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für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 058561 0034 Rev. 00

Manufacturer: **IZI Medical Products, LLC**
5 Easter Court, Suite J
Owings Mills MD 21117
USA

Product Category(ies): **Bone Biopsy Needle Sets, Vertebroplasty Needle Sets, Biopsy Access Needles, Breast Lesion Localization Needles, Spinal Implants and Associated Manual Surgical Instruments and Spinal Curettes, and Disposable Passive Array**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72150139

Valid from: 2020-07-08
Valid until: 2023-10-20

Date, 2020-07-08

Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 058561 0031 Rev. 00

Manufacturer

IZI Medical Products, LLC
5 Easter Court, Suite J
Owings Mills MD 21117
USA

Product Category(ies):

Sterile Syringes and Imaging Markers for Radiology, Radiation Therapy and Surgical Procedures

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 72153904

Valid from: 2020-07-03
Valid until: 2024-05-26

Date, 2020-07-03

Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

IZI Medical Products, LLC
5 Easter Court, Owings Mills, MD 21117, United States of America

October 19, 2023

Confirmation Letter Reference: CLNB1639 - 622229

To whom it may concern,

Confirmation of receipt 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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

IZI Medical Products, LLC
5 Easter Court
21117 Owings Mills
USA
SRN Number (if available): US-MF-000029992

Holger Rossner/ Ilumark
Hohenlindner Str.
11 C 85622 Feldkirchen
Germany
SRN Number: APP000010533

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices 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:

SGS NB1639 Confirmation letter Regulation (EU) 2023/607

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 the Notified Body SGS Belgium NV 1639,

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**:**

SGS NB 1639 - Letter Regulation (EU) 2023/607

Device name or Basic UDI-DI	**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
Device 1- Osteo-Site® Bone Biopsy Needles and Accessories (081521202OsteoSite84)	Class IIa	Bone Biopsy Needle Sets	Certificate G1 058561 0034 incl. Rev. 00 0123
Device 2- Osteo-Site® Bone Biopsy Needles and Accessories (081521202OsteoSite84)	Class IIa	Vertebroplasty Needle Sets	Certificate G1 058561 0034 incl. Rev. 00 0123
Device 3 – Quick-Core Biopsy Access Needles (081521202QuickCoreXU)	Class lla	Biopsy Access Needles	Certificate G1 058561 0034 incl. Rev. 00 0123
Device 4 – Breast Lesion Localization Needles and Coil (081521202BLN8K)	Class lla	Breast Lesion Localization Needles	Certificate G1 058561 0034 incl. Rev. 00 0123
Device 5 – Spherz Markers and Disposable Array (081521202SPHERZUW) eIFU)	Class ls	Disposable Passive Array	Certificate G1 058561 0034 incl. Rev. 00 0123
Device 6 – Osteo-Site® Bone Biopsy Needles and Accessories (081521202OsteoSite84)	Class lla	Sterile Syringes	Certificate G2S 058561 0031 incl. Rev. 00 0123
Device 7 – Spherz Markers and Disposable Array (081521202SPHERZUW) eIFU)	Class ls	Imaging Markers for Radiology, Radiation Therapy and surgical Procedures	Certificate G2S 058561 0031 incl. Rev. 00 0123
Device 8 – Sterile Visicoil marker B8871WG (HIBCC)	Class llb Specific	N/A	US19/819943472 CE1639
Device 9 – Sterile MR Visicoil (Platinum)	Class llb Specific	N/A	US19/819943472 CE1639

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Device name or Basic UDI-DI	**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
B8871WG (HIBCC)			
Device 10 – Sterile Pre-Loaded Visicoil B8871WG (HIBCC)	Class IIb Specific	N/A	US19/819943472 CE1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/19/10	Version 1	Initial issue

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607