



Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Xinhua Surgical Instrument Co. Ltd.

No.7 Taimei Rd

Zibo New&Hi-Tech Zone

Zibo Shandong China

新华手术器械有限公司 913703006132944941

中国 山东省 淄博市

高新科技开发区 泰美路7号

Holds Certificate No: MD 684698

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

> Design, development, manufacture and sales of non-sterile surgical instruments for all purpose.

非无菌外科手术器械的设计开发、制造和销售。

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical **Devices**

Original Registration Date: 2018-02-28 Latest Revision Date: 2018-02-28

Effective Date: 2018-02-28 Expiry Date: 2021-02-27

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online.

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.