

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

**Registration No.:** DD 60143318 0001

**Report No.:** 17042385 008

**Manufacturer:** Nanning Baolai Medical  
Instrument Co., LTD.  
7th Floor, General Building,  
Hetai Sci. & Tech. Park  
No.9 Gaoxin 4th RD.  
530007 Nanning, Guangxi  
China

**Products:** Ultrasonic Scalers, Handpieces and Ultrasonic Scaler Tips  
Replaces Approval, Registration No. DD 60097386 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:** 2019-11-18

**Date:** 2019-11-18

Notified Body

Wenxiang Zhang



**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.

**Business Stream Products  
Certification Department**



**Precisely Right.**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

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Instrument Co., LTD.  
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No.9 Gaoxin 4th RD.  
530007 NANNING, GUANGXI  
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Contact

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Date November 18, 2019

**Application for : QMS Produktion, Anhang V MDD**  
Certificate No. : DD 60143318 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60143318 0001 replacing  
the previous certificate.

With effective date of the new certificate, the previous certificate  
(number see new certificate) becomes invalid.

Kind regards

Certification body

Wenxiang Zhang

Test sample: no, documentation available

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LGA Products GmbH

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