Certificate of Registration

XXX 管理体系 – ISO XXXX:XXXX

兹证明：

XXXX 有限公司
统一社会信用代码
中国
北京市
XX 大街 XX 号
XX 大厦 XX 室
邮编：XXXXXX

XXXX Co., Ltd.
Rm. XX XXXX Centre
No. XX, XX Street
Beijing
XXXXXX
China

持有证书：FM XXXXXX

并运行符合 ISO XXXX:XXXX 要求的 XXX 管理体系，认证范围如下：

XXXX 的生产。
The manufacture of XXXX.

BSI 代表：

授权人员签名

授权人员职务

首次发证日期：2020-03-23
最新发证日期：2020-03-23

生效日期：2020-03-23
有效期至：2023-03-22

二维码

适用的认可标志

...making excellence a habit.™

Certificate of Registration

XXX MANAGEMENT SYSTEM – ISO XXXX:XXXX

This is to certify that: XXXX Co., Ltd.
Rm. XX XXXX Centre
No. XX, XX Street
Beijing
XXXXXX
China

XXXX 有限公司
统一社会信用代码
中国
北京市
XX 大街 XX 号
XX 大厦 XX 室
邮编：XXXXXX

Holds certificate No: FM XXXXXX

and operates a XXX Management System which complies with the requirements of ISO XXXX:XXXX for the following scope:

The manufacture of XXXX.
XXXX 的生产。

For and on behalf of BSI: **Authority Signature**
Authority Title

Original Registration Date: 2020-03-23
Latest Revision Date: 2020-03-23

Effective Date: 2020-03-23
Expiry date: 2023-03-22

Verification QR code

Accreditation Mark

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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, as well as at www.cnca.gov.cn, the official website of CNCA – Certification and Accreditation Administration of the People's Republic of China.
Further clarifications regarding the scope of this certificate and the applicability of ISO XXXX:XXXX requirements may be obtained by consulting the organization. The certified organization shall be subject to surveillance audit periodically with acceptable results for maintaining the validity of this certificate.
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.
BSI Management Systems Certification (Beijing) Co., Ltd.
Rm. 2008 East Ocean Centre, No. 24A Jianguomenwai Street, Beijing 100004, P.R. China Tel: +86 10 8507 3000
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR XXXXXX R0

Manufacturer: Name
Address: Number Street
Town, County
Country, Postal Code
Single Registration Number: SRNXXXX

EU Authorised Representative: Name
Address: Number Street
Town, County
Country, Postal Code

Scope: *See attached* ***Device Schedule***

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation.
For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Signatory

First Issued: YYYY/MM/DD Date: YYYY/MM/DD Expiry Date: YYYY/MM/DD

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body. This certificate was issued electronically.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR XXXXXX R0

Device Schedule: Class III and Class IIb devices

Class III, Implantable	**Intended purpose**
Device or Generic Device Group	As specified on the corresponding EU Technical Documentation Assessment Certificate

Class III	**Intended purpose**
Device or Generic Device Group	As specified on the corresponding EU Technical Documentation Assessment Certificate

Class IIb, Implantable	**Intended purpose**
Device or Generic Device Group	As specified on the corresponding EU Technical Documentation Assessment Certificate

Class IIb, Implantable, Well-established technologies	**Intended purpose**
Device or Generic Device Group	Intended purpose

Class IIb under Rule 12	**Intended purpose**
Device or Generic Device Group	Intended purpose

Class IIb	**Intended purpose**
Device or Generic Device Group	Intended purpose

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	**Risk Classification**
Device or Device category	Class IIa
Device or Device category	Class Is, Class Im, Class Ir
Device or Device category	Class Im, Class Ir
Device or Device category	Custom-made Class III implantable

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR XXXXXX R0

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
YYYY/MM/DD	SMO XXXXXXXX	Initial Issue

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
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