

Certificate US21/819944192

SGS

The quality management system of

Prime Dental Manufacturing, Inc.

4555 West Addison Street, Chicago, IL, 60641, United States of America

Facility number: F005232

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Device Regulations SOR/98-282, Part 1

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

The Design, Development and Manufacture of non-sterile dental filling and restorative materials, bonding agents and materials, glass ionomers luting cements, etching materials, root canal filling materials, temporary cements, core-build up materials, orthodontic adhesives and materials, sealants, desensitizers, cleaning and lubricating gels and temporary crown and bridge materials, and dental bonding materials for the area of dentistry.

This certificate is valid from Effective date 2024-01-11 until Expiry date 2027-01-11 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2021-01-12

L. Henderson

Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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