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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).

Product Name: Ten Respiratory Pathogens Antigen Test Kit

Classification: Others

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

Ref No: RP1021NNO-X **Basical UDI-DI:** 69520627J175LY

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



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