

**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

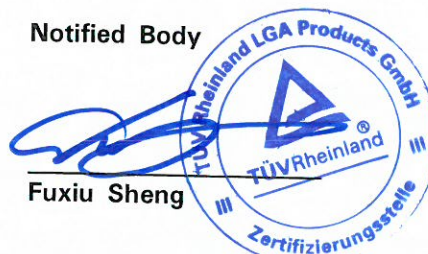
**Expiry Date:** 2024-05-26

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.