



Certificate

No. Q6 045876 0018 Rev. 01

Holder of Certificate: Changzhou Huichun Medical Equipment Co., Ltd.

Sanhekou, Zhonglu Town
 213115 Changzhou, Jiangsu
 PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Changzhou Huichun Medical Equipment Co., Ltd.

Sanhekou, Zhonglu Town, 213115 Changzhou, Jiangsu,
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Production and Distribution of Sterile Hypodermic Syringe for Single Use, Sterile Hypodermic Syringe Needle for Single Use, Infusion Set for Single Use, Vacuum Blood Collection Tube, Blood Collection Needle for Single Use, Disposable Biopsy Forceps, Sterile Insulin Syringe for Single Use, Transfusion Sets for Single use, Intravenous Needles for single use, Disposable Urine Drainage Bag, Bags in Plastic Materials for Medical Use

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1916016

Valid from: 2019-08-01

Valid until: 2022-07-31

Date, 2019-07-16

Stefan Preiß
 Head of Certification/Notified Body