Certificate

Quality Management System
EN ISO 13485:2016 + AC:2018 + A11:2021
ISO 13485:2016

Registration No.:	SX 2110503-1
Certificate Holder:	Dongguan Kaiser Technology Co., Ltd. No.6, 2nd Road, Sanjiang Industrial Block, Hengli Town, Dongguan City, 523462 Guangdong P.R. China
Scope:	Design and Development, Manufacture and Distribution of Bone Drills (machine only), Orthopedic Reamers (machine only), Electrical Surgical Bone Saws (machine only), Surgical Illuminators, Bone Cement Mixers, Bone Cement Mixer Syringes, Warming and Cooling Therapy Devices, Blanket Warming Units, Surgical Lavage Units

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.:	10927586-100
Effective date:	2026-08-10
Expiry date:	2029-08-08
Issue date:	2026-08-10

Replaces certificate SX 2110503-1 issued 2025-01-16

This certificate can be validated on https://www.certipedia.com

Joanna Huang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-00

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Hengli Town, Dongguan City,
523462 Guangdong
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Dongguan Kaiser Technology Co., Ltd. No.6, 2nd Road, Sanjiang Industrial Block, Hengli Town, Dongguan City, 523462 Guangdong P.R. China	Aspects related to Manufacture
/02	c/o Kaiser Technology Co., Ltd. 4F, No.1, Keji Road, Dali District, Taichung City 41264 Taiwan	Aspects related to Design and Development, Distribution

This certificate can be validated on https://www.certipedia.com

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