EC Certificate Full Quality Assurance System: Certificate US19/819943531

The management system of

Prime Dental Manufacturing, Inc.

4555 West Addison Street,
Chicago, IL, 60641, 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 polymer based filling and restorative materials; Dental Bonding Agents; Dental Glass Ionomer; Dental polymer based luting cements; Dental Core Build up materials; Dental Root Canal filling materials; Dental temporary cements; Dental bonding materials; Dental etching materials; Orthodontic adhesives; Dental Pit and Fissure sealants; Dental Desensitizer; Dental Root Canal cleaning and lubricating gel; Dental temporary Crown and Bridge Materials.

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 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 11 November 2019
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MW 605153

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Authorised by

Pieter Weterings
Certification Manager

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