

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

Registration No.: DD 60140570 0001

Report No.: 17038739 008

Manufacturer: Foshan Wenjian Medical Instrument
Co., Ltd.
Third Floor
No. 3, Jiebian Industrial Zone
LuoCun, ShiShan Town, Nanhai
Foshan
528226 Guangdong
China

Products:
- High-speed air turbine handpieces
- Low-speed air turbine handpieces

Replaces Approval, Registration No.: DD 60131459 0001

Expiry Date: 2024-05-27

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: 2019-07-02

Date: 2019-07-02

Notified Body



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.