



America

# CERTIFICATE

No. QS6 18 04 21608 024

**Certificate Holder:** ASA s.r.l.  
VIA A. VOLTA, 9  
36057 ARCUGNANO (VI)  
ITALY

**Certification Mark:**



**Scope of Certificate:** Design Development and Production of Therapeutical Lasers and Therapeutical Magnetic Units. Distribution and Service of Therapeutical Lasers and Therapeutical Magnetic Units for Pain Treatment and Rehabilitation

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

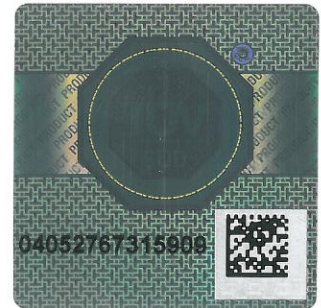
**Regulatory Authority:** TGA, Health Canada, FDA.  
See attached for listing of specific regulatory requirements.

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:** 42-953-3573  
**Effective Date:** 2018-04-05  
**Expiry Date:** 2021-04-04

Manuel Bradaric  
MHS Certification Manager





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## Audit/Certification Criteria

### Australia

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

### 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

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Manuel Bradaric  
MHS Certification Manager

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