



America

CERTIFICATE

No. QS6 096204 0006 Rev. 04

Certificate Holder:

Mesa Italia S.r.l.
Via dell'Artigianato, 35/37
25039 Travagliato (BS)
ITALY

Certification Mark:



Scope of Certificate:

Design, Production and Distribution of Cobalt, Iron, Nickel and Titanium Based Dental Alloys for Prosthesis Plates, Bridges and Crown, Ceramics and Soldering

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Australia TGA, Brazil ANVISA, Health Canada, USA 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_096204_0006_Rev_04

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

REPs Facility ID:

F002572

Report No.:

ITA200220002827

Effective Date:

2025-02-26

Expiry Date:

2028-02-25

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Date of Issue: 2025-01-09

(Renee Walker)
Director, US Certification Body, MHS

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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. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

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

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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