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 102195 0009 Rev. 00

Manufacturer:

Innolcon Medical Technology (Suzhou) Co., Ltd.
Unit 405/407/409/411, Building B2
No. 218 Xinghu Street
Suzhou Industrial Park
215123 Suzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000012689

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

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 102195 0009 Rev. 00

Report No.: SH22129202
Valid from: 2024-09-25
Valid until: 2029-09-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-25

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

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Classification:	Class IIb
Device Group:	Q020601 - PHACOEMULSIFICATION SETS
Intended Purpose:	Innolcon Phacoemulsification Surgical Equipment is suitable for the emulsification, separation, perfusion and aspiration of cataract, residual cortex and lens epithelial cells, aspiration and excision of vitreous anterior segment. Electrocoagulation at a bleeding point stops blood.

Classification:	Class IIa
Device Group:	Q020680 - PHACOEMULSIFICATION DEVICES - ACCESSORIES
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Q020680 - PHACOEMULSIFICATION DEVICES - ACCESSORIES
Intended Purpose:	PHACO Handpiece is designed to be used with Phacoemulsification Surgical Equipment and Phaco Tip Kit to realize the function of phacoemulsification during ophthalmic cataract surgery.

Classification:	Class IIb
Device Group:	Z12010801 - ULTRASONIC SCALPEL
Intended Purpose:	Ultrasonic Surgical Scalpel is used during open or laparoscopic surgery to cut, grasp, and dissect soft tissues when bleeding control and minimal thermal injury are desired. It can also be used to cut and seal vessels up to 5mm diameter. Ultrasonic Surgical Scalpel is used during open or laparoscopic surgery to cut, grasp, and dissect soft tissues when bleeding control and minimal thermal injury are desired. It can also be used to cut and seal vessels up to 7mm diameter. Ultrasonic Surgical Scalpel is used during open surgery to cut, grasp, and dissect soft tissues when bleeding control and minimal thermal injury are desired. It can also be used to cut and seal vessels up to 5mm diameter.

Classification:	Class IIb
Device Group:	Z12010880 - INSTRUMENTS FOR ULTRASONIC SURGERY - HARDWARE ACCESSORIES
Intended Purpose:	The Ultrasonic Surgical Equipment provides power to drive ultrasonic surgical scalpels that are used during open or laparoscopic surgery to cut, grasp, and dissect soft tissues and vessels when bleeding control and minimal thermal injury are desired.

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The Ultrasonic Surgical Handpiece, when used in conjunction with the Ultrasonic Surgical Scalpel, is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The scalpels can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels.

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

Revision History:

Rev.	Dated	Report	Description
00	2024-09-25	SH22129202	Initial issuance

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