



ISO 13485

CERTIFICATE of REGISTRATION



Certificate Number: QMSMDDo27270417

SHANGHAI ORTHO KING MEDICAL DEVICE CO., LTD

No. 16 LANE 818 XIA NING ROAD, SHANGHAI, CHINA

Assessment of the quality management system demonstrates evidence that the processes and activities adhere to applicable local regulatory affairs based on sustaining Quality Management System QMS MDD ISO 13485:2003 for regulatory purpose and that these are for the protection of communities and consumers. This certificate-document is not transferable and remains the property of international registration body BRSM.

Scope of activities: Production, Sale & after sales service of Medical electronic saas and drills

Date of Effectiveness: 26 April 2017

Date of Renewal: 26 April 2020

This certificate is validated annually through on-site surveillance assessments. Further clarifications regarding the scope of this certification and the application of ISO 13485 for the purpose to regulatory obligations may be obtained through communication with the holder of this certification. This registration is included in the BRSM Directory of Registered Organizations and applies within the scope shown above. By issuance of this certification the organization will update and maintain its registration in accordance to current revision of ISO 13485 and for regulatory purposes to the point of origin and commercialization. Needs to be Re-Audited to ISO 13485:2016 Version by end of 2019

H. A. Carpi

26 April 2017

Date



BRSM
BRSM, Europe Office



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Management
Systems
Certification Body
MSCB-109

