

## DECLARATION OF CONFORMITY

**MANUFACTURER:** ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.  
4<sup>th</sup> 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:** SEE ATTACHMENT

**REF:** SEE ATTACHMENT

**CLASSIFICATION:** SELF-TESTING

**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 Article 6 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 18113-4:2011, 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:** Polish Center for Testing and Certification  
469 Puławska Street, 02-844 Warsaw, Poland

**(EN) CERTIFICATE(S):** 2021-07-30

**START OF CE-MARKING:** 2021-07-30

**PLACE, DATE OF ISSUE:** HEFEI, 2021-09-15

**SIGNATURE:** CHEN FENGLING  
**GENERAL MANAGER**



DOC-COVID-19 Ag(N/1)



**DECLARATION OF CONFORMITY  
ATTACHMENT**

<b>Specification</b>	<b>REF</b>
1 piece per box	SL030101NST-1
2 pieces per box	SL030101NST-2
3 pieces per box	SL030101NST-3
5 pieces per box	SL030101NST-5
6 pieces per box	SL030101NST-6
7 pieces per box	SL030101NST-7
8 pieces per box	SL030101NST-8
9 pieces per box	SL030101NST-9
10 pieces per box	SL030101NST-10
11 pieces per box	SL030101NST-11
12 pieces per box	SL030101NST-12
15 pieces per box	SL030101NST-15
16 pieces per box	SL030101NST-16
17 pieces per box	SL030101NST-17
18 pieces per box	SL030101NST-18
19 pieces per box	SL030101NST-19
20 pieces per box	SL030101NST-20
25 pieces per box	SL030101NST-25

