REGISTRATION NO. 04718Q10000480

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shanghai Bojin Electronic Instrument &Device Co., Ltd.

Registered Address: B322 and 323, No. 1128, South Huicheng Road, Jiading Industrial Zone, Shanghai,China Postcode: 201800

Manufacturing Address:No.1719，Baojia Highway，Jiading District，Shanghai,China;Room 211~215, No.125, Longpan Road, Jiading District, Shanghai,China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design ,D evelopment, Production and Service of Medical Electric Saw and Dril Sysrem，Portable X-ray Fluoroscopy，Minitype Medical Electric Saw and Dril Sysrem

Date of issue: October 08,2018

Date of expiry:October 07,2021

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Digitally signed by Iarovoi Petru
Date: 2019.09.18 16:34:31 EEST
Reason: MoldSign Signature
Location: Moldova

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmde.com.cn). Address: 5th floor of Zhong Lian building, No.iia88

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid until:
9839-2017-CE-RGC-NA-PS	PRJC-40131-2007-PRC-RGC	25 June 2022

This is to certify that the quality system of:

Shanghai Bojin Electric Instrument & Device Co., Ltd.

B322 and 323，No.1128, Huicheng South Road, Jiading Industrial Zone, Shanghai, China

For design, production and final product inspection/testing of:

Medical Electrical Saw Drill

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 29 september 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Mariann Jeremiassen

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: 9839-2017-CE-RGC-NA-PS

Project No.: PRJC-40131-2007-PRC-RGC

Valid until: 25 June 2022

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Replaces certificate 16460-2012-CE-RGC-NA (NB 0434) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-09-22

Products covered by this Certificate:

Product Description	Product Name	Class
Medical Electrical Saw Drill	BJJZ-I, BJJ-I, BJZ-I, BJWJZ-1, BJWJ-1, BJWZ-1	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Shanghai Bojin Electric Instrument & Device Co., Ltd.

Registered address: B322 and 323，No.1128, Huicheng South Road, Jiading Industrial Zone, Shanghai, China

Manufacturing address 1: No.1719, Baojia Highway, Jiading District, Shanghai, China;

Manufacturing address 2: Room211~215, No.125, Longpan Road, jiading District, Shanghai, China

EU Representative

Bojin Italia di Maurizio Marra

Via Ortana 20, 01030 Vitorchiano VT-Italy

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid until:
9839-2017-CE-RGC-NA-PS	PRJC-40131-2007-PRC-RGC	25 June 2022

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate