





**Product Service** 

## **Certificate**

No. Q5 093263 0002 Rev. 01

Holder of Certificate: Beijing Chunlizhengda Medical

Instruments Co., Ltd.

No.10, Xinmi West 2nd Road

South Region of

Tongzhou Economic Development Zone

Tongzhou District 101112 Beijing

PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:** 



Scope of Certificate: Design and Development, Production and Sales of Hip

Joint Prosthesis, Knee Joint Prosthesis, Anterior Cervical Fixation System, Posterior Cervical Fixation System, CF Posterior Spinal Fixation System, Partial Hip Joint Prosthesis, Hip Surgical Instruments, Knee Surgical Instruments, Anterior Cervical Fixation Surgical Instruments, Posterior Cervical Fixation Surgical Instruments, CF Spinal Fixation Surgical

Instruments and Fusion Cages.

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: <a href="https://www.tuvsud.com/ps-cert?q=cert:Q5-093263-0002-Rev.01">www.tuvsud.com/ps-cert:Q5-093263-0002-Rev.01</a>

Report No.: BJ20070801

 Valid from:
 2021-07-09

 Valid until:
 2024-03-01

Date, 2021-07-09 Christoph Dicks

Head of Certification/Notified Body





## **Certificate**

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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Beijing Chunlizhengda Medical Instruments Co., Ltd.

No.10, Xinmi West 2nd Road, South Region of, Tongzhou

Economic Development Zone, Tongzhou District, 101112 Beijing,

PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Sales of Hip Joint Prosthesis, Knee Joint Prosthesis, Anterior Cervical Fixation System, Posterior Cervical Fixation System, CF Posterior Spinal Fixation System, Partial Hip Joint Prosthesis, Hip Surgical

Instruments, Knee Surgical Instruments, Anterior Cervical Fixation

Surgical Instruments, Posterior Cervical Fixation Surgical

Instruments, CF Spinal Fixation Surgical Instruments and Fusion Cages.