

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

**Registration No.:** DD 60132717 0001

**Report No.:** 15096253 002

**Manufacturer:** Jining Orodeka Medical  
Equipment Co., Ltd.  
West 15 Floor, XinchengFazhan  
East Building, Beihu District  
Jining  
272000 Shandong  
China

**Products:** Dental Root Canal Instruments  
  
(see attachment for additional site(s) included)

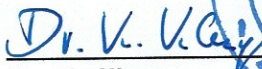
**Expiry Date:** 2023-04-11

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:** 2019-02-14

**Date:** 2019-02-14

Notified Body

  
Dr. K. Kluge



**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.



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60132717 0001  
**Report No.:** 15096253 002

**Manufacturer:**

**Jining Orodeka Medical  
Equipment Co., Ltd.  
West 15 Floor, XinchengFazhan  
East Building, Beihu District  
Jining  
272000 Shandong  
China**

**Site included:**

**Tangkou Government North 400 Meters,  
Rencheng District, Jining City, Shandong, China**

**Date: 2019-02-14**

**Notified Body**

*Dr. K. Kluge*  
**Dr. K. Kluge**





# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Jining Orodeka Medical  
Equipment Co., Ltd.  
West 15 Floor, XinchengFazhan  
East Building, Beihu District  
Jining  
272000 Shandong  
China**

has established and applies a quality management system for medical devices  
for the following scope:

**Manufacture and Distribution of  
Dental Root Canal Instruments  
(see attachment for additional site(s) included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-02-14  
Certificate Registration No.: SX 60132718 0001  
An audit was performed. Report No.: 15096253 002  
This Certificate is valid until: 2021-04-11

Certification Body



Date 2019-02-14



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60132718 0001  
**Report No.:** 15096253 002

**Organization:** Jining Orodeka Medical  
Equipment Co., Ltd.  
West 15 Floor, XinchengFazhan  
East Building, Beihu District  
Jining  
272000 Shandong  
China

**Scope:**

Site included:

Tangkou Government North 400 Meters,  
Rencheng District, Jining City, Shandong, China

Manufacture of Dental Root Canal Instruments

**Certification Body**



**Date:** 2019-02-14

*Dr. K. Kluge*  
**Dr. K. Kluge**

