EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60140608 0001

Report No.: 15073626 009

Manufacturer:
Zhejiang Shuyou Surgical
Instrument Co., Ltd.
3689#, East Yangguang Avenue
Dipu Street, Anji
Huzhou City
313300 Zhejiang
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60134546 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2019-07-24

Date: 2019-07-24

Fuxiu Sheng

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60140608 0001
Report No.: 15073626 009

Manufacturer:
Zhejiang Shuyou Surgical Instrument Co., Ltd.
3689#, East Yangguang Avenue
Dipu Street, Anji
Huzhou City
313300 Zhejiang
China

Products:

- Electrosurgical Electrodes including Disposable Electrodes
- Bipolar Forceps
- Multifunctional Operational Dissectors (Electrosurgical Pencils)
- Disposable Electrosurgical Pads
- Shaver Blades
- Suction and Irrigation Tubes
- High Frequency Electrosurgical Generators

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Holsters
- Cautery Tip Cleaners

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® III Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-07-24

TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Zhejiang Shuyou Surgical Instrument Co., Ltd.
3689#, East Yangguang Avenue
Dipu Street
Anji
Huzhou City
Zhejiang
313300
China

11 April 2024

Notified Body Confirmation Letter

Reference: EU2023-607/832698

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

Zhejiang Shuyou Surgical Instrument Co., Ltd.
3689#, East Yangguang Avenue
Dipu Street
Anji
Huzhou City
Zhejiang
313300
China

SRN Number (if available): CN-MF-000025970

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 of the corresponding devices 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 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer 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 the 20 Mar 2023 for the relevant devices.

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:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 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)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 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 BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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
N/A	N/A	N/A	N/A

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
Disposable Electrodes	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: HD 60140608 0001; NB number: 0197
Bipolar Forceps	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: HD 60140608 0001; NB number: 0197
Multifunctional Operational Dissectors (Electrosurgical Pencils)	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: HD 60140608 0001; NB number: 0197
Disposable Electrosurgical Pads	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: HD 60140608 0001; NB number: 0197
High Frequency Electrosurgical Generators	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: HD 60140608 0001; NB number: 0197
Holsters	Class I device placed on the market in sterile condition	N/A	MDD Certificate: HD 60140608 0001; NB number: 0197
Cautery Tip Cleaners	Class I device placed on the market in sterile condition	N/A	MDD Certificate: HD 60140608 0001; NB number: 0197

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Confirmation Letter Revision History

Date	Action
2024/04/11	Initial issue

NB 2797