Certificate Number US21/819944192

The management system of

Prime Dental Manufacturing, Inc.

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

Dun & Bradstreet D-U-N-S identification number : 02-748-0775

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]
Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /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
United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D
For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2021-01-12 until Expiry Date: 2024-01-11
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2023-10-16
Issue 1. Certified since 2021-01-12

Authorised by J Hall
Business Manager

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SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

Digitally signed by Smîntînă Alexandru
Date: 2022.11.17 12:33:30 EET
Reason: MoldSign Signature
Location: Moldova

The management system of

Prime Dental Manufacturing, Inc.

MDSAP (ISO 13485:2016)

Issue 1

Detailed scope

The Design, Development & 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, sealants, desensitizers, cleaning and lubricating gels and temporary crown and bridge materials, and dental bonding materials for the area of dentistry.