EC Certificate

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

Registration No.: DD 60135314 0001

Report No.: 17054526 003

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

Products: Dental Root Canal Instruments

Digitally signed by Romanenco Alexandru
Date: 2025.05.15 11:43:14 EEST
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Expiry Date: 2028-05-26

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

Effective Date: 2024-05-26

Date: 2024-05-26

Notified Body

Jing Zhang

TÜV Rheinland LGA Products GmbH – TillystraBe 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.