



DECLARATION OF CONFORMITY



MANUFACTURER: ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.
4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,
High-Tech Development Zone , 230088 Hefei, Anhui, People's
Republic of China

EUROPEAN REPRESENTATIVE: Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

PRODUCT: COVID-19 (SARS-CoV-2) Antibody Test Kit(Colloidal Gold)

Models: Strip;cassette

CLASSIFICATION: OTHER

EDMA CODE: 15 04 80 90

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.

STANDARDS APPLIED: EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO 14971:2012.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH, RIDLERSTR.
65, 80339 MUNCHEN, GERMANY

(EN) CERTIFICATE(S): Q5 18 03 03706 001

START OF CE-MARKING: 2020-02-28

PLACE, DATE OF ISSUE: HEFEI, 2020-02-28



SIGNATURE: CHEN FENGLING
GENERAL MANAGER

