

EC Declaration of Conformity

Manufacturer:
Jining Oroteka Medical Equipment Co. Ltd
West 15 floor, XinChengFazhan, East Building, Beihu
District, Shandong
China

Authorized EC Representative:
ORODEKA SRL
Via Andrea Del Castagno 9 50132 Firenze Italy
Italy

We, the manufacturer herewith declares that the products

Dental Root Canal Instruments

Product Details

Detailed in the attached schedule

The products meet the provision of Directive 93/42/ECC and its transposition in national laws which apply to it.

Standard Used:

EN ISO 13485:2016

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

Assessment details

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/ECC.

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
Registration No.: DD 60132717 0001
Report No.: 15096253 002
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/ECC. 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 Oroteka Medical Equipment Co. Ltd
Address: West 15 floor, XinChengFazhan, East Building, Beihu District, Shandong, China

Place, Date

15th Dec 2020

Legally binding signature, Function

Declaration of Conformity

Manufacturer:

Jining Orodeka Medical Equipment Co. Ltd

West 15 floor, XinChengFazhan, East Building, Beihu District, Shandong
China

Authorized EC Representative:

ORODEKA SRL

Via Andrea Del Castagno 9 50132
Firenze Italy
Italy

Brand Name	Ref#
K-FILES	DK90012100188,DK90012100189,DK90012100190,DK90012100191,DK90012100192,DK90012100193,DK90012100194,DK90012100195,DK90012100196,DK90012100197,DK90012100198,DK90012100199,DK90012100200,DK90012100201,DK90012100202,DK90012100203,DK90012100204,DK90012100205,DK90012100206,DK90012100207,DK90012100208,DK90012100209,DK90012100210,DK90012100211,DK90012100212,DK90012100213,DK90012100214,DK90012100215,DK90012100216,DK90012100217,DK90012100218,DK90012100219,DK90012100220,DK90012100221,DK90012100222,DK90012100223,DK90012100224,DK90012100225,DK90012100226,DK90012100227,DK90012100228,DK90012100229,DK90012100230,DK90012100231
H-FILES	DK90012100100,DK90012100101,DK90012100102,DK90012100103,DK90012100104,DK90012100105,DK90012100106,DK90012100107,DK90012100108,DK90012100109,DK90012100110,DK90012100111,DK90012100112,DK90012100113,DK90012100114,DK90012100115,DK90012100116,DK90012100117,DK90012100118,DK90012100119,DK90012100120,DK90012100121,DK90012100122,DK90012100123,DK90012100124,DK90012100125,DK90012100126,DK90012100127,DK90012100128,DK90012100129,DK90012100130,DK90012100131,DK90012100132,DK90012100133,DK90012100134,DK90012100135,DK90012100136,DK90012100137,DK90012100138,DK90012100139,DK90012100140,DK90012100141,DK90012100142,DK90012100143
REAMERS	DK90012100144,DK90012100145,DK90012100146,DK90012100147,DK90012100148,DK90012100149,DK90012100150,DK90012100151,DK90012100152,DK90012100153,DK90012100154,DK90012100155,DK90012100156,DK90012100157,DK90012100158,DK90012100159,DK90012100160,DK90012100161,DK90012100162,DK90012100163,DK90012100164,DK90012100165,DK90012100166,DK90012100167,DK90012100168,DK90012100169,DK90012100170,DK90012100171,DK90012100172,DK90012100173,DK90012100174,DK90012100175,DK90012100176,DK90012100177,DK90012100178,DK90012100179,DK90012100180,DK90012100181,DK90012100182,DK90012100183,DK90012100184,DK90012100185,DK90012100186,DK90012100187
TAPER-SIZED INSTRUMENTS	DK90021900100,DK90022100101,DK90022500102,DK90022800103,DK90023100104,DK90022100105,DK90022500106,DK90022800107,DK90023100108,DK90022100109,DK90022500110,DK90022800111,DK90023100112,DK90022100113,DK90022500114,DK90022800115,DK90023100116,DK90022100117,DK90022500118,DK90022100119,DK90022100120,DK90022100121,DK90022500122,DK90022800123,DK90023100124,DK90022100125,DK90022500126,DK90022800127,DK90023100128,DK90022100129,DK90022500130,DK90022800131,DK90022800132,DK90022100133,DK90022500134,DK90022800135,DK90022100136,DK90022800137,DK90022800138,DK90022100139,DK90022500140,DK90022500141,DK90022100142,DK90022500143,DK90022800144,DK90023100145,DK90022100146,DK90022500147,DK90022800148,DK90023100149,DK90022100150,DK90022500151,DK90022800152,DK90023100153,DK90021800154,DK90021800155,DK90021800156

Place, Date

15th Dec 2020

Legally binding signature, Function