



# CERTIFICATE OF REGISTRATION

This is to certify that

## Implant Protesis Dental 2004 S.L.

Cami del Mig, 71, 1° 2a, Mataró, Barcelona, 08302, Spain

**MDSAP Facility Identifier: F004926**

operates a

## Quality Management System

which complies with the requirements of

## ISO 13485:2016 and the requirements of the following regulatory authorities

**Australia:**

- Therapeutic Goods (Medical Devices) Regulations 2002: Schedule 3, Part 1 - Full Quality Assurance System

**Brazil:**

- RDC ANVISA n. 16/2013 - Good Manufacturing Practices
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009 - Vigilance

**Canada:**

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

**United States:**

- 21 CFR Part 803 - Medical Device Reporting
- 21 CFR Part 806 - Reports of Corrections and Removals
- 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing
- 21 CFR Part 820 - Quality System Regulation

for the following scope of certification

**Design, development, manufacture and distribution of prosthetic screws and abutments for the area of dentistry.**

Certificate No.: CERT-0128339

File No.: 1652601

Issue Date: 2022-01-17

Original Certification Date: 2021-02-04

Certification Effective Date: 2021-02-04

Certificate Expiry Date: 2024-02-03

Calin Moldovean  
President, Business Assurance  
SAI Global Assurance



ISO 13485:2016

SAI Global is an MDSAP  
authorized auditing organization.



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