011
EN ISO 23640:2015 EN ISO14971:2012 EN 13641:2002 EN ISO18113-2:2011
EN ISO 17511:2003

First Start of CE-MARK:20th March 2020
Place,Date of Issue: ShenZhen,China 20th March 2020

Signature： Managing Director