

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)

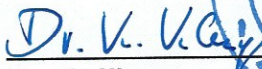
Expiry Date: 2023-04-11

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**

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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

