EC Declaration of Conformity

Manufacturer:

Jining Orodeka Medical Equipment Co. LTD
West 15 floor,XinChengFaZhan East Building Beihu District JiNing Shandong China

whose single Authorized Representative:

ORODEKA SRL.
Via Fratelli Rosselli,12 50063 Figline e Incisa Valdarno(FI) ITALY

We, the manufacturer, herewith declare that the products

Dental Root Canal Instruments

meet the provisions of Directive 93/42/EEC and its transpositions in national laws which apply to it.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.
Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: 15096253002
Issue date: 2019-02-14
Expiry date: 2023-04-11

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Jining Orodeka Medical Equipment Co. LTD

Address: West 15 floor,XinChengFaZhan East Building Beihu District JiNing Shandong China

Jining /2019-02-14
Place, date

2019-02-14

huifang-tian / manager
Legally binding signature, Function

huifang Tian