



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 099406 0008 Rev. 01

Manufacturer:

Sinol Dental Limited

No.3 Biyuan Road
712000 Xianyang, Shaanxi
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

**High Speed Air Turbine Handpiece,
Dental Low Speed Handpiece including Air Motor,
Straight and Geared Angle Handpiece,
Dental Low Voltage Electrical Motor,
Dental Unit with Chair, Portable Dental Unit**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

SH18189EXT01

Valid from:

2019-01-23

Valid until:

2024-01-22

Date,

2019-01-10

Stefan Preiß



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Facility(ies):

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REPUBLIC OF CHINA