

Declaration of conformity

Manufacturer name: **Wuhu Ruijin Medical Instrument & Device Co., Ltd**

Address: No.33, Wanchun Road, Economic and Technological Development Zone, Wuhu City, Anhui Province, P.R.China

European Representative name: **Wellkang Ltd**

Address: Suite B ,29 Harley Street LONDON W1G 9QR, England, United Kingdom

Tel: 0049-40-2513175 Fax: 0049-40-255726

Product: **Medical electrical saw drill**

Please refer to the appendix.

Classification (MDD, Annex IX): **IIa**

According to the ANNEX IX of MDD93/42/EEC, Rules 9,

Conformity Routes: MDD93/42/EEC Annex V (Production quality assurance)

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr.65, 80339, Munich, Germany.

NB identification number: 0123

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.

DIRECTIVES

General applicable directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC +amendment 2007/47/EC).

Standards:

All applicable harmonized Standards (see standards list in the CE technical file)

Certificate No.: G2160695446002

Issue date: 2016-11-08

Expiry date: 2021-11-07

Date CE mark was affixed: CE0123

Place, date of issue: Wuhu, China

Signature: 

Name/Position: Yang shangbing / GM 2019-07-29



Appendix

No.	Model	Code:
1	RJ-MP	NM100
2		NM101
3		NM300
4		NM500
5	RJ-MP	EM100
6		EM300
7	RJ-MP	SM100
8		SM300
9	RJ-PD	ND-1001
10		ND-2011
11		ND-3011
12		ND-5001
13		ND-1501
14		ND-2511
15		ND-3511
16	RJ-PS	NS-1011
17		NS-3031
18		NS-3032
19		NS-2011
20		NS-4031
21		NS-1511

22		NS-3531
23		NS-3532
24	RJ-PS	ES-1011
25		ES-3031
26		ES-3032
27		ES-2011
28		ES-4031
29	RJ-PS	SS-1011
30		SS-3031
31		SS-3032
32		SS-2011
33		SS-4031