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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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Product Service

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

## No. G10 049319 0007 Rev. 04

**Manufacturer:**

**joimax® GmbH**
Amalienbadstraße 41
RaumFabrik 61
76227 Karlsruhe
GERMANY

SRN Manufacturer - DE-MF-000009201

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 049319 0007 Rev. 04

| | |
|---|---|
| **Report No.:** | 713304151 |
| **Preceding Certificate No.:** | G10 049319 0007 Rev. 03 |
| **Valid from:** | 2025-01-09 |
| **Valid until:** | 2029-01-31 |
| **Date of Initial Issuance:** | 2024-02-01 |

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2025-01-09


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| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z120202 - MOTORISED INSTRUMENTS FOR ENDOSCOPIC SURGERY |
| **Intended Purpose:** | - |
| **Classification:** | Class IIa |
| **Device Group:** | Z120114 - SURGICAL NAVIGATION INSTRUMENTS |
| **Intended Purpose:** | - |
| **Classification:** | Class IIa |
| **Device Group:** | Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY |
| **Intended Purpose:** | - |
| **Classification:** | Class IIb |
| **Device Group:** | Z120109 - ELECTROSURGICAL INSTRUMENTS |
| **Intended Purpose:** | The device is intended exclusively for the generation of electrical power for monopolar and bipolar cutting and coagulation of soft tissue excluding all soft tissue structures of the central nervous system, namely spinal cord and meninges, during open or minimally invasive surgical procedures. |
| **Classification:** | Class IIb |
| **Device Group:** | K020199 - MONO- AND BIPOLAR DEVICES, SINGLE USE - OTHER |
| **Intended Purpose:** | Electrosurgical instruments are used for cutting and/or coagulation of soft tissue excluding all soft tissue structures of the central nervous system, namely spinal cord and meninges during open or minimally invasive surgical procedures when used in conjunction with a compatible RF generator. |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | ./. |


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### Revision History:

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2024-02-01 | 713254107 | Initial issuance |
| 01 | 2024-02-27 | 713254107 | Amended: Other |
| 02 | 2024-08-07 | 0713304152 / 0713304151 | Supplemented: Device(s)/group of device(s) added |
| 03 | 2024-12-23 | 713304151 | Supplemented: Device(s)/group of device(s) added |
| 04 | 2025-01-09 | 713304151 | Amended: Other |



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