

Certificate

Certificate No.: MD 1561847-1-2

Manufacturer: Sterngold Dental LLC

23 Frank Mossberg Drive Attleboro MA 02703

USA

REPs Facility ID: F001129

Certification criteria: ISO 13485:2016

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,

RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,

PMD Act (as applicable)

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 -

Subparts A to D

Scope: Design and Development, Manufacture and Distribution of Dental

Implantable products, dental prosthetic products, surgically invasive dental instruments, ceramic crown and bridge dental alloys, and dental composites and dental cements used in the area of dental

restorations.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 234208641-11
Issue Date: 2024-06-03
Effective Date: 2024-06-03
Expiry Date: 2027-06-02

Melissa DRusso



Certification officer: Melissa Di Buono-Russo TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com or calling 1-888-743-4652.

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