



Certificate

No. Q5 093930 0004 Rev. 02

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, Intravenous Needles, Hypodermic Needles, Auto-disable Syringes, Insulin Syringes, Medical Stainless Steel Tube, Disposable Syringes, Burette Set, Dental Needles, Insulin Needles, Blood Collecting Needles, Self-destruction Safety Syringes, Infusion Extension Tube, Transfusion Sets" for Single Use, Sterile Safety Hypodermic Needles for Single Use, Safety Insulin Needle for Single Use, Safety Blood Collection Needle for Single Use, Dispensing Needle for Single Use, Irrigation Needle for Single Use, Blood Collection Needle Rubber Seal for Single Use, Blood Collection Tube Closure for Single 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 and certification regulation of 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. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_093930_0004_Rev.02)

Report No.: BJ21084401

Valid from: 2021-07-15
Valid until: 2024-05-31

Date, 2021-07-15

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 093930 0004 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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