



EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 118298 0002 Rev. 00

Manufacturer:

**LeadSurgical Medical
Technology Co., Ltd.**

Building F-2, No.32 Hongxi Road, Suzhou New District
215000 Suzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000037578

**Authorized
Representative:**

Riomavix S. L.
Calle de Almansa 55, 1D, 28039 Madrid, SPAIN

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.

The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to

- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.

If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 118298 0002 Rev. 00

Report No.: SH24206701
Valid from: 2025-07-10
Valid until: 2030-07-09

Christoph Dicks
Head of Certification/Notified
Body

Issue date: 2025-07-10



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Classification: Class IIb
Device Group: Z12010801 - ULTRASONIC SCALPEL
Intended Purpose: Disposable Ultrasonic Soft Tissue Scalpel is intended to be used in conjunction with Ultrasonic Soft Tissue Surgical Equipment for soft tissue incisions when bleeding control and minimal thermal injury are desired, and for sealing blood vessels not exceeding 5 mm in diameter.

Classification: Class IIb
Device Group: Z120108 - INSTRUMENTS FOR ULTRASONIC SURGERY
Intended Purpose: Ultrasonic Soft Tissue Surgical Equipment is intended to be used in conjunction with Disposable Ultrasonic Soft Tissue Scalpel for soft tissue incisions when bleeding control and minimal thermal injury are desired, and for sealing blood vessels not exceeding 5 mm in diameter.

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2025-07-10	SH24206701	Initial issuance