Certificate

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

Registration No.:	SX 2112180-1
Certificate Holder:	Shenzhen Rogin Medical Co., Ltd. Room 3109, Block 6, Tian'an Cloud Park, Bantian street, Longgang District, Shenzhen, 518129 Guangdong P.R. China
Scope:	Design and Development, Manufacture and Distribution of Dental Root Canal Instruments, Endo Motor, Apex Locator, Gutta Percha Obturation System, Endo Activator, Tungsten Carbide Dental Burs, Gutta Percha Points, Root canal Irrigation Needle

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.:	10924487-100
Effective date:	2024-10-08
Expiry date:	2027-09-17
Issue date:	2024-10-08

Replaces certificate SX 2112180-1 issued 2021-09-17

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

Danny Duan
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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Room 3109, Block 6,
Tian'an Cloud Park, Bantian street, Longgang District,
Shenzhen,
518129 Guangdong
P.R. China

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Shenzhen Rogin Medical Co., Ltd. Room 3109, Block 6, Tian'an Cloud Park, Bantian street, Longgang District, Shenzhen, 518129 Guangdong P.R. China	Aspects related to Administration, Design and Development, Manufacture and Distribution
/02	c/o Shenzhen Rogin Medical Co., Ltd. Huizhou branch Room 301A, Block 5, Renluo 6 Road No. 6, Shuikou Street, Huicheng District, Huizhou, 516000 Guangdong P.R. China	Aspects related to Warehouse

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