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DECLARATION OF CONFORMITY

MANUFACTURER:	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD. No. 777 Jimingshan Road, 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:	Swab
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 Article 110(3) Regulation (EU) 2017/746 (Legacy Device).

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE ARTICL 110(3) REGULATION (EU) 2017/746 (LEGACY DEVICE). 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 14971:2019.
START OF CE-MARKING:	2020-07-31
PLACE, DATE OF ISSUE:	HEFEI, 2024-03-12

SIGNATURE:

CHEN FENGLING

GENERAL MANAGER

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