



# 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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT