



America

# CERTIFICATE

No. QS6 096204 0006 Rev. 00

Certificate Holder:

**Mesa di Sala Giacomo & C. S.n.c.**  
Via dell'Artigianato, 35/37  
25039 Travagliato (BS)  
ITALY

Certification Mark:



Scope of Certificate:

**Design, Production and Distribution of Cobalt, Iron and Nickel Based Dental Alloys for Prosthesis Plates, Bridges and Crowns, Ceramic 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 <https://www.tuev-sued.de/product-testing/certificates>

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

DUNS No:

**43-174-3186**

Effective Date:

**2019-02-26**

Expiry Date:

**2022-02-25**

Page 1 of 2

Date of Issue: 2019-03-15

( Arie Henkin )  
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • [www.tuvsud.com](http://www.tuvsud.com)

TUV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

# CERTIFICATE

No. QS6 096204 0006 Rev. 00

**Regulatory Requirements: Audit/Certification Criteria**

**Australia**

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

**Brazil**

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

**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 169, Article 4 to Article 68
- PMD Act

**Facility(ies):**

Mesa di Sala Giacomo & C. S.n.c.  
Via dell'Artigianato, 35/37, 25039 Travagliato (BS), ITALY

**Facility Scopes:**

Design, Production and Distribution of Cobalt, Iron and Nickel Based Dental Alloys for Prosthesis Plates, Bridges and Crowns, Ceramic and Soldering  
DUNS No: 43-174-3186



( Arie Henkin )  
Manager, Certification Body MHS