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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) -Saliva

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 Section 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): 1434-IVDD-484/2021

START OF CE-MARKING: 2021-11-10

PLACE, DATE OF ISSUE: HEFEI, 2021-11-12

SIGNATURE: CHEN FENGLING

GENERAL MANAGER



EC Declaration of Conformity

DOC-COVID-19 Ag(M/0)



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DECLARATION OF CONFORMITY ATTACHMENT

DEEPBLUE, ShenLanTest, Highbluetest, NewBluetest, Quicklyblue

Specification	REF
1 piece per box	SL030101SST-1
2 pieces per box	SL030101SST-2
3 pieces per box	SL030101SST-3
4 pieces per box	SL030101SST-4
5 pieces per box	SL030101SST-5
6 pieces per box	SL030101SST-6
7 pieces per box	SL030101SST-7
8 pieces per box	SL030101SST-8
9 pieces per box	SL030101SST-9
10 pieces per box	SL030101SST-10
11 pieces per box	SL030101SST-11
12 pieces per box	SL030101SST-12
13 pieces per box	SL030101SST-13
14 pieces per box	SL030101SST-14
15 pieces per box	SL030101SST-15
16 pieces per box	SL030101SST-16
17 pieces per box	SL030101SST-17
18 pieces per box	SL030101SST-18
19 pieces per box	SL030101SST-19
20 pieces per box	SL030101SST-20
21 pieces per box	SL030101SST-21
22 pieces per box	SL030101SST-22
23 pieces per box	SL030101SST-23
24 pieces per box	SL030101SST-24
25 pieces per box	SL030101SST-25

