



# 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



Product Service

# 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



America

# CERTIFICATE

No. QS 093930 0009 Rev. 01

**Certificate Holder:**

**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 Tube Closure for Single Use, Blood Collection Needle Rubber Seal for Single Use**

**Standard(s):**

**ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

**Report No.:**

**BJ21084401/TPS; TAM**

**Effective Date:**

**2021-06-22**

**Expiry Date:**

**2024-06-21**

Page 1 of 1

Date of Issue: 2021-07-12

Tina Israel  
 Manager, US Certification Body,  
 Medical and Health Services