Declaration of Conformity

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

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China
Authorized Representative (Name, Address)	**Lotus NL B.V.** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Medical device	One Step Test for Novel Coronavirus(2019-nCoV) IgG antibody (Colloidal Gold) One Step Test for Novel Coronavirus(2019-nCoV) IgM antibody (Colloidal Gold) One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold)
Classification	Others
Applicable coordination standards	EN ISO 14971:2012 EN 13612:2002 EN 1041:2008 IEC 61010-1:2010 IEC 61326-1:2013 EN ISO 23640:2015 EN ISO15223-1:2012 EN ISO 18113-1:2011 IEC 61010-2-101:2015 IEC 61326-2-2:2013 EN ISO 13485:2016 EN ISO 18113-2:2011 EN ISO 18113-3:2011 IEC 61010-2-081:2015

Signatory representative declares herein the above mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex III. This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by TÜV Rheinland (Shanghai) Co., Ltd.

General Manager Enben Su

Nanjing, 4th, Mar, 2020

(place and date of issue)

(name and signature or equivalent marking of authorized person)

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