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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: COVID-19 /Flu A /Flu B & RSV /ADV /HMPV Antigen ComboTest Kit (LFA)

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 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

CE

Name of Authorized Signatory	ZHANG CHAO
Position Held In The Company	CHAIRMAN OF THE BOARD
Signature	Zhang Chao
Date	2023-07-01
Place	China
Version Number	2.0

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Revision history

Version:	2.0
Revision Reason:	Change of address on July 1, 2023, no significant changes in the design or purpose of the product since the statement on May 9, 2022
Revision Date:	2023-07-01
Revised By:	ZHANG CHAO