EC Declaration of Conformity

Manufacturer:

Foshan Wenjian Medical Instrument Co.,Ltd

whose single Authorized Representative:

Foshan Wenjian Medical Instrument Co.,LtdThird Floor No.3,Jiebian Industrial Zone LuoCun,ShiShan

Lotus NLB.V

Address: Koningin Julianaplein 10, le Verd, 2595AA, The Hague Netherlands

Town, Nanhai Foshan 528226 Guangdong China

We, the manufacturer, herewith declare that the products

High speed handpiece

(including system components and accessories)

UMDNS-Code: 11-161

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa, rule 5,9 according to Annex IX of the Directive 93/42/EEC.

It bears the mark

C €0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

Certificate No.: DD601405700001 Issue date: 2019-07-02

Expiry date: 2024-05-27

following the procedure relating to the EC Declaration of Conformity set out in of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Foshan Wenjian Medical Instrument Co., Ltd

FOSHAN GUANG DONG CHINA

SUMEI YUAN

ion

instration representative

Place, date

Legally binding signature, Function