



America

# CERTIFICATE

No. QS6 096204 0006 Rev. 02

**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, 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](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** F002572

**Effective Date:** 2022-03-17

**Expiry Date:** 2025-02-25

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**Date of Issue:** 2022-03-30

( Renee Walker )  
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):**

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

**Facility Scopes:**

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