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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.  
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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).

**GMDN code:** CT923

**REF no:** CFRAINPO-X

**Product Name:** SARS-CoV-2 & Influenza A+B & RSV & ADV 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



<b>Name of Authorized Signatory</b>	CHEN FENGLING
<b>Position Held In The Company</b>	GENERAL MANAGER
<b>Signature</b>	
<b>Date</b>	2023-07-01
<b>Place</b>	China
<b>Version Number</b>	2.0

