



Product Service

Certificate

No. Q5 065913 0016 Rev. 00

Holder of Certificate: **Changzhou Xin Neng Yuan
Medical Stapler Co., Ltd.**

No.51, Shuishan Road
Zhonglou Economic Development District
213023 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Changzhou Xin Neng Yuan Medical Stapler Co., Ltd.
No.51, Shuishan Road, Zhonglou Economic Development District,
213023 Changzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
Circular Staplers, Linear Staplers,
Endobronchial Blocker Tube Series Products,
Disposable Trocar Series Products**

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, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1923513

Valid from: 2020-03-01

Valid until: 2023-02-28

Date, 2020-02-12

Christoph Dicks
Head of Certification/Notified Body