EC Certificate Full Quality Assurance System: Certificate US19/819943643

The management system of

Parkell Inc.

300 Executive Drive
11717 Edgewood, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Dental Materials: resin-based restorative materials (SmarTemp SNAP Absolute Dentin family Hyperfil family), denture reline materials (MucoSoft; MucoHard); dental cements (Retrieve DC Temporary Cement); and dental desensitizers (Parkell desensitizer). Dental Equipment: Ultrasonic tooth scalers with inserts, tips, and irrigators; Pulp Tester (Digitest 3 with probes, ground clips and lead wire).

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 12 January 2021 until 04 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 04 July 2006
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MC 213011

Authorised by

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