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

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

Certificate No. G15 005392 0006 Rev. 00

Manufacturer:

Beijing Nubway S & T Co., Ltd.
202, No.5 workshop
No.1 caida 3rd Road Nancai Shunyi District
101300 Beijing
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000017636

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 005392 0006 Rev. 00

Report No.: BJ24012203
Valid from: 2025-06-13
Valid until: 2030-06-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-06-13

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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EU Quality Management System Certificate

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

Certificate No. G15 005392 0006 Rev. 00

Classification:	Class IIa
Device Group:	MDA 0302 - Active non-implantable devices utilising non-ionizing radiation
Device Properties:	MDS 1012 - Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
Classification:	Class IIb
Device Group:	Z12040202 - PHOTOTHERAPY EQUIPMENT
Device Properties:	MDS 1012 - Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
Intended Purpose:	The Intense Pulsed Light devices (IPL) is used for hair removal, skin rejuvenation, improving pigmentation problems, and enhancing the appearance of vascular lesions.It is Indicated for use on all skin types (Fitzpatrick I-VI).
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2025-06-13	BJ24012203	Initial issuance

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To whom it may concern

Munich, 2025-07-08
Order No.: 713378767

Confirmation concerning EU Certificate G15 005392 0006 Rev. 00

We confirm that the following certificate:

G15 005392 0006 Rev. 00 (valid until 2030-06-12)

issued to the legal medical device manufacturer:

Beijing Nubway S & T Co., Ltd.
202, No.5 workshop
No.1 caida 3rd Road Nancai Shunyi District
101300 Beijing
PEOPLE'S REPUBLIC OF CHINA

covers the Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I with the device groups:

MDA 0302 - Active non-implantable devices utilising non-ionizing radiation
Z12040202 - Phototherapy equipment

and device properties:

MDS 1012 - Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745

and the following devices:

	Device Name	Model	EMDN Code
1	Diode laser hair removal machine	QDTM-02	Z120615
2	Diode laser hair removal machine	QDTM-06	Z120615
3	Intense pulsed light devices （IPL）	QITM-02	Z12040202

With this letter we confirm that the above-mentioned devices are covered by a quality management system that has been established by the manufacturer and is certified by the Notified Body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the Regulations 2017/745 by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificate is valid.

R. Köhler

Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH
PS-MHS-AU-9
Medical Health Services Foreign Affairs