CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

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

EU Quality Management System Certificate

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

Certificate No. G15 097889 0008 Rev. 00

Manufacturer:

Wuhan Pioon Technology Co., Ltd.
12th Floor, Building 1, Innovative Unit
R&D Center Project
Marine World Shipbuilding Park
No.16, Fozuling 3rd Road
East Lake High-tech Development Zone
430205 Wuhan, Hubei
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000018399

Authorized Representative:

Humiss Beratung GmbH
Gneisenaustraße 8, 40477 Düsseldorf, GERMANY

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 (excluding custom-made implantable devices) 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 097889 0008 Rev. 00

Report No.: SH2593002
Valid from: 2026-08-20
Valid until: 2031-08-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-08-20

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

CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

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

EU Quality Management System Certificate

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

Certificate No. G15 097889 0008 Rev. 00

Classification:	Class IIb
Device Group:	Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose:	The Medical Diode Laser is intended for oral soft tissue surgery procedures and as an adjunct in periodontal, endodontic and photobiomodulation/low-level laser therapy procedures in the oral cavity and associated perioral tissues.
Classification:	Class IIb
Device Group:	Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose:	The Medical Diode Laser is intended for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue.
Classification:	Class IIb
Device Group:	Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose:	The Medical Diode Laser is intended for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue. For the 650nm Wavelength, it's adjunctive use in providing temporary relief of nociceptive musculoskeletal pain.
Classification:	Class IIb
Device Group:	Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose:	The Medical Diode Laser is intended for use in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb.
Classification:	Class IIb
Device Group:	Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose:	The Medical Diode Laser is intended for oral soft tissue surgery procedures and as an adjunct in periodontal, endodontic and photobiomodulation/low-level laser therapy procedures in the oral cavity and associated perioral tissues. The Medical Diode Laser is intended for use in podiatric and foot/ankle applications. It is intended for incision, excision, ablation, vaporization and coagulation of soft tissue, and for laser treatment of nail-unit related lesions. It is also intended for adjunctive treatment of foot and ankle musculoskeletal conditions for temporary pain relief, temporary increase in local blood circulation, and relaxation of soft tissue.
The validity of this certificate depends on conditions and/or is limited to the following:	-None-

Revision History:

Rev.	Dated	Report	Description
00	2026-08-20	SH2593002	Initial issuance

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®