# Declaration of Conformity

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

Ref. No.:20210124-A01

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|---|---|
| **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. |

| | **Product Name** | **GMDN Code** |
|---|---|---|
| **Medical device** | One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold) | 64756 |
| | One Step Test for SARS-Cov-2 Antigen (Colloidal Gold) | 64787 |

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| **Classification** | Others | | |
| **Applicable coordination standards** | EN 13612:2002 | EN ISO 14971:2012 | EN ISO15223-1:2016 |
| | EN ISO 18113-1:2011 | EN ISO 18113-2:2011 | EN ISO 18113-3:2011 |
| | EN ISO 23640:2015 | EN ISO 13485:2016 | ISO 780:2015 |

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 BSI Group The Netherlands B. V..

**General Manager** Enben Su

Nanjing, 24th Jan. 2021
(place and date of issue)

Enben Su
(name and signature or equivalent marking of authorized person)

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