

EU Quality Management System Certificate CN24/00001171

The management system of

BEIJING UNT Technology Co., Ltd.

M2-1 Area, Xinggu Development Zone, Pinggu District, 101200, Beijing, P.R. China

SRN Number: CN-MF-000019748

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

Class IIb - MDA 0302, MDS 1009 - EMDN: Z120110

Diode Laser Therapy Systems for the treatment of hirsutism (Model: Alpha)

Basic UDI-DI: 697366379104P9

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation:

N/A

Certification is based on following reports: CN/BJS/252745 - S2A 1.3

Authorized representative name and address (if relevant): Medpath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 26 February 2024 until 26 February 2029 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 26 August 2028

Issue 1. Certified since 26 February 2024

Authorised by

Virginie Siloret

Global Medical Device Certification
Manager

SGS Belgium NV NB1639

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Certificate CN23/00006794

The quality management system of

BEIJING UNT Technology Co., Ltd.

SGS

M2-1 Area, Xinggu Development Zone, Pinggu District, 101200, Beijing, P.R. China
Facility number: F007060

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Device Regulations SOR/98-282, Part 1
Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 60 (2021); Japan PMD Act (as applicable)
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, manufacture and servicing of Diode Laser Therapy System used in areas of general and plastic surgery and in dermatology

This certificate is valid from Effective date 2024-02-22 until Expiry date 2026-12-18 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2023-12-19

L. Henderson

Authorised by

Lynn Henderson

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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Certificate CN23/00000762

The management system of

BEIJING UNT Technology Co., Ltd.

SGS

M2-1 Area, Xinggu Development Zone, Pinggu District, 101200, Beijing, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design, manufacture and servicing of Diode Laser Therapy System

This certificate is valid from 20 February 2026 until 20 February 2029 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 20 February 2023

L. Moran

Authorised by

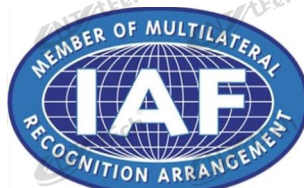
Liz Moran

Business Manager

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