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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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Product Service

# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 102917 0006 Rev. 00**

**Manufacturer:**

**Prima Dental Manufacturing Ltd**

Gemba House  
Stephenson Drive  
Gloucester, GL2 2HA  
UNITED KINGDOM

**Product  
Category(ies):**

**Dental Burs (Sterile and non-sterile)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G2\\_102917\\_0006\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G2_102917_0006_Rev.00)

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**Date,** 2020-09-10

Christoph Dicks  
Head of Certification/Notified Body