



MDSAP CERTIFICATE

Certificate No. 001.23-1/MDSAP

This is to certify that
TALLADIUM ESPAÑA S.L.
Virginia Woolf 17, 25005 Lleida, Spain
Facility ID: F006610

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

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (as applicable)

Canada:

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

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, development, manufacture and distribution of clinical screws, prosthetic screws, abutments instruments and accessories for dental implantology purpose

Reference to IMQ files Nos.:
DM23-0086040-01; DM23-0086788-01

Effective Date: 2023-08-28
Expiry Date: 2026-08-27
Issued on: 2023-08-01

IMQ
Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization