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# DECLARATION OF CONFORMITY

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| MANUFACTURER: | ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.<br>No. 777 Jimingshan Road, High-Tech Development Zone, 230088<br>Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA |
| EUROPEAN REPRESENTATIVE: | Luxus Lebenswelt GmbH<br>Kochstr. 1, 47877, Willich, Germany |
| PRODUCT: | Influenza A+B & COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) |
| MODELS: | Strip; Cassette |
| CLASSIFICATION: | OTHER |
| EDMA CODE: | 15 70 90 90 00 |

CONFORMITY ASSESSMENT ROUTE:Following the procedure relating to the EC Declaration of Conformity set out in Annex III of Directive 98/79/EC.

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

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| STANDARDS APPLIED: | EN ISO 13485:2016<br>EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN ISO 14971:2019. |
| START OF CE-MARKING: | 2024-03-11 |
| PLACE, DATE OF ISSUE: | HEFEI, 2026-01-21 |

SIGNATURE:

**ZHANG CHAO** zhang chao

**CHAIRMAN OF THE BOARD**

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