



EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II

No. V76 003706 0007 Rev. 00

Manufacturer:

**ANHUI DEEPBLUE MEDICAL
TECHNOLOGY CO.,LTD.**

No. 777 Jimingshan Road, High-Tech Development Zone
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000018785

Authorized Representative:

Luxus Lebenswelt GmbH
Kochstr. 1, 47877 Willich, GERMANY

The technical documentation has been evaluated in accordance with Regulation (EU) 2017/746,
Annex IX Chapter II with a positive result.

Details on devices covered by the technical documentation are described on the following page(s).
The report referenced below summarises the results of the assessment and includes reference to
relevant CS, harmonised standards and test reports.

If class B or C self-/near-patient testing are covered by this certificate, the assessment was conducted
according to section 4 and 5.1. An EU Quality Management System Certificate in accordance with
Annex IX Chapter I is required before placing them on the market.

If class C companion diagnostics devices are covered by this certificate, the assessment was
conducted according to section 4 and 5.2. An EU Quality Management System Certificate in
accordance with Annex IX Chapter I is required before placing them on the market.

If class D devices are covered by this certificate, verification of batches of manufactured devices
according to Annex IX Sections 4.12 and 4.13 is applicable. An EU Quality Management System
Certificate in accordance with Annex IX Chapter I is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV
SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V76 003706 0007 Rev. 00

Report No.: SH23130304_TD01
Valid from: 2025-08-14
Valid until: 2030-08-13

Marta Carnielli
Head of Certification IVD

Issue date: 2025-08-14



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Classification:	Class B self-testing
Basic UDI-DI:	69520627J001KW
Intended Purpose:	<p>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.</p> <p>The HCG Pregnancy Test (Colloidal Gold) is designed for both self-testing and professional laboratory use, not for near patient testing.</p>
Device Group:	IVR 0607 - Devices intended to be used for detection of pregnancy or fertility testing
Device(s):	HCG Pregnancy Test (Colloidal Gold) Cassette Strip Midstream

Packaging	HCG-UST-01 (Cassette)		HCG-UST-02 (Strip)		HCG-UST-03 (Midstream)	
	Catalogue	UDI-DI	Catalogue	UDI-DI	Catalogue	UDI-DI
1 pc/box	HCG1UST-1	06952062770688	HCG2UST-1	06952062778080	HCG3UST-1	06952062770633
2 pcs/box	HCG1UST-2	06952062770695	HCG2UST-2	06952062778097	HCG3UST-2	06952062770640
3 pcs/box	HCG1UST-3	06952062779155	HCG2UST-3	06952062779100	HCG3UST-3	06952062779209
4 pcs/box	HCG1UST-4	06952062779162	HCG2UST-4	06952062779117	HCG3UST-4	06952062770657
5 pcs/box	HCG1UST-5	06952062770701	HCG2UST-5	06952062770916	HCG3UST-5	06952062770664
10 pcs/box	HCG1UST-10	06952062779179	HCG2UST-10	06952062779124	HCG3UST-10	06952062779223
20 pcs/box	HCG1UST-20	06952062779186	HCG2UST-20	06952062779131	HCG3UST-20	06952062779230
25 pcs/box	HCG1UST-25	06952062770718	HCG2UST-25	06952062772064	HCG3UST-25	06952062770671
40 pcs/box	HCG1UST-40	06952062711438	HCG2UST-40	06952062711445	HCG3UST-40	06952062711452
50 pcs/box	HCG1UST-50	06952062770725	HCG2UST-50	06952062770732	HCG3UST-50	06952062779216
100 pcs/box	HCG1UST-100	06952062779193	HCG2UST-100	06952062779148	HCG3UST-100	06952062779247



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The validity of this certificate - none -
 depends on conditions and/or
 is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2025-08-14	SH23130304_TD01	Initial issuance