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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 093119 0003 Rev. 02

Holder of Certificate: **SteriLance Medical (Suzhou) Inc.**
No.168 PuTuoShan Road
New District
215153 Suzhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Disposable Blood Lancets (Sterile), Disposable Safety Lancets (Sterile), Heel Incision Safety Lancets (Sterile), Disposable Scalpels (Sterile), Disposable Surgical Blades (Sterile), Disposable Insulin Pen Needles (Sterile), Disposable Swabs (Sterile), Lancing Devices, Safety Scalpel Cartridge (Sterile), Disposable Steel Lancets (Sterile), Disposable Skin Prick Lancets (Sterile), Safety Metal Handle**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 093119 0003 Rev. 02

Report No.: SH25188702

Valid from: 2025-12-02
Valid until: 2028-12-01

Date, 2025-11-19

Christoph Dicks
Head of Certification/Notified Body

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

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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):

SteriLance Medical (Suzhou) Inc.
No.168 PuTuoShan Road, New District, 215153 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

See scope of certificate

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