

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60154538 0001

**Report No.:** 15096114 006

**Manufacturer:** Shanghai Bojin Medical Instrument  
Co., Ltd.  
A Zone of F2, C Zone of F1  
Building 6  
No. 125, Longpan Road, Jiading District  
201801 Shanghai  
P.R. China

**Products:**

- Medical Saw Blades
- Medical Drill Bits
- Arthroscopic Surgery Blades
- Medical Electrical Saw Drills

Replaces Approval, Registration No.: DD 60117721 0001

**Expiry Date:** 2024-05-26

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:** 2021-04-14

**Date:** 2021-04-14

Notified Body

Jason Pan



**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.

**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY  
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers: / **Shanghai Bojin Medical Instrument Co., Ltd.**  
 Name and address of the manufacturer: / **A Zone of F2, C Zone of F1, Building 6, No.125, Longpan Road,**  
 Nom et adresse du fabricant: / **Jiading District, Shanghai 201801, China**  
 Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /  
 Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Medical electrical saw drills**  
 the medical device: / **Medical saw blades**  
 le dispositif médical: / **Medical drill bits**  
 il dispositivo medico:

der Klasse: / **Class IIa**  
 of class: /  
 de la classe: /  
 di classe:

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /  
 selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / **Directive 93/42/EEC Annex V**  
 Conformity assessment procedure: /  
 Procédure d'évaluation de la conformité: /  
 Procedura di valutazione della conformità:

Registrier-Nr.: / **DD 60154538 0001**  
 Registration No.: /  
 N°d'enregistrement: /  
 Numero di registrazione:

Benannte Stelle: / **TÜV Rheinland LGA Products GmbH**  
 Notified Body: / **Tillystraße 2**  
 Organisme notifié: / **90431 Nürnberg**  
 Organismo notificato: **Deutschland**  
**CE 0197**

EU representative: **Shanghai International Holding Corp. GmbH (Europe)**  
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**Tel: +49-40-2513175 Fax: +49-40-255726**  
**Dimdi No.:DE/0000040627**  
**E-mail: shholding@hotmail.com**

Shanghai  
2021/12/24

2021.12.24

General manager

Ort, Datum / Place, date /

Name und Funktion / Name and function /

Lieu, date / Luogo, data

Nom et fonction / Nome e funzione

**List of product models**

Product name	Model	REF	Description	GMDN code	Classification
Medical electrical saw	BYJ-II 1101	BJ1101	Oscillating saw	33541	Ila
	BYJ-II 1106	BJ1106	Sternum saw	33541	Ila
	BYJ-II 1109	BJ1109	Reciprocating saw	33541	Ila
	BYJ-II 4101	BJ4101	Oscillating saw	33541	Ila
	BYJ-II 4106	BJ4106	Sternum saw	33541	Ila
	BYJ-II 4109	BJ4109	Reciprocating saw	33541	Ila
	BYJ-II 8101	BJ8101	Oscillating saw	33541	Ila
	BYJ-II 5501	BJ 5501	Oscillating saw	33541	Ila
	BYJ-II 5506	BJ 5506	Sternum saw	33541	Ila
BYJ-II 5509	BJ 5509	Reciprocating saw	33541	Ila	
Medical electrical drill	BYZ-II 1102	BJ1102	High speed drill	33541	Ila
	BYZ-II 1103	BJ1103B BJ1103D	Cannulated drill	33541	Ila
	BYZ-II 1104	BJ1104	Cranial drill	33541	Ila
	BYZ-II 1105	BJ1105	Cranial bur	33541	Ila
	BYZ-II 1107	BJ1107B BJ1107D	Acetabulum reamer	33541	Ila
	BYZ-II 4102	BJ4102	High speed drill	33541	Ila
	BYZ-II 4103	BJ4103B BJ4103D	Cannulated drill	33541	Ila
	BYZ-II 4104	BJ4104	Cranial drill	33541	Ila
	BYZ-II 4105	BJ4105	Cranial bur	33541	Ila
	BYZ-II 4107	BJ4107B BJ4107D	Acetabulum reamer	33541	Ila
	BYZ-II 8102	BJ8102	High speed drill	33541	Ila
	BYZ-II 8103	BJ8103	Cannulated drill	33541	Ila
	BYZ-II 5502	BJ5502	High speed drill	33541	Ila
	BYZ-II 5503	BJ5503B BJ5503D	Cannulated drill	33541	Ila
	BYZ-II 5504	BJ5504	Cranial drill	33541	Ila
	BYZ-II 5505	BJ5505	Cranial bur	33541	Ila
BYZ-II 5507	BJ5507B BJ5507D	Acetabulum reamer	33541	Ila	
Medical electrical saw drill	BYJZ-I 21	BJ2100, BJ2101, BJ2102, BJ2102SAO , BJ2103B, BJ2103D, BJ2104, BJ2105, BJ2106, BJ2107B, BJ 2107D, BJ2109, BJ2112, BJ21 13A, BJ2113B	Multifunctional medical electrical saw drill	33541	Ila
	BYJZ-I 42	BJ4200, BJ4201, BJ4202, BJ4 202SAO, BJ4203B, BJ4203D, BJ4207B, BJ4207D, BJ4209, BJ4213A, BJ4213B	Multifunctional medical electrical saw drill	33541	Ila

	BYJZ-I 56	BJ5600, BJ5601, BJ5602, BJ5602SAO, BJ5607B, BJ5607D, BJ5613	Multifunctional medical electrical saw drill	33541	Ila
	BYJZ-I 82	BJ8200, BJ8201, BJ8202, BJ8202SAO, BJ8203, BJ8209, BJ8213A, BJ8213B	Multifunctional medical electrical saw drill	33541	Ila
	BYJ-I 2101	BJ2100, BJ2101	Oscillating saw	33541	Ila
	BYJ-I 2106	BJ2100, BJ2106	Sternum saw	33541	Ila
	BYJ-I 2109	BJ2100, BJ2109	Reciprocating saw	33541	Ila
	BYJ-I 2112	BJ2100, BJ2112	Oscillating saw (tplo)	33541	Ila
	BYJ-I 4201	BJ4200, BJ4201	Oscillating saw	33541	Ila
	BYJ-I 4209	BJ4200, BJ4209	Reciprocating saw	33541	Ila
	BYJ-I 5601	BJ5600, BJ5601	Oscillating saw	33541	Ila
	BYJ-I 8201	BJ8200, BJ8201	Oscillating saw	33541	Ila
	BYJ-I 8209	BJ8200, BJ8209	Reciprocating saw	33541	Ila
	BYZ-I 2102	BJ2100, BJ2102, BJ2102SAO	High speed drill	33541	Ila
	BYZ-I 2103	BJ2100, BJ2103B, BJ2103D	Cannulated drill	33541	Ila
	BYZ-I 2104	BJ2100, BJ2104	Cranial drill	33541	Ila
	BYZ-I 2105	BJ2100, BJ2105	Cranial bur	33541	Ila
	BYZ-I 2107	BJ2100, BJ2107B, BJ2107D	Acetabulum reamer	33541	Ila
	BYZ-I 2113	BJ2100, BJ2113A, BJ2113B	K wire driver	33541	Ila
	BYZ-I 4202	BJ4200, BJ4202, BJ4202SAO	High speed drill	33541	Ila
	BYZ-I 4203	BJ4200, BJ4203B, BJ4203D	Cannulated drill	33541	Ila
	BYZ-I 4207	BJ4200, BJ4207B, BJ4207D	Acetabulum reamer	33541	Ila
	BYZ-I 4213	BJ4200, BJ4213A, BJ4213B	K wire driver	33541	Ila
	BYZ-I 5602	BJ5600, BJ5602, BJ5602SAO	High speed drill	33541	Ila
	BYZ-I 5607	BJ5600, BJ5607B, BJ5607D	Acetabulum reamer	33541	Ila
	BYZ-I 5613	BJ5600, BJ5613	K wire driver	33541	Ila
	BYZ-I 8202	BJ8200, BJ8202, BJ8202SAO	High speed drill	33541	Ila
	BYZ-I 8203	BJ8200, BJ8203	Cannulated drill	33541	Ila
	BYZ-I 8213	BJ8200, BJ8213	K wire driver	33541	Ila
Medical saw blades	BJ	BJ90221.0A, BJ90141.0A, BJ70240.8B, BJ90101.0A, BJ90181.0A, BJ90251.0A	Surgical saw blade, sagittal	43376	Ila
Medical saw blades	WF	WF70131.0B	Surgical saw blade, reciprocating	45493	Ila
Medical saw blades	2WF	2WF70131.0B	Surgical saw blade, reciprocating	45493	Ila
Medical drill bits	ZC	BJZC-1.5-35-115 BJZC-2.0-35-115 BJZC-2.5-35-115 BJZC-2.7-50-115 BJZC-3.0-50-115 BJZC-3.2-50-115 BJZC-3.5-50-115 BJZC-4.0-55-115 BJZC-4.5-50-115	Fluted surgical drill bit	43390	Ila

### List of Model Accessories

Product name	REF	Description
Accessories	BJ1001, BJ4001, BJ8001, BJ43001,	Battery
Accessories	BJ1002, BJ1002-4, BJ43002, BJ43002-4	Chargers
Accessories	BJ1004, BJ4004, BJ43004	Transfer kit
Accessories	BJ1005, BJ8005, BJ43005	Key
Accessories	BJ43003	Battery case
Accessories	BJXDH1101, BJXDH1106, BJXDH1109, BJXDH4101, BJXDH4106, BJXDH4109, BJXDH8101, BJXDH5501, BJXDH5506, BJXDH5509, BJXDH1102, BJXDH1103B, BJXDH1103D, BJXDH1104 BJXDH1105, BJXDH1107B, BJXDH1107D, BJXDH4102 BJXDH4103B, BJXDH4103D, BJXDH4104, BJXDH4105 BJXDH4107B, BJXDH4107D, BJXDH8102, BJXDH8103 BJXDH5502, BJXDH5503B, BJXDH5503D, BJXDH5504 BJXDH5505, BJXDH5507B, BJXDH5507D, BJXDH2100 BJXDH4200, BJXDH8200, BJXDH5600	Sterilized case
Accessories	BJ1003, BJ2003	Hand piece cover