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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 093119 0001 Rev. 02

Manufacturer:

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

SRN Manufacturer - CN-MF-000002860

Authorized Representative:

Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 093119 0001 Rev. 02

Report No.: SH24188702

Preceding Certificate No.: G10 093119 0001 Rev. 01

Valid from: 2025-07-11
Valid until: 2027-11-23

Date of Initial Issuance: 2022-11-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-07-11

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 093119 0001 Rev. 02

Classification:	Class IIa
Device Group:	A019013 - PERCUTANEOUS NEEDLES V010101 - SCALPELS WITH SAFETY SYSTEMS, SINGLE-USE V010302 - BLADES WITHOUT SAFETY SYSTEMS, SINGLE-USE - NOT INCLUDED IN OTHER CLASSES V010401 - LANCETS WITH SAFETY SYSTEMS, SINGLE-USE V010402 - LANCETS WITHOUT SAFETY SYSTEMS, SINGLE-USE
Intended Purpose:	/
The validity of this certificate depends on conditions and/or is limited to the following:	-NONE-

Revision History:

Rev.	Dated	Report	Description
00	2022-11-24	SH22188701	-
01	2023-06-19	SH23188701_CN	Amended: Editorial change of authorized representative
02	2025-07-11	SH24188702	Supplemented: Device(s)/group of device(s) added

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®