

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2040784-1

Organization: Beijing AK Medical Co., Ltd.
No.10, Baifuquan Road, Changping Science Park,
102200 Beijing, P. R. China

Scope: Design and Development, Manufacture and Distribution of Bone Cement Application Kits, Hip Prosthetic Joints, Knee Prosthetic Joints, Orthopedic Surgical Instruments, Disposable Surgical Lavage Units, Dental Implant System, Vertebral Prostheses and Interbody Fusion Cages

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190128968 110

Effective date: 2020-12-19

Expiry date: 2023-12-18

Issue date: 2020-12-21


Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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No.	Facility	Scope
/01	Beijing AK Medical Co., Ltd. No.10, Baifuquan Road, Changping Science Park, 102200 Beijing, P. R. China	Manufacture and Distribution of Bone Cement Application Kits, Hip Prosthetic Joints, Knee Prosthetic Joints, Disposable Surgical Lavage Units, Dental Implant System, Vertebral Prostheses and Interbody Fusion Cages. Distribution of Orthopedic Surgical Instruments
/02	Beijing AK Medical Co., Ltd. Habatun Industrial Park, Machikou Town, Changping, 102200 Beijing, P. R. China	Manufacture of Hip Prosthetic Joints and Dental Implant System

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No.10, Baifuquan Road, Changping Science Park,
102200 Beijing, P. R. China

:
/03 Beijing AK Medical Co., Ltd.
North Factory of NO.21, Huoju Street,
Changping Science Park,
102200 Beijing, P. R. China

Design and Development of Bone Cement
Application Kits, Hip Prosthetic Joints, Knee
Prosthetic Joints, Orthopedic Surgical
Instruments, Disposable Surgical Lavage
Units, Dental Implant System, Vertebral
Prostheses and Interbody Fusion Cages.
Manufacture of Orthopedic Surgical
Instruments, Hip Prosthetic Joints, Knee
Prosthetic Joints, Dental Implant System,
Vertebral Prostheses and Interbody Fusion
Cages

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3 / 3