TÜVRheinland®

EC Certificate

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

Registration No.: DD 60118791 0001

Report No.: 15096045 001

Manufacturer:

Shanghai Smedent Medical
Instrument Co., Ltd.
Room 111, Building E
No. 681, North Huifeng Road, Fengxian
201403 Shanghai
China

Products:

- Dental Carbide Burs
- Dental Diamond Burs

(see attachment for site included)

Expiry Date: 2021-11-25

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.

Notified Body

Effective Date: 2017-06-12

Date: 2017-06-12

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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