

**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

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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.