

Declaration of Conformity

Applicant: **Coyote Bioscience Co., Ltd**
Room509, 510, Chuangye Zhonglu#36, Haidian
District, 100085, Beijing P. R. China

Ref. No.: **DOC 20200224001**

EU Authorized Representative

**Whose single
Authorized EU
Representative:** **Lotus NL B.V.**
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

Product(s): Coyote DirectDetect™ SARS-CoV-2 Detection Kit

Classification: Others of ANNEX II of IVDD

We, Coyote Bioscience Co., Ltd, declared that the product listed above is in conformity with the essential requirements and provision of council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC in accordance with annex III.

Standards Applied

EN ISO 13485: 2016

EN ISO 18113-1:2011

EN 61326-2-6:2006

EN ISO 14971:2012

EN ISO 18113-3:2011

EN 13612:2002


EN 1041:2008

EN 61010-2-101:2002

EN 62366:2008

Coyote Bioscience Co., Ltd

*This is not a CE-Mark and is only provided as
an image for informational demonstrate


Mr. Xuan Wang
January 24th, 2020

