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America

# CERTIFICATE

**No. QS6 17 12 95419 009**

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

**Certification Mark:**

**Scope of Certificate:** The Design and Development, Manufacture and Service of Laser Devices, Intense Light Devices, Laser Hand-Pieces, Intense Light Hand-Pieces, 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

**Standard(s):** ISO 13485:2016

**Regulatory Authority:** TGA, ANVISA, Health Canada, 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
http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Authorized Auditing Organization.

**DUNS No:** 43-604-5833
**Effective Date:** 2017-12-18
**Expiry Date:** 2020-12-17

Manuel Bradaric
MHS Certification Manager







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## Audit/Certification Criteria

### Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

### Brazil

- Federal Law n. 6360/76
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009
- RDC ANVISA n. 56/2001

### Canada

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

### United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

### Japan

- MHLW Ministerial Ordinance No.169, 2004

**Effective Date:** 2017-12-18
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Manuel Bradaric
MHS Certification Manager





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