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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 093930 0004 Rev. 05

Holder of Certificate:

Berpu Medical Technology Co., Ltd
No.14 Xingji Road
Yongxing Street, Longwan District
325000 Wenzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:

Design, Development, Production and Sales of Sterile (Infusion Sets, Scalp Vein Set, Hypodermic Needles, Auto-Disable Syringes, Insulin Syringes, Medical Stainless Steel Tube, Disposable Syringes, Burette Set, Dental Needles, Insulin Needles, Self-Destruction Safety Syringes, Infusion Extension Tube, Transfusion Sets, Safety Hypodermic Needles, Safety Insulin Needle, Safety Blood Collection Needle, Dispensing Needle, Irrigation Needle, Blood Collection Tube Closure, Blood Collection Needle Rubber Seal, Needleless Connector, Multiple Sample Blood Collection Needle) for Single Use, Disposable Specimen Container, Disposable Vacuum Blood Collection Tube, Sterile Multi Screw Needle, Sterile Irrigation Syringe (With Needle), Specimen Pipettes for In-vitro Diagnostic Use.

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 093930 0004 Rev. 05

Report No.: BJ25084401/BJ25084402

Valid from: 2025-09-10
Valid until: 2028-09-09

Date, 2025-09-10

Christoph Dicks
Head of Certification/Notified Body

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

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

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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):

Berpu Medical Technology Co., Ltd
No.14 Xingji Road, Yongxing Street, Longwan District, 325000
Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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