EC Certificate

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

Registration No.: DD 60147804 0001

Report No.: 17057065 008

Manufacturer:

Shenzhen Denco Medical Co., Ltd.
Room 301, No. 8 1st road of Xiawei
Industrial Zone, Zhangkengjing Community
Guanhu Street, Longhua District
518110 Shenzhen
P.R. China

Products:

Dental Root Canal Instruments

Replaces Approval, Registration No.: DD 60134120 0001

Expiry Date: 2024-05-26

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: 2020-08-07

Date: 2020-08-07

Notified Body

Fuxiu Sheng

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.