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EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer: Anhui Deepblue Medical Technology Co., Ltd.
No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei,
Anhui, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000018785

European Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

SRN: DE-AR-000005110

Product Name: HCG Pregnancy Test (Colloidal Gold)

Intended Use The HCG Pregnancy Test (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The HCG Pregnancy Test (Colloidal Gold) is designed for both self-testing and professional laboratory use, not for near patient testing.

EMDN: W0102160302

Basic UDI-DI: 69520627J001KW

Classification acc. to IVDR Ax. VIII: Class B, rule 4 (a) of IVDR Annex VIII

Conformity Assessment Procedure: Pursuant to Regulation (EU) 2017/746, Annex IX Chapter II(Class B device for self-testing excluding near-patient-testing and companion diagnostics)

CE Certificate No.: V76 003706 0007 Rev. 00

Name and ID of the Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany
NB number: 0123
E-mail: medical_devices@tuev-sued.de
Tel: +49 (89) 50084261

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

START OF CE-MARKING: August 29th, 2025



PLACE, DATE OF ISSUE: Anhui Hefei, China, September 4th, 2025

SIGNATURE: Zhang Chao / Chairman

EC Declaration of Conformity

SL-CER-HCG-8.1 (A/0)



**DECLARATION OF CONFORMITY
ATTACHMENT**

Specification	REF (Cassette)	REF (Strip)	REF (Midstream)
1 pc/box	HCG1UST-1	HCG2UST-1	HCG3UST-1
2 pcs/box	HCG1UST-2	HCG2UST-2	HCG3UST-2
3 pcs/box	HCG1UST-3	HCG2UST-3	HCG3UST-3
4 pcs/box	HCG1UST-4	HCG2UST-4	HCG3UST-4
5 pcs/box	HCG1UST-5	HCG2UST-5	HCG3UST-5
10 pcs/box	HCG1UST-10	HCG2UST-10	HCG3UST-10
15 pcs/box	HCG1UST-15	HCG2UST-15	HCG3UST-15
20 pcs/box	HCG1UST-20	HCG2UST-20	HCG3UST-20
25 pcs/box	HCG1UST-25	HCG2UST-25	HCG3UST-25
50 pcs/box	HCG1UST-50	HCG2UST-50	HCG3UST-50

