

MDSAP CERTIFICATE

Certificate No. 010.22/MDSAP

This is to certify that

TERRATS MEDICAL S.L.

Calle Mogoda 75-99, Barbera del Valles, Barcelona, 08210, Spain

Facility ID: F004869

Operates a

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

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

Japan:

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

for the following scope of certification

Design, development, manufacture and distribution of clinical screws, abutments, sterile dental implants, accessories and instruments for dental implantology.

Reference to IMQ files Nos.: DM22-0084792-01

Original Certification Date: 2022-11-29
Certification Effective date: 2022-11-29
Expiry Date: 2023-08-09

IMQ

Eng. Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP auditing organization

