TÜVRheinland®

# 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.

Notified Body

**Effective Date:** 2019-02-14

**Date:** 2019-02-14

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.

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Doc. 1/1, Rev. 0

# 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

**Notified Body**

**Date:** 2019-02-14

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle