



America

CERTIFICATE

No. QS6 095419 0011 Rev. 01

Certificate Holder:

Quanta System S.P.A.
Via Acquedotto, 109
21017 Samarate (VA)
ITALY

Certification Mark:



Scope of Certificate:

Design and Development, Manufacture and Service of Laser Devices, Intense Light Devices, Laser Handpieces, Intense Light Handpieces, Cutaneous Stimulation Devices, Sterile and Non-Sterile Optical Fibers for the areas of Aesthetic Medicine, Dermatological Medicine, Therapeutic and Surgical Applications, Distribution of Cold Air Therapy Devices and of Urological Morcellator Systems

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

51-406-5812

Effective Date:

2020-12-21

Expiry Date:

2023-12-20

Page 1 of 2

Date of Issue: 2020-12-31

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

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Page 2 of 2

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