



# Certificate

No. Q5 102917 0007 Rev. 03

**Holder of Certificate:** **Prima Dental Manufacturing Ltd**  
Gemba House  
Stephenson Drive  
Gloucester, GL2 2HA  
UNITED KINGDOM

**Certification Mark:**



**Scope of Certificate:** Design and development, manufacture, sales and distribution of sterile and non-sterile rotary dental instruments and dental carbide milling tools used in digital dentistry. Manufacture, sales and distribution of dental impression paste, dental prophylaxis cleaning pastes and dental waxes, dental mirrors and dental hand-held instruments. Sales and distribution of dental materials, dental filling materials, dental cements and dental etching gels.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 102917 0007 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_102917_0007_Rev.03)

**Report No.:** 75958035

**Valid from:** 2024-02-16

**Valid until:** 2026-09-27

**Date,** 2024-02-19



Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Prima Dental Manufacturing Ltd**  
Gemba House , Stephenson Drive, Gloucester, GL2 2HA, UNITED  
KINGDOM

Design and development, manufacture and sales of sterile and non-sterile rotary dental instruments and dental carbide milling tools used in digital dentistry.  
Manufacture and sales of dental impression paste, dental prophylaxis cleaning pastes and dental waxes, dental mirrors and dental hand-held instruments.

**Prima Dental Manufacturing Ltd**  
Horizon House, Stephenson Drive , Gloucester, GL2 2HA,  
UNITED KINGDOM

Design and development, manufacture and sales of sterile and non-sterile rotary dental instruments and dental carbide milling tools used in digital dentistry.

**Prima Dental Manufacturing Ltd**  
The Hive, Unit 32 & 33, Brunel Court , Waterwells Business Park,  
Gloucester, GL2 2AL, UNITED KINGDOM

Manufacture, sales and distribution of sterile and non-sterile rotary dental instruments and dental carbide milling tools used in digital dentistry.  
Sales and distribution of dental impression paste, dental prophylaxis cleaning pastes and dental waxes, dental mirrors, dental hand held instruments, dental materials, dental filling materials, dental cements and dental etching gels.

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