

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

Registration No.: DD 60140570 0001

Report No.: 17038739 008

Manufacturer: BAISTRA INDUSTRIES CORPORATION LIMITED
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.

EC Declaration of Conformity

Manufacturer: BAISTRA INDUSTRIES CORPORATION LIMITED

whose single Authorized Representative:

BAISTRA INDUSTRIES CORPORATION LIMITED

Third Floor No.3,Jiebian Industrial Zone LouCun, ShiShan Town,
Nanhai Foshan 528226 Guangdong China

Lotus Global Co.,Ltd

**Address: 15 Alexandra Road London UK
NW8 0DP**

We, the manufacturer, herewith declare that the products

High-speed air turbine handpiece

Low-speed air turbine handpiece

UMDNS-Code: **11-161**

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

The medical device has been assigned to class **Ila**, rule **5,9** according to Annex IX of the Directive 93/42/EEC. It bears the mark



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

**TÜV Rheinland Product Safety GmbH
Am Grauen Stein D-51105 Köln**

Certificate No.: DD 60140570 0001

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

BAISTRA INDUSTRIES CORPORATION LIMITED

FOSHAN GUANG DONG CHINA SUMEI YUAN Administration representative *Place, date*

Legally binding signature, Function

