

EC Certificate Full Quality Assurance System: Certificate US14/841781



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.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 6 June 2014 until 6 June 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 January 2017
Issue 1. Certified since 6 June 2014

Certification is based on reports numbered WW/MC 605153

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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