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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: LH Ovulation Test (Colloidal Gold)

EMDN: W0102160304

Basic UDI-DI: 69520627J002KY

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

Intended Use LH Ovulation Test (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of Luteinizing Hormone (LH) in female urine to predict when there is a LH surge, and in turn, when you are likely to ovulate.
LH Ovulation Test (Colloidal Gold) is designed for both self-testing and professional laboratory use, not for near patient testing.

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 0008 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 / *Zhang Chao*

EC Declaration of Conformity

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



**DECLARATION OF CONFORMITY
ATTACHMENT**

Specification	REF (Cassette)	REF (Strip)	REF (Midstream)
1 pc/box	LH1UST-1	LH2UST-1	LH3UST-1
2 pcs/box	LH1UST-2	LH2UST-2	LH3UST-2
3 pcs/box	LH1UST-3	LH2UST-3	LH3UST-3
5 pcs/box	LH1UST-5	LH2UST-5	LH3UST-5
10 pcs/box	LH1UST-10	LH2UST-10	LH3UST-10
15 pcs/box	LH1UST-15	LH2UST-15	LH3UST-15
20 pcs/box	LH1UST-20	LH2UST-20	LH3UST-20
25 pcs/box	LH1UST-25	LH2UST-25	LH3UST-25
50 pcs/box	LH1UST-50	LH2UST-50	LH3UST-50

