

INSTRUMENTE

<p>Motor oscilant</p> <p>NS-1511 OSCILLATING SAW</p> 	<p>Reamer</p> <p>ND-3511</p> 
<p>Technical description</p> <ol style="list-style-type: none"> 1) For application in hand surgery 2) Ingenious technological skill, high quality 3) Perfect ergonomic design, widely compatibility, used in a variety of surgery 4) Main unit can be sterilized by high temperature and high pressure, reach the requirement of ministry of healthy 5) lightweight allows for optional maneuverability, minimizing joint fatigue 6) Ni-MH battery without memory enviroment friendly 7) Autoclavable 8) For large bones cutting. <p>Standard Configuration</p> <ol style="list-style-type: none"> 1) One Hand piece 2) Two Batteries 3) One Charger 4) One Aluminium box <p>Product feature</p> <ol style="list-style-type: none"> 1) Can be sterilized up to 135°C 2) Motor is imported from Germany 3) Strong power, low noise, small vibration 4) Variable speed and lightweight for better accuracy 	<p>Technical description</p> <ol style="list-style-type: none"> 1. For joint operation. 2. Low speed, great torque, can be connected by any kinds of the acetabulum burnishing tools and medullary cavity expanding tools. 3. Main unit can be sterilized by high temperature and high pressure up to 135 °C. 4. Excellent quality, portable, low noise, variable speed control, carbonless motor available for increased power, allows for easy selection of power during operation. 5. Scientific balance technics, reduces vibration and enhances handpiece control, afford surgeon a comfortable operation. 6. High concentricity ensures the precision of polishing acetabulum in HIP operation. 7. Large torsional moment to give more powerful polishing. 8. Low speed, high torque. <p>Standard Configuration</p> <ul style="list-style-type: none"> - One handpiece - One charger - Two batteries - One sterilizing channel - One drill chuck - One aluminum alloy box

Saw Blade

The surgical saw blade is manufactured from stainless surgical steel, are deployed in joint surgery, thoractomy surgical, orthopaedic traumatology etc. extremely exact cut and sharpness, cut through bone rapidly, offers a broad range of sharpened and straight-set saw blades with different lengths and widths.



Saw Blade

Model NO.:RJ-0310	Type:Saw Blade
Application:Orthopedic, Neurosurgery, Microsurgery, Used for Surgical Operations	Material:Stainless Steel
Feature:Reusable	Certification:CE, ISO13485
Group:Adult	Medical Device Regulatory Type:Type 2
Medical Devices Reg./Record No.:Wsyjxzz2012-2100053	Properties:Orthopedic Surgical Accessories
Size:Can Be Design for You	Trademark:RUIJIN
Transport Package:White Box	Specification:Normal
Origin:China(Mainland)	HS Code:9018909000



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Zentralstelle der Länder
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Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 095446 0005 Rev. 00

Manufacturer:

**Wuhu Ruijin Medical Instrument & Device
Co., Ltd.**

No.33, Wanchun Road
Economic and Technological Development Zone
241000 Wuhu City, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Wuhu Ruijin Medical Instrument & Device Co., Ltd.
No.33, Wanchun Road, Economic and Technological
Development Zone, 241000 Wuhu City, Anhui Province,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Medical Electric Saw Drill,
Medical Electric Drill,
Medical Electric Saw**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

SH19104901

Valid from:

2020-01-08

Valid until:

2024-05-26

Date,

2020-01-08

Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q6 095446 0004 Rev. 01

Holder of Certificate: **Wuhu Ruijin Medical Instrument & Device Co., Ltd.**

No.33, Wanchun Road
Economic and Technological Development Zone
241000 Wuhu City, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Wuhu Ruijin Medical Instrument & Device Co., Ltd.
No.33, Wanchun Road, Economic and Technological
Development Zone, 241000 Wuhu City, Anhui Province,
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate:

**Production and Distribution of
Medical Electric Saw Drill,
Medical Electric Drill, Medical Electric Saw,
Saw Blade, Drill Bit, Autoclavable Box, Flexible Reamer**

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6_095446_0004_Rev.01

Report No.: SH22104901

Valid from: 2022-11-08

Valid until: 2025-11-07

Date, 2022-10-24

Christoph Dicks
Head of Certification/Notified Body