



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

Registration No.: DD 60145213 0001

Report No.: 17054623 002

Manufacturer: SHENZHEN FLYDENT MEDICAL CO.,LTD
Synésio de Guimarães , 806 – Sala 01
João Pessoa
P.R. China

Products: Dental Root Canal Instruments

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 I and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-05-09

Date: 2020-05-09

Notified Body



TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nurnberg

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