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EC Declaration of Conformity

Manufacturer:

Name: ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

Address: 4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, People's Republic of China

Whose Authorized Representative:

Name: MedUnion S.L.
(ES-AR-000019366)

Address: Carrer de Tapioles,33, 2-1, Barcelona, 08004, Spain

Tel: +0034-644173535

We, Anhui Deepblue Medical Technology Co., Ltd. (Manufacturer), here declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them. The declaration of conformity is exclusively under the responsibility of Anhui Deepblue Medical Technology Co., Ltd. (Manufacturer).

Product Name: SARS-CoV-2 & Influenza A+B & RSV Antigen Combo Test Kit (Colloidal Gold)

Classification: Others

Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding section 6).

Applicable Standards:

EN ISO 13485:2016

EN ISO 18113-2:2011

EN 13612:2002

EN ISO 14971:2019

EN 13641:2002

EN ISO 23640:2015

EN ISO 18113-1:2011

ISO 15223-1:2016

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| Name of Authorized Signatory | CHEN FENGLING |
| Position Held In The Company | GENERAL MANAGER |
| Signature | |
| Date | 2022-02-09 |
| Place | China |