

EC Certificate

Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Registration No.: DD 60125716 0001

Report No.: 17026086 007

Manufacturer: Foshan SOCO Precision

Instrument Co., Ltd. 2FI. Bldg 3, District A Guangdong New Light

Source Industrial Base, Luocun Shishan Town, Nanhai District

Foshan City

528226 Guangdong

Products: China

- High and Low Speed Handpieces

- Dental Root Canal Instruments

Replaces Approval, Registration No.: DD 60099459 0001

Expiry Date: 2023-03-10

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-03-11

Date: 2018-03-06

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.