



MDSAP CERTIFICATE

Certificate No. 009.22-1/MDSAP

This is to certify that

Implant Protesis Dental 2004 S.L.

Carrer Rosa dels Vents 9-15, 08338 Premià de Dalt (Barcelona), Spain

Facility ID: F006598

Operates a

Quality Management System, which complies with the requirements of ISO 13485:2016 and with the requirements of the following Regulatory Authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada:

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

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

United States:

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 - Subparts A to D
- 21 CFR Part 820

for the following scope of certification

Design, manufacture and distribution of abutments, prosthetics accessories and instruments for the area of dentistry.

Reference to IMQ files Nos.:

DM22-0084574-01; DM22-0084577-01; DM23-0090604-01

Effective Date: 2024-01-19

Expiry Date: 2027-01-18

Issued on: 2024-01-19

IMQ

Matteo Raimondi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization