EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Manufacturer:	**ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.** No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui PEOPLE'S REPUBLIC OF CHINA
Single registration number:	CN-MF-000018785
Authorized representative:	**Mega Eurostar Sp. z o. o.** Obrzeżna, 5 lok. XIP/1 02-691 Warsaw Poland
Single registration number:	PL-AR-000042730

Notified Body Sertio Oy declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the

REGULATION (EU) 2017/746
on In Vitro Diagnostic Devices

have been met for the products listed in this certificate.
The above mentioned manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation.

Certificate validity is subject to manufacturer fulfilling the obligations arising from the Annex IX of the aforementioned regulation. Validity of the certificate is subject to following the General terms of Business by Sertio Oy and Terms of conformity assessment of IVD medical devices.
NOTE: For class A sterile devices: "Audit by the notified body was limited to the aspects of manufacture concerned with securing and maintaining sterile conditions".

For placing in the market class D devices, companion diagnostic devices, devices for self testing and devices for near patient testing, in addition to this certificate a separate EU technical documentation assessment certificate according to Annex IX chapter II is required and has been issued with certificate number: EU-TDA-FI-20642-800030-2025-1

Certificate number	EU-QMS-FI-44290-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Mikko Soikkeli
Sertio Oy
Biokatu 10, 33520 Tampere, Finland

SERTIO SERTIO SERTIO SERTIO NOTIFIED BODY CE 3018

Sertio Oy is Notified Body 3018 according to Regulation (EU) 2017/746

PRODUCTS

Certificate number	EU-QMS-FI-44290-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Class C for self testing

IVR 0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
IVP 3007	Immunoassays
W0105	Infectious diseases

Certificate history

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Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Version	Date issued	Description
1	21.03.2025	Initial certification

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 003706 0001 Rev. 03

Holder of Certificate: **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**
No. 777 Jimingshan Road, High-Tech Development Zone
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Immunology, Immunochemistry, Clinical Chemistry, Samples Collection devices and Medical ultrasonic couplant**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 003706 0001 Rev. 03

Report No.: SH24130302

Valid from: 2024-06-22
Valid until: 2027-06-21

Date, 2024-06-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany