

Certificate US18/81841210

The quality management system of

Parkell Inc.

300 Executive Drive, Edgewood, NY, 11717, United States Of America

Facility number: F001068

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

Japan: MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
Japan PMD Act (as applicable)

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

Design, manufacture, and distribution of:

Dental Materials: resin-based restorative materials; denture reline materials; dental cements; dental bonding agents; dental impression materials, retraction paste, and dental primers for the area of dentistry.

Dental Equipment: Ultrasonic tooth scalers with inserts, tips, and irrigators; electrosurgical unit; pulp testers for the area of dentistry.

This certificate is valid from Effective date 2024-06-23 until Expiry date 2027-06-23 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2018-10-15

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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