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

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Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 003706 0001 Rev. 03

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

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

See Scope of Certificate

.

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 003706 0004 Rev. 00

Certificate Holder:

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

Certification Mark:

TÜV SÜD ISO 13485

Scope of Certificate:

Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents for Immunochromatography, Immunochemistry, and Non-Sterile Sampling Collection Devices, Non-Sterile Medical Ultrasonic Couplant

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 003706 0004 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F007073**
Report No.: **SH23130302**
Effective Date: **2023-11-22**
Expiry Date: **2026-11-21**

Date of Issue: 2023-11-27

(Renee Walker)
Director, US Certification Body, MHS

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 003706 0004 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

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

Facility Scopes: Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents for Immunochromatography, Immunochemistry, and Non-Sterile Sampling Collection Devices, Non-Sterile Medical Ultrasonic Couplant
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