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) Antigen Test Kit (Colloidal Gold)
Models:	Saliva: Midstream 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.

STANDARDS APPLIED:	EN ISO 13485:2016 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 14971:2012.
START OF CE-MARKING:	2020-07-31
PLACE, DATE OF ISSUE:	HEFEI, 2021-07-07

SIGNATURE: **CHEN FENGLING**
GENERAL MANAGER

CE

EC Declaration of Conformity
DOC-COVID-19 Ag- (M/0)