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.

Digitally signed by Iarovoi Petru
Date: 2023.04.07 16:25:23 EEST
Reason: MoldSign Signature
Location: Moldova

Business Stream Products
Certification Department

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LGA
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TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 25, 2024

Notified Body Confirmation Letter
Reference. : 326011355

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following 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
SRN Number (if available): CN-MF-000020042

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

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51105 Köln
Germany

Headquarter

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90431 Nuremberg

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service@de.tuv.com
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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Jason Pan
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Medical Electrical Saw Basic UDI-DI: 697301152BYJMK	IIa	Medical Electrical Saw Drills	Certificate#: DD 60154538 0001 NB#: 0197
Medical Electrical Drill Basic UDI-DI: 697301152BYZNK	IIa	Medical Electrical Saw Drills	Certificate#: DD 60154538 0001 NB#: 0197
Medical Electrical Saw Drills Basic UDI-DI: 697301152BYJZHE	IIa	N/A	Certificate#: DD 60154538 0001 NB#: 0197
Medical Saw Blades (Sterile) Sterile Type Basic UDI-DI: 697506929WJJPV9	IIa	Medical Saw Blades Sterile Type	Certificate#: DD 60154538 0001 NB#: 0197
Medical Saw Blades (Non-Sterile) Non-sterile Type	IIa	Medical Saw Blades Non-sterile Type	Certificate#: DD 60154538 0001 NB#: 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 697506929JP4X			
Medical Drill Bits (Non-Sterile) Basic UDI-DI: 697506929ZT6P	IIa	Medical Drill Bits	Certificate#: DD 60154538 0001 NB#: 0197
Arthroscopic Surgery Blades (STERILE) Basic UDI-DI: 69422978ASBSX6	IIa	Arthroscopic Surgery Blades	Certificate#: DD 60154538 0001 NB#: 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-04-26	326011355	Initial issue

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Shanghai Bojin Medical Instrument Co., Ltd.
Manufacturer address and contact details	A Zone of F2, C Zone of F1, Building 6, No.125, Longpan Road, Jiading District, 201801 Shanghai P.R. China
Single Registration Number (SRN) (if available)	CN-MF-000020042

Authorised Representative name (if applicable)	Shanghai International Holding Corp. GmbH(Europe)
Authorised Representative address and contact details	Address: Eiffestraße 80, 20537 Hamburg Email: shholding@hotmail.com Telephone number: +49402513175
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH ☑ See attached schedule
Notified body number (if applicable)	0197 ☑ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	DD601545380001 ☑ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if	2024-05-26

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

applicable)	□ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 14 April 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Unclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Shanghai Bojin Medical Instrument Co., Ltd.

Location & Date: Shanghai, 2024-5-10

Signature, Print Name, Title Wang Xijiong, General Manager

Contact Details (at least email): bojin6800@bojin-medical.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Medical Electrical Saw	DD 60154538 0001	2024-05-26	TÜV Rheinland LGA Products GmbH NB#: 0197	TÜV Rheinland LGA Products GmbH NB#: 0197	2028-12-31	N/A
Medical Electrical Drill	DD 60154538 0001	2024-05-26	TÜV Rheinland LGA Products GmbH NB#: 0197	TÜV Rheinland LGA Products GmbH NB#: 0197	2028-12-31	N/A
Medical Electrical Saw Drills	DD 60154538 0001	2024-05-26	TÜV Rheinland LGA Products GmbH NB#: 0197	TÜV Rheinland LGA Products GmbH NB#: 0197	2028-12-31	N/A
Medical Saw Blades (Sterile) Sterile Type	DD 60154538 0001	2024-05-26	TÜV Rheinland LGA Products GmbH NB#: 0197	TÜV Rheinland LGA Products GmbH NB#: 0197	2028-12-31	N/A
Medical Saw Blades (Non-Sterile) Non-sterile Type	DD 60154538 0001	2024-05-26	TÜV Rheinland LGA Products GmbH NB#: 0197	TÜV Rheinland LGA Products GmbH NB#: 0197	2028-12-31	N/A
Medical Drill Bits (Non-Sterile)	DD 60154538 0001	2024-05-26	TÜV Rheinland LGA Products GmbH NB#: 0197	TÜV Rheinland LGA Products GmbH NB#: 0197	2028-12-31	N/A
Arthroscopic Surgery Blades (STERILE)	DD 60154538 0001	2024-05-26	TÜV Rheinland LGA Products GmbH NB#: 0197	TÜV Rheinland LGA Products GmbH NB#: 0197	2028-12-31	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.	SX 2182378-1
Certificate Holder	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
Scope	Design and Development, Manufacture and Distribution of Medical Saw Blades, Medical Drill Bits, Arthroscopic Surgery Blades, Medical Electrical Saw Drills, Bone Trauma Devices Tool Kits including Artificial Joints Extractor Devices (Modular Extractor Systems), Bone Reamers and Broaches, Electric Plaster Saws

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	244490615-200
Effective date	2023-04-06
Expiry date	2026-03-22
Issue date	2023-04-06

Replaces certificate SX 2182378-1 issued 2022-08-09

This certificate can be validated on https://www.certipedia.com

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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