



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 102851 0001 Rev. 03

Holder of Certificate: **Jiangsu Wanhai Medical Instruments Co., Ltd.**
Building 7, No. 9-2
south of Changyang Road
and west of Jinrui Road, west taihu lake, Wujin District
213149 Changzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): **Jiangsu Wanhai Medical Instruments Co., Ltd.**
Building 7, No. 9-2, south of Changyang Road, and west of Jinrui Road, west taihu lake, Wujin District, 213149 Changzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Pen Injector, Disposable Pen Injector**

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

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 102851 0001 Rev. 03

Report No.: SH25146101

Valid from: 2025-11-15

Valid until: 2028-11-14

Date, 2025-06-03

Christoph Dicks
Head of Certification/Notified Body