EC Certificate

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

Registration No.: DD 60131459 0001

Report No.: 17038739 004

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 60093691 0001

Expiry Date: 2019-07-06

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: 2018-08-10

Date: 2018-08-10

Notified Body

S. Liu

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.

Digitally signed by Jighili Tatiana
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