





Certificate

No. Q5 052731 0031 Rev. 01

Holder of Certificate: Xuzhou Kaixin Electronic Instrument

Co., Ltd. Kaixin Mansion

C-01, Economic Development Zone

221004 Xuzhou, Jiangsu

PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Xuzhou Kaixin Electronic Instrument Co., Ltd.

Kaixin Mansion, C-01, Economic Development Zone, 221004

Xuzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,

Production and Distribution of Ultrasonic Diagnostic Instruments

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.: SH1913401

 Valid from:
 2020-04-01

 Valid until:
 2023-03-31

2020-02-25 Christoph Dicks

Head of Certification/Notified Body

3Z

SUD

Date,