

Certificate Number US18/81841210

The quality management system of

Parkell Inc.

300 Executive Drive,
Edgewood, NY, 11717, United States
Dun & Bradstreet D-U-N-S identification number: 00-990-0424

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

SGS



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 (OR 21 CFR 820.180 and 198) / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D



For the following activities and devices

Design, manufacture, service and distribution of:

Dental Materials: resin-based restorative materials; denture reline materials; dental cements; dental bonding agents; and dental primers.

Dental Equipment: Ultrasonic tooth scalers with inserts, tips, and irrigators; electro-surgical unit; apical foramen locator; dental polishers; and pulp tester.

This certificate is valid from
Effective Date: 2018-10-15 until Expiry Date: 2021-10-14
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2021-06-14

Issue 1. Certified since 2018-10-15

Authorised by H Crick
Business Manager

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Certificate US06/69109

The management system of

Parkell Inc.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

Design, manufacture, service and distribution of:
Dental Materials: resin-based restorative materials; denture reline materials; dental cements; dental bonding agents; and dental primers.
Dental Equipment: Ultrasonic tooth scalers with inserts, tips, and irrigators; electrosurgical unit; apical foramen locator; dental polishers; and pulp tester.

This certificate is valid from 01 November 2018 until 04 July 2021 and remains valid subject to satisfactory surveillance audits. Re certification audit due before 14 June 2021 Issue 9. Certified since 04 July 2006

Expiry date of last certificate: 07 July 2018
End date of last recertification audit: 30 March 2018

Authorised by

A handwritten signature in black ink, appearing to be 'AR'.

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