



Certificate

No. Q5 102917 0007 Rev. 01

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.

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. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_102917_0007_Rev.01)

Report No.: 75949066

Valid from: 2021-10-11
Valid until: 2023-09-27

Date, 2021-10-11

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

See scope of certificate

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

See scope of certificate

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

See scope of certificate

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