



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park

CaoHeJing Development District

Shanghai 201612 China 上海形状记忆合金材料有限公司

中国上海

漕河泾开发区 松江高科技园 莘砖公路258号 41幢一层,五层

邮编: 201612

Holds Certificate No: MD 698501

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

The design, development, manufacture and distribution of occluder systems, occluder delivery systems and snares.

封堵器系统、封堵器输送系统及圈套器的设计开发、制造及分销。

IM Slan

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-06-04 Latest Revision Date: 2019-06-04 Effective Date: 2019-06-04 Expiry Date: 2022-06-03

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...making excellence a habit."

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Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN 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.