Certificate

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

Registration No.:	SX 2063742-1
Certificate Holder:	Apex (Guangzhou) Tools & Orthopedics Co. No. 25, Yonghua Road, Yonghe, GETDD, 511356, Guangzhou P.R. China
Scope:	Design and Development, Manufacture and Distribution of Surgical Instruments (including Disposable Pulse Lavages, Disposable Pulse Irrigation Kits, Surgical Saw Blades, Surgical Drill Bits, Kirschner Wires and Steinmann Pins, Disposable Lavage Tips and Disposable Irrigation Bags), Instruments for Support of Surgical Devices and Other General Surgery Instruments; Contract Manufacture of Surgical Instruments, Orthopedics Implants, Metal Components and Plastic Components for medical devices

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.:	10924542-100
Effective date:	2024-10-30
Expiry date:	2027-10-29
Issue date:	2024-10-29

Replaces certificate SX 2063742-1 issued 2021-11-01

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

Danny Duan
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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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No. 25, Yonghua Road, Yonghe, GETDD,
511356, Guangzhou
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Apex (Guangzhou) Tools & Orthopedics Co. No. 25, Yonghua Road, Yonghe, GETDD, 511356, Guangzhou P.R. China	Design and Development, Manufacture and Distribution of Surgical Instruments (including Disposable Pulse Lavages, Disposable Pulse Irrigation Kits, Surgical Saw Blades, Surgical Drill Bits, Kirschner Wires and Steinmann Pins, Disposable Lavage Tips and Disposable Irrigation Bags), Instruments for Support of Surgical Devices and Other General Surgery Instruments; Contract Manufacture of Surgical Instruments, Orthopedics Implants, Metal Components and Plastic Components for medical devices
/02	c/o Apex (Guangzhou) Tools & Orthopedics Co. 101-102-103 of Building A3, No. 76, Chuangyu Road, Ningxi Street, Zengcheng District, 511356, Guangzhou P.R. China	Manufacture of Surgical Saw Blades, Surgical Drill Bits, Kirschner Wires and Steinmann Pins, Instruments for Support of Surgical Devices and Other General Surgery Instruments; Contract Manufacture of Surgical Instruments, Orthopedics Implants, Metal Components and Plastic Components for medical devices

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