ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 113957 0001 Rev. 00

Holder of Certificate: **Guilin Refine Medical Instrument Co., Ltd.**
No.8-3, Information Industrial Park, High-Tech Zone
Qixing District
541004 Guilin, Guangxi
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Ultrasonic Scaler, Ultrasonic Scaler Tip, Gutta-Percha Obturation System, Gutta-Percha Tip, Gutta-Percha Injection Needle, Ultrasonic Surgical System Tip, Dental Scaler, Apex Locator**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 113957 0001 Rev. 00

Report No.: GZ2146701

Valid from: 2023-12-11
Valid until: 2026-12-10

Date, 2023-12-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. Q5 113957 0001 Rev. 00

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Guilin Refine Medical Instrument Co., Ltd.
No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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