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EC Declaration of Conformity

Manufacturer:

Name: ANHUI DEEPBLUE MEDICAL TECHNOLOGY
CO.,LTD.

Address: No. 777 Jimingshan Road, 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 & ADV & Mycoplasma Pneumoniae
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 13485:2016/AC:2018,
EN ISO 13485:2016/A11:2021)

EN ISO 14971:2019
EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN 13641:2002
ISO 15223-1:2016

EN 13612:2002

EN ISO 23640:2015



Name of Authorized Signatory

CHEN FENGLING

Position Held In The Company

GENERAL MANAGER

Signature

Date

2025-01-18

Place

China

DOC- SARS-CoV-2 & Influenza A+B & RSV &
ADV & MP (A/Q)