

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

Operates a

Facility ID: F006598

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	IMQ	
Issued on:	2024-01-19	Matteo Raimondi – IMQ MDSAP Director	
IMQ is an authorized MDSAP Auditing Organization			
		Page 1 of 1	

This MDSAP certificate is subjected to the provisions laid down by IMQ in the "Regulation for Conformity Assessment Activities pursuant to Medical Device Single Audit Program (MDSAP) for which IMQ operates as Auditing Organization". The validity of this certificate can be verified by writing to MDSAP@imq.it.

Mod. 4606-MDSAP/4